Nottingham University
Business School

Building a Performance Measurement Internal Auditing Framework for the ISO 9001 Quality Management System

Flor Mónica Gutiérrez Alcántara, BEng., MEng.(Hons.)

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This thesis is dedicated to the memory of my father

"I never dreamt that I would get to be
The creature that I always meant to be
But I thought in spite of dreams
You'd be sitting somewhere here with me"
(Tennant & Lowe, 1990)

For Esperanza & Luis

ABSTRACT

During the last two decades, ISO 9000 standards have become one of the most important management approaches in the world. Currently, the standards are used by more than one million companies in more than 170 countries. ISO 9001 audits are the most widely used performance measurement (PM) method to assess ISO 9001 quality management systems (QMS). However, in recent years the effectiveness of ISO 9001 quality auditing has been questioned for: (1) only focusing on compliance; (2) failing to detect problems in products and processes; (3) failing to predict QMS failures; and (4) failing to provide added value to organisations.

To overcome these problems, two main conversations have taken place in the literature. The first advocates changing the current compliance focus of auditing for a performance oriented one, to promote improvements in business processes and the QMS. The second theme seeks to develop different methods, guidelines, tools and techniques to improve auditing practice. In order to generate a change of focus from compliance towards improvement, some recent research has also advocated incorporating concepts and techniques from the PM field into the ISO 9000 world. However, there have been no substantial previous attempts to provide internal quality auditing with a performance focus, which was the aim of this research. Hence, this thesis intends to establish how ISO 9001:2008 certified organisations can better measure their QMS performance using internal audits.

In order to provide answers to this question, an empirical study using mixed methods research was conducted. Firstly, the current state of the art of the ISO 9001:2008 internal auditing process was determined using a mixed methods study, including two surveys of 272 ISO 9001 experts and 25 interviews. This allowed the identification of the current problems that ISO 9001 certified organisations face when conducting audits, as well as the impacts on the performance of the QMS due to deficient internal auditing. Secondly, using the statistical technique of path analysis, a model identifying the relationships between internal audit problems and their impacts on QMS performance was developed. The model indicated that an intricate network of individual and organisational deficits link auditing and QMS performance. Finally, 'Audit+' a detailed and comprehensive procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS was developed. The procedure was thoroughly tested and validated by a further mixed methods study, including three in-depth case studies and a survey of 174 ISO 9001 auditors. Although some minor changes were recommended, the results of the Audit+ validation were encouraging, showing that PM approaches can be successfully incorporated into the ISO 9001 world, to help organisations to better measure their QMS performance.

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ABBREVIATIONS

BEM	Business Excellence Models
BSI	British Standards Institution
CB	Certification Bodies
CBS	Certification Bodies Survey
CMMI	Capability Mature Model Integration
CO	Certified Organisations
COS	Certified Organisations Survey
DIS	Draft of International Standard
FDIS	Final Draft of International Standard
IAF	International Accreditation Forum
ISO	International Organisation for Standardisation
ISO/CASCO	ISO Technical Committee for Conformity Assessment
ISO/COPOLCO	ISO Technical Committee for Consumers
ISO/DEVCO	ISO Technical Committee for Developing Countries
IS0/TC	ISO Technical Committee
ISO/TC 176	ISO Technical Committee for Quality Assurance and Quality Management
ISO/TC 207	ISO Technical Committee for Environmental Management
KPIs	Key Performance Indicators
MS	Management systems
PM	Performance Measurement
QM	Quality Management
QMS	Quality Management Systems
SME	Small and Medium Enterprises
TQM	Total Quality Management

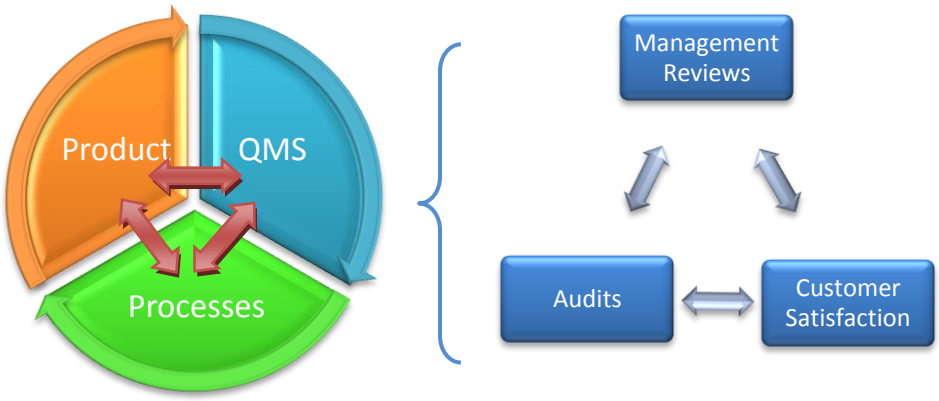
CHAPTER 1
INTRODUCTION

1.1 Background

Quality Management is a major business activity which has developed strongly in recent decades. The most important themes of Quality Management (QM) are: Total Quality Management (TQM), Six Sigma, the Business Excellence Models and Quality Management Systems (QMS). This study is focussed on QMS, which is defined as a "management system to direct and control an organization with regard to quality" (ISO 9000, 2005, pp. 8). The purpose of a QMS is "to establish a framework of reference points to ensure that every time a process is performed the same information, methods, skills and controls are used and applied in a consistent manner" (Dale, 2007, pp. 280). In addition to internal benefits, organisations that have implemented a QMS are able to demonstrate that they have the capabilities to supply the same goods and services to clients all around the world. Those organisations with certifications to a recognised QMS such as ISO 9001 are able to export their products to international markets more easily than those that do not have it. During the last two decades the ISO 9000 family of international standards has become the most successful QMS in the world (Martínez-Costa *et al.*, 2009). More than 1 million companies in around 170 countries have implemented the standards (ISO Survey, 2010). Furthermore, it has been taken as the basis for many other management systems, such as the Capability Maturity Model Integration (CMMI) for IT and the Telecommunications TL 9000 QMS.

One of the reasons for the success of the ISO 9000 QMS is its approach that "encourages organizations to analyse customer requirements, define processes that contribute to the achievement of a product which is acceptable to the customer, and keep this processes under control" (ISO 9000, 2005, pp. 1). Hence, an ISO 9001 QMS can become a foundation for increased customer satisfaction through continuous improvement, leading to increased competitiveness for the organisation. In fact, Dale (2007) argues that a good ISO 9001 QMS provides "an effective managerial framework on which to build a company-wide approach to a process of continuous improvement" (pp. 281). Although ISO 9001 does not specifically require the improvement of product and process, it states that a certified company "shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data,

corrective and preventive actions and management review" (Clause 8.5.1). For this purpose, the standard includes clauses which address different levels of scrutiny towards product, processes and QMS (i.e. Clauses 8.2.3, 8.2.4 & 5.6.3). Figure 1.1 suggests how the QMS improvement process could help to enhance processes and products through its Performance Measurement (PM) System.



Adapted from ISO 9001:2008

Figure 1.1 The ISO 9000 performance measurement system

The ISO 9001 standard requires that Certified Organisations (CO) implement controls, to assure that they are appropriately assessing each level of their QMS. Hence, companies must implement and maintain three QMS performance measurement methods: *top management reviews, customer satisfaction measurement* and *audits*. In theory, the implementation of these methods ensures that the organisation's QMS is performing correctly and providing top management with the information needed to improve the QMS (ISO 9001, 2008). Nevertheless, organisations, especially Small and Medium Enterprises (SME), experience considerable problems with the measurement of their QMS (Briscoe *et al.,* 2005). This is due to the lack of standards and guidelines regarding QMS performance measurement. For example, even if the ISO 9004:2009 standard suggests that organisations should implement key performance indicators (KPIs) in their processes to control their operations, many organisations face problems in identifying and implementing KPIs for effectively measuring their QMS performance because the ISO 9004 does not address how to implement KPIs.

The three QMS performance measurement methods (*management reviews, customer satisfaction measurement* and *audits*) are granted the same importance within the ISO 9001 standard. Nevertheless, in practice, audits are the most important method for evaluating the performance of QMS because "[a]udit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement" (ISO 9000, 2005, pp.5). Audits are used by Certification Bodies (CB) to grant ISO 9001 certification (external audits), as well as

being used as a self-assessment tool by certified companies (internal audits). This dual usage of audits makes them the primary PM method in the ISO 9000 context. Moreover, the use of audits as a PM method for QMS is reinforced in the management process of the ISO 9001 standard, where the results of both internal and external audits are used as an input for conducting management reviews (see ISO 9001:2008, Clause 5.6.2).

Hence, audits are of great importance for evaluating the performance and improvement of QMS in CO, and this is precisely the reason why companies and CB need to be certain that they are conducting effective audits, which are providing the top management with correct inputs. Nevertheless, during the last decade the current auditing process, internal and external, has been criticised for failing to:

- *focus on anything more than compliance and missing a clear improvement approach* (Karapetrovic &Willborn, 2000a, 2000b, 2001b and 2002; Dalgleish, 2003; Ni &Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Privka, 2004; Biazzo, 2005; Rajendran &Devadasan, 2005; Power &Terziovski, 2007; Terziovski &Power, 2007; Kaziliunas; 2008; Alic &Rusjan; 2010 and 2012; Gupta, 2010);
- *detect problems in products/services and processes* (Dalgleish, 2002; Karapetrovic &Willborn, 2002; Beckmerhagen *et al*., 2004; Vouzas &Gotzamani, 2005; Kaziliunas; 2008; Gupta, 2010);
- *identify faults in the QMS* (Karapetrovic &Willborn, 2001a; Ni &Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Alic &Rusjan; 2010 and 2012; Le Saux, 2010); and
- *provide added-value to organisations* (Liebesman, 2002; Karapetrovic &Willborn, 2002; Ni &Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Privka, 2004; Rusell, 2004; Biazzo, 2005; Power &Terziovski, 2005 and 2007; Alic &Rusjan; 2010 and 2012; Gupta, 2010).

Due to the fact that this thesis aimed to explore the relationship between QMS performance and the audit process, this study was focused on internal auditing whose primary objective is detecting problems and improvements in the QMS (ISO 9001, 2008). Because the main objective of external auditing is assessing compliance with the standard, this type of auditing was not included in the scope of this thesis.

Askey and Dale (1994) were the first to list detailed failings of the internal audit process at an ISO 9000 certificated organisation. They found nine specific failings ranging from lack of auditor commitment to lack of action on audit results. Later, Karapetrovic and Willborn (2000b) identified 16 failings in quality auditing, mostly at a detailed level (such as absence of opening meetings and deficient verification of evidence). This list included failing in both types of audits: internal and external. Comparing these two very different lists for internal audit failures shows that it is possible to catalogue a number of audit process failings from empirical studies or anecdotal sources, that these may be established at different levels of detail, but also suggests that such lists are not readily related to theory.

Acknowledging these problems with the audit process, the ISO Technical Committee for Quality Assurance and Quality Management (ISO/TC 176) published in 2002 a revisited audit standard for quality and environment management systems, the ISO 19011 which is used to conduct internal and third party audits. Also, in 2003 the ISO/TC 176 and the International Accreditation Forum (IAF), created the 'ISO 9001 Auditing Practice Group', an international committee of experts, aiming to develop audit guidance for the ISO 9001 standard. The first output of this group was the 'Sydney Model' (ISO 9001 Auditing Practices Group, 2004b), which proposed the identification of organisational objectives to be assessed in the audit against organisational results, using a gap analysis. The ISO 9001 Auditing Practice Group expected to solve most of the failures in the audit process including a PM oriented approach to audits with the Sydney Model.

Nevertheless, in 2004 Beckmerhagen *et al.* (2004) released a study which incorporated the 16 audit problems identified by Karapetrovic & Willborn (2000b) in the context of the new ISO 19011 standard. However, because ISO 19011 was only one year old at the time, it is likely that other audit problems were missed because the audit process in organisations using the new standard was not mature enough.

Due to these problems, some researchers have tried to deepen the understanding of the audit process in two main areas: 1) compliance versus performance focus auditing (Karapetrovic & Willborn 2000a and 2000b; Biazzo, 2005; Power & Terziovski, 2007; Kaziliunas, 2008; Alic & Rusjan, 2010)); and 2) developing methods, guidelines, tools and techniques to improve internal auditing as a whole (Kazuliunas, 2008; Mors, 2008; Bernardo *et al*., 2010; Alic & Rusjan, 2010 and 2012; Wells, 2010; Le Saux, 2010).

However, the impetus among scholars and practitioners for trying to identify and understand the problems in internal auditing has apparently been lost. It is important to resume this initial conversation on the basis of empirical research because only with accurate knowledge about the current state of the art of the internal audit process, can effective methods to improve it be developed.

The ISO 9001 audit performance measurement problem

The main criteria for conducting both internal and third party audits are within the ISO 9001 standard itself. Organisations may include other criteria when conducting internal audits, but the standard identifies the minimum which they must use. For CB, the ISO 9001 standard provides the mandatory criteria when conducting certification or surveillance audits. Unfortunately, the ISO 9001 standard is insufficient to correctly evaluate the performance of a QMS, due to its lack of clarity and focus in several key clauses. For example, clause 8.2.1 'customer satisfaction' requires an organisation to "monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined" (ISO 9001, 2008, pp. 12).

In an ISO 9001 audit, the auditor will ask what kinds of methods for evaluating customer satisfaction the organisation has implemented in order to fulfil this requirement. Nevertheless, using only clause 8.2.1 as audit criteria, he/she will not be able to determine if the methods or outputs are correct because the clause is vague and does not specify them. Unfortunately, the ISO 9001 standard contains many clauses such as 8.2.1, where the lack of clarity and focus does not permit the performance or improvement of the QMS to be correctly evaluated using audits. As a result, some ISO 9001 CO are dissatisfied with the current audit results they are receiving (Power & Terziovski, 2007).

With the current ISO 9001 audit criteria, the auditor is only able to evaluate QMS compliance with the ISO 9001 standard, rather than measure QMS performance. This compliance audit approach misses the opportunity to effectively add value to organisations, because it does not help them to improve their QMS. Indeed, in a study by Power & Terziovski (2007) on third party auditors and ISO 9001 CO in Australasia, it was found that clients perceive that third party auditors mainly focus on checking compliance with the requirements of the standard instead of profoundly reviewing the whole QMS in order to provide feedback that helps organisations to improve their performance. Power & Terziovski (2007) also argue that the audit approach of compliance with the ISO 9001 standard should be expanded to focus upon organisational performance, as part of a continuous improvement process.

Some academics and practitioners have tried to tackle this problem by providing a more PM oriented focus for the ISO 9000 series of standards. For instance, Najmi & Kehoe (2000) attempted to connect the ISO 9000 QMS with the PM body of knowledge by developing a PM system framework for ISO 9000 CO. However, the proposed framework was not properly linked with ISO 9001 clauses and referred to an outdated version of the standard.

Biazzo (2005) undertook a study in order to understand to what extent third party auditors focus on PM when they conduct external audits. The author concludes that "[t]he conceptual evolution of the ISO 9001 standard has intensified the problem of ceremonial conformity and made it necessary to move from the traditional conformance audit model towards the 'performance audit' model." (pp. 382). Biazzo also highlights that a performance focus in audits is necessary to provide credibility to ISO 9001 certification.

Despite the advances achieved with these studies, the main problem of how to improve ISO 9001 audits (internal and third party) through changing the focus from compliance to performance still persists in the body of QMS knowledge and in audit practice.

1.2 The research gap and research question

Hence, in order to change the approach from compliance to PM auditing, the ISO 9000 family must upgrade its approach to provide additional PM audit criteria (for internal and external auditing). The recent ISO 9004:2009 standard includes some relevant PM concepts. However, as these are not specified in the current certification standard (ISO 9001:2008), it is not clear how organisations should implement and evaluate them. Furthermore, in the absence of explicit PM audit criteria, auditors may be basing their decisions on subjective judgements. This is a very important consideration in the context of internal audits[1] because top management needs internal audits to provide valuable information in order to review and change the QMS and company strategies and policies; this is not possible with the current compliance focus of ISO 9001 internal audits.

Thus, an academic research study which aims to clarify how to measure the performance of the ISO 9001:2008 QMS through internal audits is needed. In the practical context, this requires the development of a performance oriented internal audit approach, and this research attempts to cover this gap through answering the following question:

> "How can ISO 9001:2008 certified organisations better measure their QMS performance using internal audits?"

Thus, the aim of this work is to help ensure that ISO 9001:2008 certified companies will be able to use internal audits to correctly measure the performance of their QMS.

In order to answer the research question other intermediate questions related to the current start of the art of the internal audit process and its linkages with PM need to be addressed:

1. What problems do ISO 9001 certified organisations experience when conducting internal audits?
2. How do audit problems impact product/services, processes and QMS performance?
3. How and to what extent are the internal audit problems affecting the performance of the QMS?
4. What are the PM techniques currently most used by ISO 9001:2008 certified organisations?

1.3 Research objectives

In order to answer these questions, the following specific research objectives were identified:

[1] The objective of third party audits is compliance not improvement

1. Conduct a literature review which identifies the key concepts of both the QMS and PM bodies of knowledge together with relevant operations management theories;
2. Investigate the views of ISO 9001 experts in order to establish the current state of the art of internal audit practice, including the state of PM knowledge, awareness and application within this professional group;
3. Develop a procedure for conducting ISO 9001 internal audits with a focus on the performance of QMS; and
4. Validate the procedure by means of trial internal audits using the proposed document in real company audits and investigate its generalisation by a survey of ISO 9001 experts.

1.4 Scope, intended audience and contribution of the research

This research aims to develop and validate a generic internal audit procedure for the ISO 9001 standard. Nevertheless, this study does not attempt to develop any type of international standard or mandatory requirements for ISO 9001 CO. Therefore, the research has the following scope, intended audience and contributions:

Scope

It is focused on the application of PM (i.e. the procedure for conducting ISO 9001 audits with a focus on the performance of the QMS) at company level in the ISO 9001 internal audit context, using existing PM approaches.

Intended audiences

The results of this work may be interesting for two types of audience, academics and practitioners. The study regarding the current state of the art of internal audits should be of interest to quality and operations management scholars. Whereas, the developed internal audit procedure is designed to be used by internal auditors, quality managers, top management representatives, top management, consultants and ISO 9000 experts. Also third party auditors and certification managers may be interested in using the procedure to conduct an impartial assessment of the QMS when required by CO.

Contributions

The proposed contributions of this work in terms of theoretical knowledge and practical application will be:

- **Theoretical**
    1. A literature review covering the ISO 9000 core of standards, their relationship with the PM field and the creation of a new synthesis between these two bodies of knowledge;
    2. An assessment of the current state of the art of the ISO 9001:2008 internal audit process;

3. A path model of the relationships between the current internal audit problems and their impacts on the performance of both the QMS and organisations; and
4. The identification of how ISO 9001:2008 QMS can be improved through a novel application of PM approaches in the ISO 9001 audit context, based on empirical data.

- **Practical**
  5. The development, refinement and testing of a procedure to conduct ISO 9001:2008 audits with a focus on the performance of the QMS.

1.5 Structure of the thesis

This work is divided into the following chapters for ease of understanding:

1. The introduction, describes the research background as well as the research objectives, scope, intended audience and structure of the thesis;
2. A literature review about the ISO 9000 family of international standards highlights the research gap;
3. A literature review about the field of performance measurement (PM) and how some of the concepts from PM can be incorporated into ISO 9000 QMS;
4. The methodology used to address the research question;
5. An explanation of the current state of the art of ISO 9001:2008 internal audits from the data gained by conducting a mixed methods study including two surveys and 25 interviews with ISO 9000 experts;
6. A path model to understand the relationships between the current internal audit problems and their impacts on the performance of both QMS and organisations;
7. A proposal of a procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS;
8. The testing of the procedure thorough mixed methods research including three in-depth case studies and a survey of 174 ISO 9001 auditors; and
9. The conclusions which discuss the research outcomes and findings, the accomplishment of research objectives, limitations, the contribution to the body of knowledge and proposes future research.

CHAPTER 2
THE ISO 9000 FAMILY OF INTERNATIONAL QUALITY MANAGEMENT SYSTEMS STANDARDS

The aim of this chapter is to conduct a review of the literature published during the last decade in relation to ISO 9001 internal audits, in order to address the first research objective of this work:

> "conduct a literature review which identifies the key concepts of both the QMS and PM bodies of knowledge together with relevant organisational theories".

To provide the reader with the necessary background to delve into this subject, the first section of this chapter, 2.1, is dedicated to the ISO 9000 family of international standards. It describes how ISO standards are developed, how the ISO 9000 series is constituted and the impact of ISO 9001 in organisations.

Section 2.2 explains the current state of research in the ISO 9001 audit process, including the current debate about compliance versus performance auditing and the current trends to try to improve the internal audit process.

Finally, Section 2.4 provides the conclusions of this chapter.

2.1 The ISO 9000 family of international standards

2.1.1 Background

The International Organisation for Standardisation (ISO[2]) is the body responsible for developing and publishing ISO 9000 standards. The ISO is a non-governmental network of 161 national standards institutes, one member per country. Since its foundation in 1947, it has developed over 17500 international standards on different subjects. Currently, the organisation publishes 1100 new standards every year and it is the worlds' largest publisher of international standards (ISO, 2012).

The ISO develops new standards in response to sectors and stakeholders that express a need for them. The proposals of new standards are typically communicated to one of the ISO's national members, who proposes the new work item to the relevant ISO Technical Committee (ISO TC) developing standards in that area (ISO, 2010). When work items do not relate to existing ISO TC, ISO national members may propose to set up a new ISO TC to address it (ISO, 2010).

To be accepted for development, a proposed work item must receive majority support from the participating members of the ISO TC which, amongst other criteria, verify that the proposed item responds to an international need and will be suitable for implementation worldwide (ISO, 2010).

ISO standards are developed by ISO TC, (subcommittees or project committees) comprising experts from industrial, technical and business sectors as well as by representatives of government agencies, testing laboratories, consumer associations, non-governmental organisations and academic circles (ISO, 2010). Experts participate as national delegates, chosen by the ISO national member body for the country concerned. National delegations are required to represent not just the views of the organisations in which their participating experts work, but those of other stakeholders too. National delegations are usually based on and supported by national mirror committees to which the delegations report.

The ISO also has policy development committees addressing the standardisation needs of developing countries (DEVCO), consumers (COPOLCO) and conformity assessment (CASCO). These committees may recommend the development of new standards for their stakeholder groups, which are then submitted to the approval process described above, or in the case of CASCO, develop new standards itself (ISO, 2010).

The national delegations of experts of an ISO TC meet to discuss until they reach consensus on a draft agreement. The organisations in liaison also take part in this

[2] As "International Organization for Standardization" would have different acronyms in different languages ("IOS" in English, "OIN" in French for Organisation Internationale de Normalisation), its founders chose "ISO", derived from the Greek '*isos*', meaning "equal". (www.iso.org)

work. When they have agreed a draft, the resulting document is circulated as a draft international standard (DIS) to of all ISO's member bodies for voting and comment. If the voting is in favour, the document, with eventual modifications, is circulated to the ISO members as a final draft international standard (FDIS). If that vote is positive, the document is then published as an international standard (ISO, 2010).

For a document to be accepted as an ISO international standard, it must be approved by at least two-thirds of the ISO national members that participated in its development and not be disapproved by more than a quarter of all ISO members who vote on it (ISO, 2010).

2.1.2 The ISO 9000 standards

During the 20th century, organisations increasingly needed to demonstrate to customers that their products were reliable and processes to manufacture them were effective and controlled. Dale (2007) traces the origins of QMS standards to the 1950's, when the US Department of Defence and NATO allies identified "a need for greater reliability in purchased products and a reduced reliance on customer or purchaser inspection as the main assurances of quality" (pp. 282). The early US and NATO military standards were taken as the basis for national civil QMS standards and by the 1970's there was a proliferation of civil standards and of supplier auditing carried out by customers. Juran (1999) recalled, "[t]here was no provision for pooling results of audits into some common data bank, and customers generally were unwilling to accept the findings of audits conducted by personnel other than their own. The resulting multiple audits were especially burdensome to small suppliers" (pp. 2.14). In order to address this problem, in 1979 the British Standards Institution (BSI) published the British Standard BS 5750 for quality systems which was developed from the original defence standards. Later, this standard was taken as the basis for the first set of international standards for QM, the ISO 9000 family (Dale & Oakland, 1991), which set the scene for the current global system of ISO 9001 accreditation, third party auditing and certification with international customer acceptance.

The vast majority of ISO standards are highly specific to a particular product, material or process. However in 1987, the ISO, through the ISO Technical Committee of Quality Management and Quality Assurance (ISO/TC 176), published the ISO 9000 family of standards, its first QMS Standards. The ISO 9000 family has experienced some changes during last 25 years and nowadays it is integrated by:

- 16 published standards;
- internet based documents;
- the ISO Handbook: ISO for small business; and
- the ISO Handbook: Guide to the integrated use of management systems standards.

Nevertheless, the most used standards of the family are the following four, also known as "the core standards":

- ISO 9000:2005 Quality management systems - Fundamentals and vocabulary;
- ISO 9001:2008 Quality management systems - Requirements;
- ISO 9004:2009 Managing for the sustained success of an organization - A quality management approach; and
- ISO 19011:2011 Guidelines for auditing management systems[3].

The core standards are designed to complement each other despite the fact that ISO 9001 is the only certifiable standard in the family. The ISO 9000 standard provides the whole set of QMS principles and the reference vocabulary used in the core standards. Whereas ISO 9001 specifies the QMS requirements that organisations need to achieve, in order to demonstrate their ability to provide product and services that fulfil customers and regulatory requirements. ISO 9004 provides complementary guidance for improving the performance of the organisation and satisfaction of stakeholders. Finally, ISO 19011 is used to conduct internal and external audits.

ISO 9001 is a generic[4] standard and it is the only one in the family for which organisations can be certified – although certification is not a compulsory requirement of the standard (ISO 9000 Essentials, 2009). Until now, the ISO has published four versions of the ISO 9001 standard (ISO 9001:1987, ISO 9001:1994, ISO 9001:2000 and ISO 9001:2008). It is expected that another version will be published in 2015.

According to the ISO Survey (2010), in December 2003 there were 497,919 ISO 9001:2000 certified organisations in 146 countries but at the end of 2011 this figure had increased to more than 1 million companies in 175 countries (see Figure 2.1). Martínez-Costa, *et al*. (2009) point out that the number of ISO 9001:2000 certified organisations has grown in the period of 2003 to 2006 at a higher rate than economic growth. This increase is a clear indication of the importance of the standard in the QMS field. In fact, the number of organisations using the standard should be higher than the official ISO figure if it is considered that many organisations may be using the standard without being certified. As De Ascarraeta (2008) states, an organisation is free to implement the standard for the internal and external benefits that it brings to them and their clients without being certified, because it is not a requirement of the standard to grant the certification.

Many authors have studied the benefits of ISO 9000 series implementation and their effects on organisational performance. While some, especially earlier, research

[3] A complete list of the whole family of ISO 9000 standards and supporting documents can be found at www.iso.org/iso/iso_technical_committee_176

[4] In the management systems field "generic" is the term used to describe systems that can transcend industries or geographical boundaries.

suggested that organisations did not improve their performance (e.g. Terziovski *et al.*, 1997; Martínez-Lorente and Martínez-Costa, 2004), most recent studies agree that it does (Naveh *et al.,* 2004; Corbett *et al.,* 2005; Martínez-Costa *et al.*, 2007; Singh, 2007; Benner and Veloso, 2008; Martínez-Costa *et. al.,* 2009; Hannah, 2011). One possible explanation for this change, are the improvements to the 2000 version of ISO 9001, particularly the 'process approach'. This encourages organisations to define, control and manage their QMS as a set of interrelated processes, in order to develop products and services to satisfy customer needs. A good QMS helps to stabilise the internal organisational environment, enabling the operational and business processes of the organisation to operate repeatably and efficiently, with minimum waste and non-conformance, within a business environment that may be turbulent, in order to satisfy clients' demands.

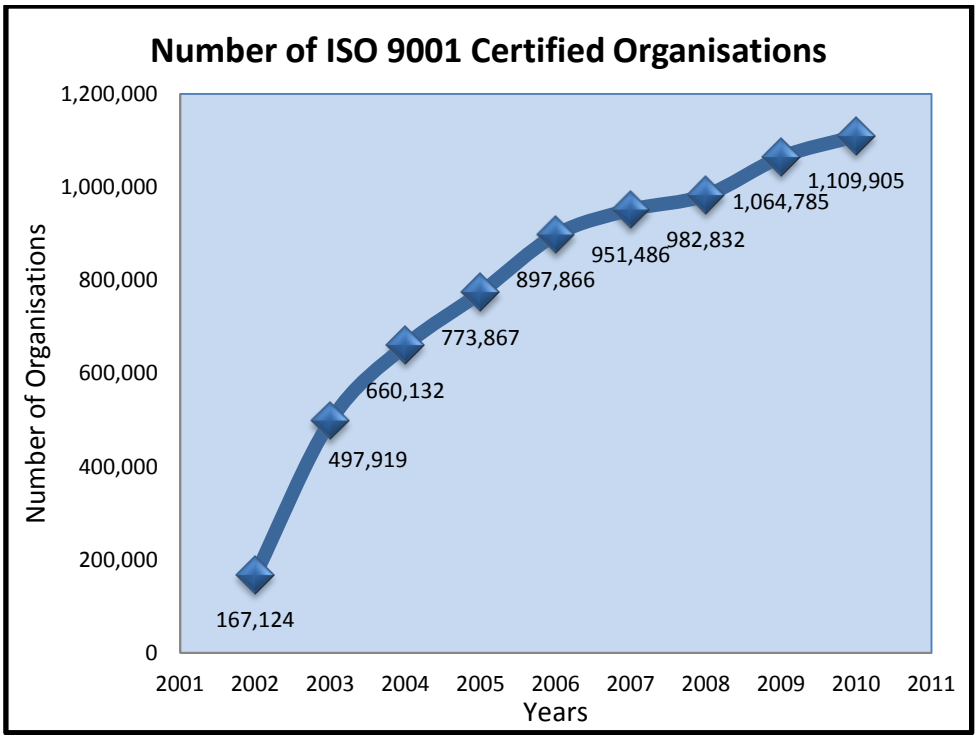


Figure 2.1 The growth of ISO 9001 certification

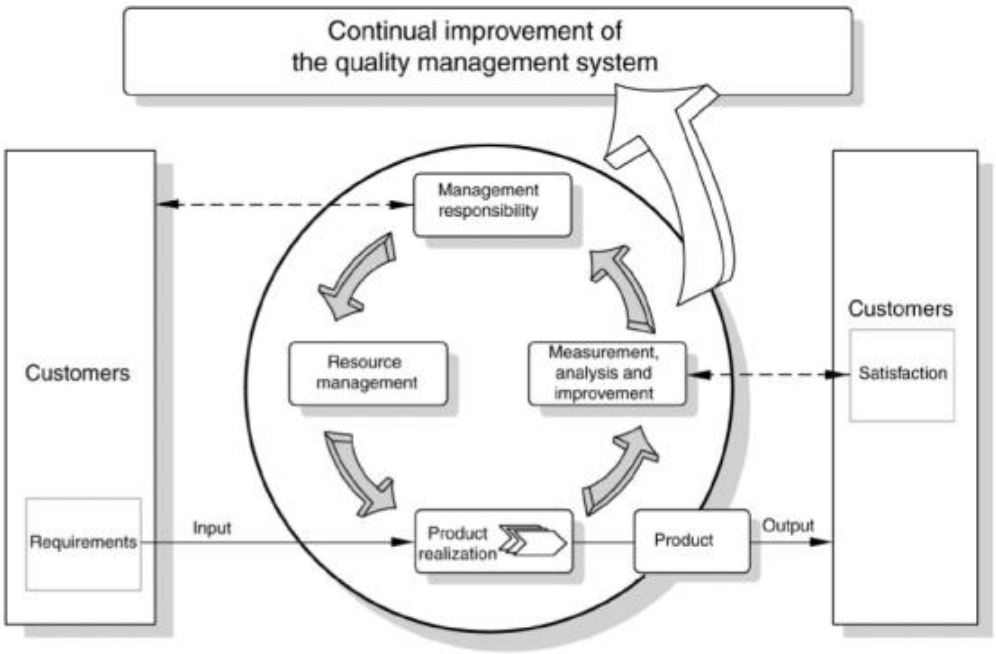
2.1.3 The ISO 9000 QMS process-based model

One of the major changes to the ISO 9000 core of standards in 2000 was the inclusion of the process approach. A process is a set of interrelated activities which use resources to transform inputs to outputs (ISO 9001, 2008). Figure 2.2 shows a generic schematisation of a process.

Figure 2.2 Generic schematisation of a process

To illustrate this concept, consider the number of basic activities that any organisation conducts to buy a product. Firstly, the buyer reviews and analyses the purchase-order requested (input). Later, he or she requests the prices of the product from suppliers. Then, he performs a comparison table and selects the best supplier. Finally, he agrees with the supplier the delivery date and conditions, which the buyer has to register in the purchase-order (output). This series of steps that describes the purchase of a product is called the 'process' of purchase. Frequently in organisations, the output of one process becomes the input of another. Using the same example, one of the outputs of the purchase process is the purchase-order which in turn is the input to the inspection process. The systematic identification, management and control of the processes and their interactions within an organisation are known as the 'process approach' (ISO 9000, 2005).

The ISO 9000 core of standards state that organisations can group all of their processes into four main sets: product realisation; resource management; measurement, analysis and improvement; and management responsibility. This process configuration is known as the 'ISO 9000 QMS process-based model' and is shown in Figure 2.3.



Source: ISO 9000:2005

Figure 2.3 The ISO 9000 QMS process-based model

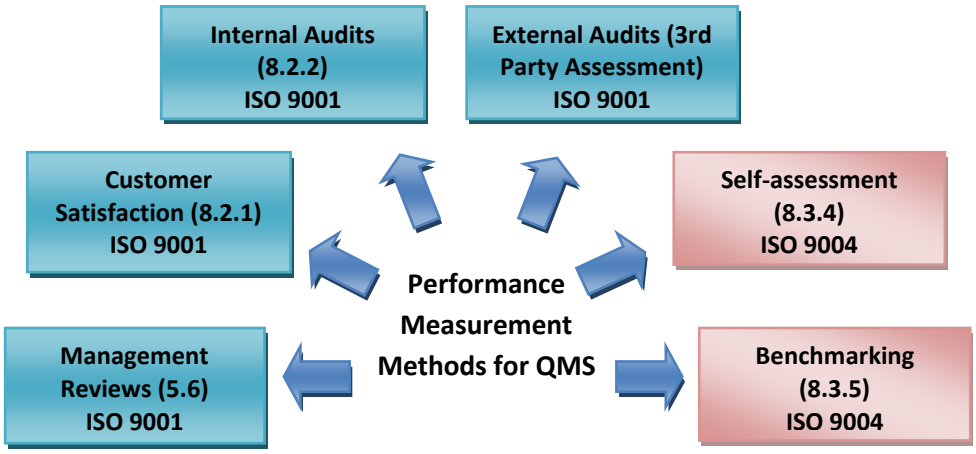
The cycle of quality management in the ISO 9000 QMS process-based model begins with the understanding of customer requirements, which is the input of the product realisation process. Therefore, the output of this process will be the product or service expected by the customer. The product realisation process (section 7 of ISO 9001) interacts closely with the processes of resource management (section 6) and

measurement, analysis and improvement (section 8). In the resource management process all those activities related to infrastructure, equipment, supplies and human resources will be involved. If this process is not performing correctly, then the product realisation process will hardly deliver the desired result. In a similar way, if the measurement, analysis and improvement process is not efficient, the organisation will not be able to detect failures in its QMS, which will lead to deficient products and processes, high reworking costs and customer dissatisfaction. The cycle of quality management continues with the above processes interacting with the process of management responsibility (section 5). The top management of the organisation has to have an explicit commitment to address all of the activities regarding the QMS, from establishing the quality policy of the organisation to providing the necessary resources for the QMS. Finally, the last element of the ISO 9000 QMS process-based model is the continual improvement of the QMS. In the ISO 9000 context, all of the QMS processes must be measurable and quantifiable to ensure the system operates properly and is improving as expected. The ISO 9000 core of standards establishes three methods to measure the performance of the QMS: *management reviews*, *customer satisfaction measurement* and *audits*. In the following paragraphs these methods will be discussed.

2.1.4 The ISO 9000 PM system

The ISO 9000 core of standards considers three different levels of PM: *product*, *processes* and *QMS* (i.e. clauses 8.2.3, 8.2.4 & 5.6.3). Performance measures of product are mainly stated in section 8 of the ISO 9001 standard, whereas different performance measures of processes can be found in sections 4-8, depending on the type of process. Section 8 mainly addresses QMS PM methods, however management review is found in section 5.

Since its 2000 version, the ISO 9001 standard considers four methods of measuring QMS performance in organisations: management reviews (clause 5.6), customer satisfaction measurement (clause 8.2.1), internal audits (clause 8.2.2) and external audits (third party assessment) (see Figure 2.4). It is important to point out that ISO 9004:2009 suggests another two additional performance methods: self-assessment (clause 8.3.4) and benchmarking (clause 8.3.5). Nevertheless, because these methods are not included in ISO 9001:2008 as mandatory requirements, organisations usually do not implement them.



Source: ISO 9001:2008 and ISO 9004:2009

Figure 2.4 ISO 9000 PM methods for QMS

In the following sections, the three methods for measuring the performance of ISO 9001 QMS will be analysed. The discussion is limited to ISO 9001 because the requirements of this standard are used to grant certification, whereas ISO 9004 is an optional standard. Additionally, a discussion about the importance of audits in the ISO 9001 context, as a method of self-assessment for CO, as well as external evaluation is included.

2.1.4.1 Management reviews

Management reviews are a mandatory requirement of the standard and this requirement is part of the process of management responsibility. This process requires that the top management of the organisation is committed to the development, implementation and improvement of the QMS of the organisation for gaining and maintaining the certification (clause 5.1). In order to demonstrate their commitment, top management have to conduct the following mandatory activities (ISO 9001, 2008):

- communicating to all the personnel of the organisation the importance of meeting customer, regulatory and statutory requirements;
- establishing the quality policy;
- ensuring that quality objectives are established;
- ensuring the availability of resources; and
- conducting management reviews.

Regarding the last point, the standard also states that top management is responsible for conducting periodic management reviews. In fact, clause 5.6.1 states that (ISO 9001, 2008, pp. 5):

> "Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives."

However, the standard does not state how top management should conduct a management review. The ISO 9001:2008 standard only provides guidance about the possible inputs (clause 5.6.2) and outputs (clause 5.6.3) that top management should consider when conducting a review. Regarding the inputs, the ISO 9001:2008 standard states that management reviews should include: results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement. It is important to highlight that audit results and customer satisfaction feedback, which are also the other QMS PM methods, are key inputs to management review. Hence, there is natural overlap in the ISO 9000 QMS PM methods to complement each other (see Figure 2.5).

Figure 2.5 Overlap of ISO 9001 PM methods

After conducting the management review activities, it is expected that top management will take actions related to (ISO 9001, 2008):

- improvement of the effectiveness of the QMS and its processes;
- improvement of the product related to customer requirements; and
- resource needs.

There is no official ISO standard for conducting management reviews. However, the flowchart shown in Figure 2.6, describes how a typical management review would be conducted.

As far as ISO 9004 is concerned, the concept of management reviews has slightly changed in the 2009 version. Management reviews are now included in the new clause 8.5 entitled 'Review of information from monitoring, measurement and

analysis'. Clause 8.5 specifically requires that top management use a systematic approach to reviewing available information regarding (ISO 9004, 2009):

- monitoring of the organisation's environment;
- measurements of the organisation's performance, including KPIs;
- assessments of the integrity and validity of the measurement processes;
- results of internal audit, self-assessment and benchmarking activities;
- risk assessment; and
- feedback from customers and other interested parties.

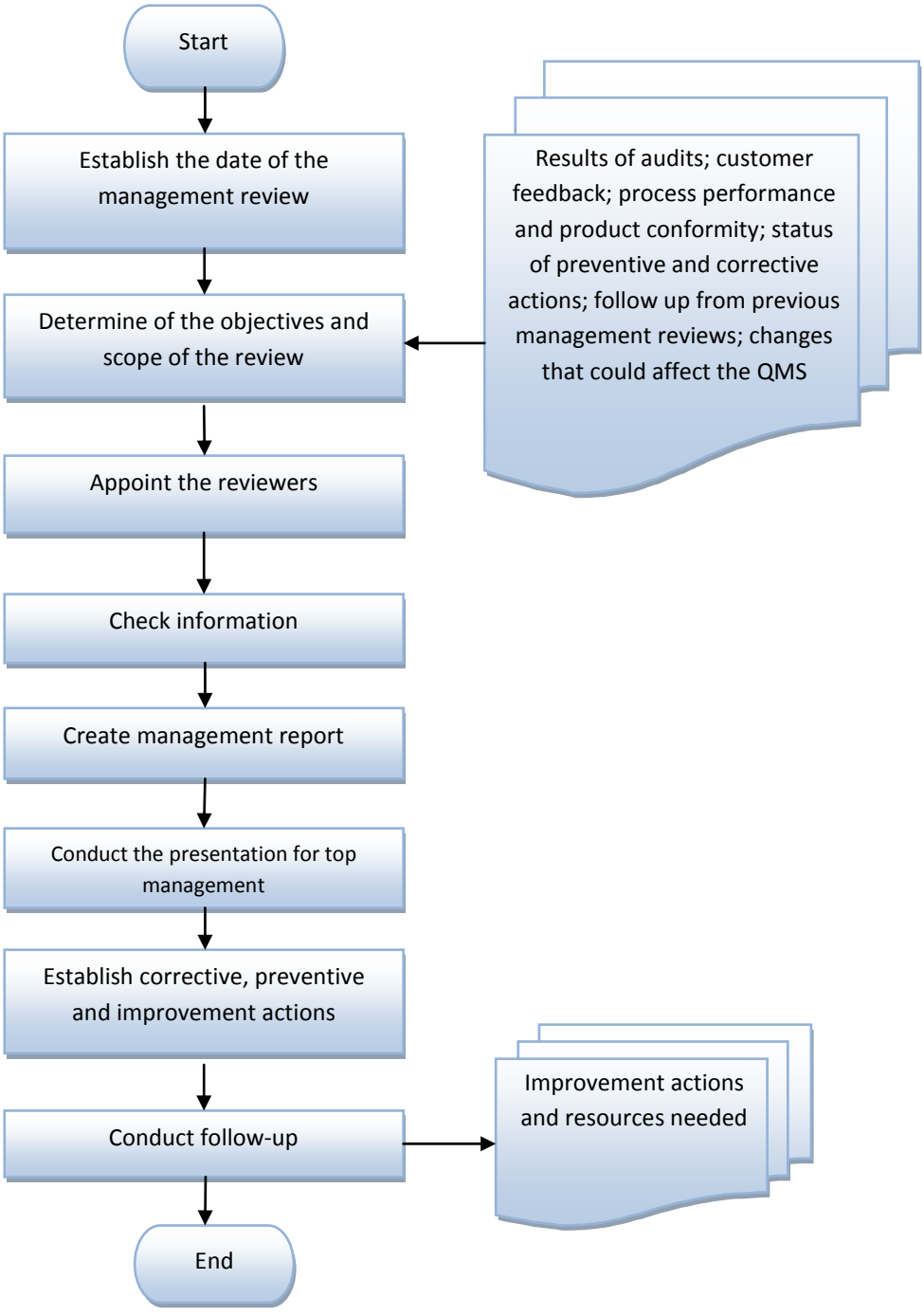


Figure 2.6 Management review flowchart

Thus, the focus of ISO 9004 now goes beyond the traditional approach of the ISO 9001 standard, with the inclusion of input elements such as KPIs, measurements of the organisation's performance and risk assessment. Therefore following the ISO 9004 guidance, top management would be provided with a greater range of objective performance information, not only regarding the QMS but the organisation as a whole.

2.1.4.2 Customer satisfaction measurement

Customer satisfaction measurement is one of the most important features of the ISO 9000 QMS concept. In fact, the principle of 'customer focus' is the first quality management principle of the ISO 9000 core of standards (ISO 9000, 2005). The ISO 9000 standard provides a description of this principle (ISO 9000, 2005, pp. v):

> "Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations"

Also, the customer focus principle is used as the basis for the 'fundamentals of QMS' of the ISO 9000 core. Moreover, the 'rationale for QMS' section points out that QMS "can assist organizations in enhancing customer satisfaction" (ISO 9000, 2005, pp. 1). Customers require products which satisfy their needs and expectations. These needs and expectations are expressed in product specifications and are commonly known as 'customer requirements'. Organisations have to continuously monitor and measure customer satisfaction in order to improve their product and processes because customer requirements change constantly (ISO 9000, 2005). The ISO 9000 standard argues that a QMS can provide the framework for the continuous improvement of the product and processes of the organisation to increase the probability of enhancing customer satisfaction (ISO 9000, 2005). However, these intentions are not clearly expressed in requirement 8.2.1 'customer satisfaction' of ISO 9001, which merely states (ISO 9001, 2008, pp.12):

> "as one of the measurements of the performance of quality management systems, the organization shall monitor information related to customer perception as to whether the organization has met customer requirements"

As with the management review, the customer satisfaction measurement clause of ISO 9001 is very general and does not provide guidelines on how to accurately measure customer satisfaction. Clause 8.2.1 only includes one note clarifying that monitoring customer perception can be done through different methods such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports. However, no more guidance is provided in the standard on ways to fulfil the ISO 9001:2008 requirement.

As far as the ISO 9004 standard is concerned, its previous version had a special section that provided guidance about methods to measure customer satisfaction. However in the 2009 version, this section has disappeared and the customer satisfaction concept has been included as a method for collecting information regarding KPIs of organisation (clause 8.3.1). This change may be partly due to the fact that the ISO/TC 176 developed the technical specification ISO/TS 10004 in 2010, addressing precisely the topic of customer satisfaction.

2.1.4.3 Audits

Finally, the last method for measuring the performance of QMS in the ISO 9001 context is audits. The ISO 9000:2005 defines the word 'audit' as (ISO 9000, 2005, pp. 16):

> "[a] systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled"

There are two different types of audits, internal and external. Internal audits are those conducted by, or on behalf of, the organisation itself for management review and other internal purposes (ISO 9000, 2005). Whereas external audits are also classified into second and third party audits. Second party audits are conducted by parties having an interest in the organisation, such as customers. Third party audits are conducted by external organisations, such as certification bodies (see Figure 2.7).

An ISO 9001 organisation has to conduct internal audits on a periodic basis (ISO 9001, 2008) and has to receive periodic (usually annual) third party audits to maintain its certification (IAF MD5, 2009). It is important to consider that, despite third party audits not being a requirement of the standard, most organisations use them to give their clients confidence that the organisation is capable of delivering products or services that will meet their requirements (ISO 9000 Essentials, 2009). Moreover, as Karapetrovic & Willborn (2000a) state, quality audits are of great importance to managers who can call for an internal or external audit to conduct an impartial examination of the compliance of the QMS with the standard, as well as an evaluation of the QMS's suitability to achieve quality objectives.

That is why nowadays, conducting quality audits is one of the most important activities for ISO 9001 organisations. In fact, Power & Terziovski, (2007) suggest that one of the most significant developments in the operations management field, over the last twenty years, has been the implementation of quality audits to measure the effectiveness of QMS in organisations.

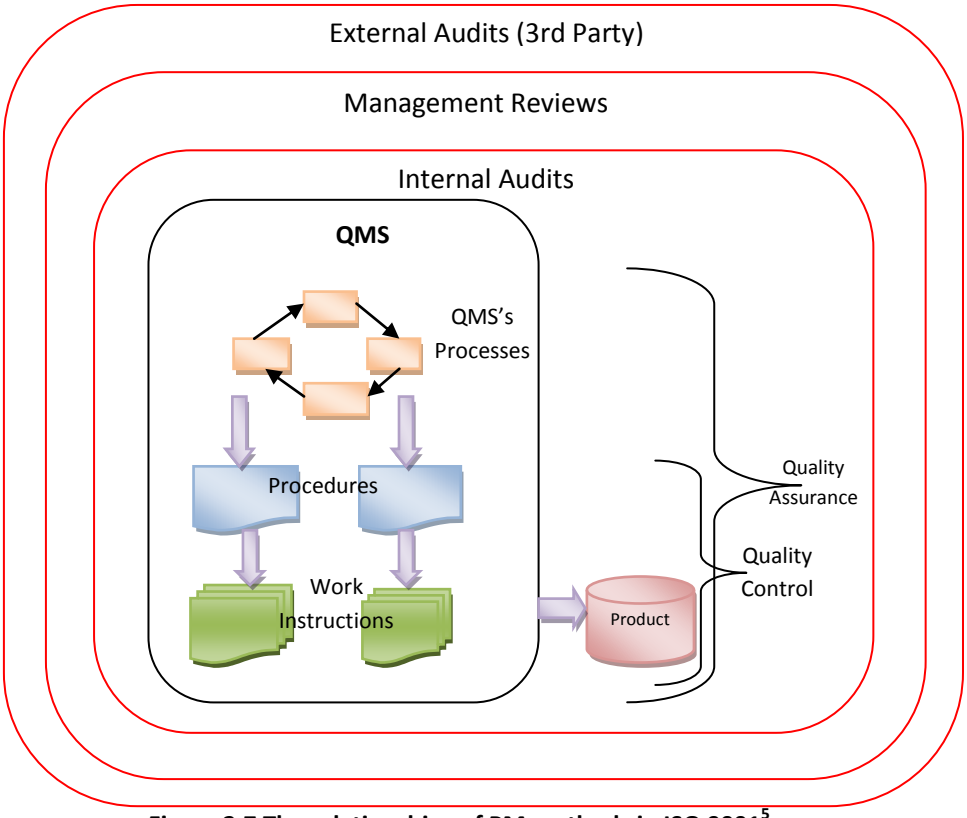


Figure 2.7 The relationships of PM methods in ISO 9001[5]

Conducting internal audits has been a mandatory requirement of ISO 9001 since 1984. The 2008 version includes clause 8.2.2 entitled 'internal audits' which states (ISO 9001, 2008, pp. 12):

> "The organization shall conduct internal audits at planned intervals to determine whether the quality management system
>
> a) conforms to the planned arrangements (see 7.1) [those related to develop all the processes needed for realising the products and services], to the requirements of this international standard and to the quality management system requirements established by the organization, and
> b) is effectively implemented and maintained.
>
> An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditor and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

[5] Customer satisfaction measurement is usually documented as a process in a ISO 9001 QMS, however it may be a method or procedure

A documented procedure shall be established to define responsibilities and requirements for planning and conducting audits, establishing records and reporting results."

The logic behind the standard requiring organisations themselves to audit their QMS is to verify that the organisations are managing their processes effectively or, as the ISO 9001 has stated, to check that they are fully in control of their activities (ISO 9000 Essentials, 2009). It is important to note that ISO 9001 contains several clauses to control and assure the quality of products, services and processes on a daily basis. When carrying out audits, it is necessary to verify that these clauses are correctly carried out, this will ensure that the QMS is operating properly. Thus, quality audits are oriented towards measuring QMS performance, process capability and product quality.

Moreover, the ISO 9001 standard demands that organisations implement a procedure in order to conduct internal audits and an annual auditing program which includes internal and external audits. The standard also suggests that organisations use the ISO 19011 standard for developing these tasks.

The ISO 19011:2011 Audit Standard

ISO 19011:2011 is a generic set of guidelines for auditing management systems. The standard was prepared by the ISO/TC 176 and provides guidance on the management of audit programmes, the conduct of internal or external audits of management systems, as well as on the competence and evaluation of auditors. The ISO 19011 standard is divided into four main clauses (ISO 19011, 2011):

- *Clause 4 describes the principles of auditing*. These principles help the user to understand the nature of auditing;
- *Clause 5 provides guidance on managing audit programmes*. This section covers such issues as assigning responsibility for managing audit programmes, establishing the audit programme objectives, coordinating auditing activities and providing sufficient audit team resources;
- *Clause 6 provides guidance on conducting audits of management systems*, including the selection of audit teams; and
- *Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors*.

The 19011 standard was the result of the integration of six previous standards (ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991, ISO 14010:1996, ISO 14011:1996 and ISO 14012:1996) and it was released as a consequence of continuous user pressure to integrate the audit process of the ISO 9001 and the ISO 14000[6] standards (Mors, 2008). When it was first released in 2002, the standard

[6] The ISO 14000 standards are for environmental management systems

provided clarity about how to conduct an audit for quality and/or environmental management systems and what kind of competences auditors need in order to perform management audits. The 2011 version of the standard includes guidelines about how to conduct a management system audit and specific examples of the knowledge and skills needed by auditors in each management system discipline.

Despite these important improvements, the issue of the PM of management systems is not included as a topic in ISO 19011:2011. One of the reasons why ISO 19011 is not aimed at auditing QMS performance is that when the standard was developed in 2002, the ISO 14000 family had not implemented a process approach. ISO 19011 started left with the same 'compliance with the requirements' approach of the ISO 10011 and ISO 14000 series. Thus, the standard is focused on compliance rather than on performance. Unfortunately for the ISO 9000 PM system, this decision postponed the development of its audit process with respect to the progress of the 9000 standards (Gupta, 2010).

Figures A.1 and A.2 in Appendix A illustrate the ISO 19011 auditing process for both internal and external audits, whereas Tables A.1 and A.2 show the interaction of actors in each activity.

In the following section, the current problems that organisations face when conducting audits will be discussed.

2.2 The state of the art of the ISO 9001 audit process

The three QMS PM methods analysed in the previous sections are granted the same importance within the ISO 9001 standard (ISO 9000, 2005; ISO 9001, 2008). Nevertheless, in practice, audits are the most important method for evaluating the performance of QMS because of their versatility (ISO 9001 Auditing Practices Group, 2004a). Audits can be used by both CB to grant the ISO 9001 certification, and CO as an assessment tool (ISO 17021, 2011). This dual usage of audits makes them the primary PM method in the ISO 9000 context (ISO 9000, 2005; ISO 9001, 2008). Moreover, the use of audits as a PM method for QMS is reinforced in the management process of the ISO 9001 standard, where the results of both internal and external audits are used as an input for conducting management reviews (ISO 9001, 2008).

During the last decade, several academics have suggested that concerns have arisen in industry about the value and consistency of audit results for both third party and internal auditing. In fact, the efficacy of the audit process has been seriously questioned for:

- *only being focused on compliance and missing a clear improvement approach* (Karapetrovic & Willborn, 2000a, 2000b, 2001b and 2002; Dalgleish, 2003; Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Privka, 2004; Biazzo, 2005; Rajendran & Devadasan, 2005; Power &

Terziovski, 2007; Terziovski & Power, 2007; Kaziliunas; 2008; Alic & Rusjan, 2010 and 2012; Gupta, 2010);

- *not detecting problems in products/services and processes* (Dalgleish, 2002; Karapetrovic & Willborn, 2002; Beckmerhagen *et al*., 2004; Vouzas & Gotzamani, 2005; Kaziliunas; 2008; Gupta, 2010);
- *failing to identify problems with the QMS* (Karapetrovic & Willborn, 2001a; Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Alic & Rusjan, 2010 and 2012; Le Saux, 2010); and
- *not providing sufficient added-value to organisations* (Liebesman, 2002; Karapetrovic & Willborn, 2002; Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Privka, 2004; Rusell, 2004; Biazzo, 2005; Power & Terziovski, 2005 and 2007; Alic & Rusjan, 2010 and 2012; Gupta, 2010).

Beckmerhagen *et al.* (2004) argue that the audit process has been highly criticised since a much publicised tyre recall by Firestone. The authors recount that "during the proceedings of the case, the quality system registrar[7] has apparently been implicated by the tire manufacture's top management for failure to identify the problem" (Beckmerhagen *et al.,* 2004, pp. 14). As these researchers suggest, this example is not unique and failures in the auditing process are unfortunately not rare.

Askey and Dale (1994) were the first authors to identify problems in the internal audit process with the first version of the auditing standard, ISO 10011. These scholars identified the following nine potential failures in the internal audit process when conducting case study research at one organisation:

1. Lack of commitment on the part of auditors and auditees;
2. Poor timekeeping during the audit;
3. A bureaucratic reporting system;
4. Not keeping to the annual schedule;
5. Lack of differentiation between a nonconformity and an improvement suggestion;
6. Failure of the audit mechanism to take into account that the original procedures may have omissions and that change to procedures may have distorted the original intent;
7. Lack of action on results is usually indicative of a lack of senior management commitment to the audit programme;

[7] In the early ISO 9000 standards, the terms "registration" and "accreditation" were used to refer to when an organisation had fulfilled the requirements of the standard. Consequently the concept "registrar" was applied to the third party institution or certification body that audited the organisation. However, some certification institutions, to avoid confusion with the terms started to use "certification" as well. In 2006 the ISO 17021 standard clarified these concepts and nowadays "certification" is used to imply that an organisation has fulfilled the requirements of the ISO 9001 standard whereas "accreditation" is used for the certification bodies that have a "registration" as "accredited" institutions to conduct third party audits. In the literature it is frequent to common find confusion amongst these terms.

8. Audits that do not have a clear objective and checklist may become swamped in detail; and
9. A concern among auditees that problems highlighted in their areas may reflect poorly on their abilities as managers.

In 2000, this list was updated by Karapetrovic and Willborn (2000b) who detected 16 failures in internal quality auditing:

1. Absence of opening meetings;
2. Errors in audit planning stages;
3. Inadequate audit program management;
4. Use of unqualified or incompetent auditors to conduct a specific audit;
5. Inadequate and improper use of sampling methods and other audit methodologies when collecting evidence;
6. Lack of a sufficient amount of audit evidence;
7. Deficient or missing verification of evidence;
8. Biased evaluation of audit evidence against audit criteria;
9. Acceptance of a non-compliant or ineffective management system in certification audits;
10. Rejection of a compliant and effective management system in certification audits;
11. Subjective, biased or unduly-influenced audit report;
12. Audit objectives do not reflect the underlying policy;
13. Audits are declared feasible when they are not;
14. Audit errors remain undetected;
15. Deficiencies in material resources and lack of available time to conduct the audit; and
16. Inconsistencies in audit findings between internal and external [Third Party] audits.

The approach of these scholars was anecdotal or theoretical and did not provide empirical evidence about which of these failures represented the greatest problems for organisations. However, it is clear that many organisations, especially SMEs, experience problems with their internal audits and hence the assessment of their QMS (Briscoe *et al.,* 2005).

Acknowledging these problems, the ISO/TC 176 published a revisited audit standard in 2002 for quality and environment management systems, the ISO 19011:2002. In 2004 Beckmerhagen *et al.* (2004) published a study which incorporated the 16 audits problems identified by Karapetrovic & Willborn (2000b) in the context of the new ISO 19011:2002 standard. These authors documented two case studies in the nuclear industry as serious examples of bad quality auditing practice. Due to the ISO 19011:2002 standard only having one year in force when this study was published, it is likely that some internal auditing problems reported by Beckmerhagen *et al.* (2004) have been solved by ISO 19011:2002 and that others have remained hidden because the audit process using the standard was not mature enough.

After conducting a detailed review of the literature on internal audits from the last decade and having reviewed the changes in the new versions of the auditing and requirements standards (ISO 19011:2011 and ISO 9001:2008), eight current internal audit problems have been identified. Table 2.1 shows these problems with their source in the literature.

Audit problems	Source in the literature
Lack of internal auditor competence	Karapetrovic & Willborn, 2002; Beckmerhagen *et al.* 2004; Rajendran & Devadasan, 2005; Power & Terziovski, 2007; Kaziliunas, 2008
Lack of knowledge of ISO 9000 standards	Beckmerhagen *et al.* 2004; Kaziliunas, 2008
Lack of knowledge of auditing practices	Ni & Karapetrovic, 2003; Kaziliunas, 2008
Lack of top management commitment	Terziovski & Power, 2007; Alisic & Rusjan, 2010 and 2012; Wells, 2010
Inadequate audit planning ability	Karapetrovic & Wilborn 2002; Ni & Karapetrovic, 2003; Beckmerhagen *et al.* 2004; Kaziliunas, 2008;
Lack of follow-up of audit findings	Karapetrovic & Willborn, 2002; Ni & Karapetrovic, 2003; Wells, 2010
Lack of ability to measure audit performance	Beckmerhagen *et al.,* 2004; Biazzo, 2005, Rajendran & Devadsan, 2005; Power & Terziovski, 2007; Le Saux, 2010
Lack of ability to measure QMS performance	Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Briscoe *et al.,* 2005; Biazzo, 2005; Gupta, 2010

Table 2.1 Audit problems indentified in the literature in the period 2002-2012

It is important to note that these eight problems may be linked; for example a 'lack of knowledge of ISO 9000 standards' and 'lack of knowledge of audit practices' might be associated with 'lack of auditors competence'. Also, it is likely that audit problems impact the performance of the QMS; for example a 'lack of auditors competence' could lead to 'lack of ability to measure QMS performance' and 'lack of follow up of audit findings'. Such a causation chain might adversely impact the organisational capability to detect problems with operational processes, perhaps leading to undetected non-conforming products or services. The QMS may not be performing correctly; top management may be dissatisfied with it; and it is probable also that the overall quality capabilities of the organisation are not improving as expected when it was decided implement ISO 9001.

Similarly, five main impacts on the QMS due to poor audit practice were identified in the literature from the last decade (see Table 2.2).

Impacts on the performance of the QMS and organisations due to poor internal audits	Source in the literature
Organisations are not detecting all non-conforming products	Karapetrovic & Willborn, 2002; Beckmerhagen *et al*., 2004
Organisations are not detecting problems in their QMS processes	Dalgleish, 2002; Vouzas & Gotzamani, 2005
QMS is not performing correctly	Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Terziovski & Power, 2007; Alic & Rusjan, 2010 and 2012; Le Saux, 2010
Organisations are not improving their capabilities as expected	Karapetrovic & Willborn, 2002; Liebesman, 2002; Ni & Karapetrovic, 2003; Beckmerhagen *et al*., 2004; Biazzo, 2005; Alisic & Rusjan, 2010 and 2012; Gupta, 2010
Top Management is dissatisfied	Power & Terziovski, 2007; Wells, 2010

Table 2.2 Main impacts on the QMS and organisations due to poor auditing as reported in the literature during the period of 2002-2012

Although these connections are widely assumed and discussed among quality practitioners and auditors, the author found no research to shed light on the subject. In fact, the conversation about the problems that organisations face when conducting internal audits has been lost during the last eight years, scholars have been more concerned about how to improve the audit process. This issue of internal audit problems nevertheless, represents an interesting area of investigation that should be addressed because in order to improve internal audits, it is necessary to determine the current state of the art of the internal audit process. In the next section of this work, this position will be widely explained.

2.2.1 The debate between compliance versus performance

The continual problems that organisations face when conducting internal audits and the current top management dissatisfaction regarding audit results (Power and Terziovski, 2007) make it imperative to improve the internal audit process. In order to make this improvement possible, several authors have stated the need to change the current focus of internal auditing from compliance to performance (Karapetrovic & Willborn 2000a and 2000b; Biazzo, 2005; Power & Terziovski, 2007; Kaziliunas, 2008; Alic & Rusjan, 2010 and 2012). This new approach would permit organisations to focus on assessing the performance of their QMS processes instead of only looking at compliance with ISO 9001 clauses. An effective assessment of the performance of the QMS during internal audits would permit organisations to improve their products/services, processes and the QMS itself.

As pointed out above, the conversation about quality audits has moved precisely to this area. During the last decade, researchers have tried to deepen the understanding of the quality audit process by expanding the debate about

compliance versus performance auditing (Biazzo, 2005; Power & Terziovski, 2007) and by providing guidelines to improve internal auditing as a whole (Kaziliunas, 2008; Mors, 2008; Bernardo *et al*., 2010 and 2011; Alic & Rusjan, 2010 and 2012; Wells, 2010; Le Saux, 2010).

It is important to highlight that any change in the focus of the audit process would also require an update to the current audit criteria. Audit criteria are those policies, procedures or requirements used to perform an audit (ISO 19011, 2002). The main criteria for conducting both internal and third party audits are within the ISO 9001 standard itself. Organisations may include other criteria when conducting internal audits, but the standard identifies the minimum which they must use. For CB, the ISO 9001 standard also provides the mandatory criteria when conducting certification or surveillance audits.

Unfortunately, ISO 9001 is insufficient to correctly evaluate the performance of a QMS, due to its lack of clarity and focus in several key clauses. For example, clause 8.2.1, entitled 'customer satisfaction' requires that an organisation "monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined" (ISO 9001, 2008, pp. 12). In an ISO 9001 audit, auditors will ask what kinds of methods for evaluating customer satisfaction the organisation has implemented in order to fulfil this requirement. Nevertheless, using only clause 8.2.1 as audit criteria, they will not be able to determine if the methods or outputs are correct because the clause is vague and does not specify them. Hence, auditors will only be able to assess compliance with clause 8.2.1 of the standard, but they will not be able to assess if the implemented methods to measure customer satisfaction are providing the organisation with the correct results.

The ISO 9001 standard contains many clauses such as 8.2.1, where a lack of clarity and focus does not permit the performance and improvement of the QMS to be correctly evaluated using audits. The following are some examples of the lack of clarity in ISO 9001 clauses:

- 5.5.3 Internal Communication - "[t]op management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system" (ISO 9001, 2008, pp. 5);
- 6.4 Work Environment - "[t]he organization shall determine and manage the work environment needed to achieve conformity to product requirements" (ISO 9001, 9008, pp. 6); and
- 8.5.1 Continual Improvement - "[t]he organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review" (ISO 9001, 9008, pp. 14).

Requirements such as these do not assist auditors to perform competent work and, as a result, managers of some ISO 9001 certified organisations are dissatisfied with the current audit results they are receiving (Power & Terziovski, 2007).

Hence, using the current ISO 9001 audit criteria, auditors are only able to evaluate QMS compliance with the ISO 9001 standard, rather than assess the performance of the QMS processes in order to improve. The compliance audit approach misses the opportunity to effectively add value to organisations, because it does not help them to improve their QMS. This fact is very important because the ISO 9000 core of standards establish that when a QMS based on ISO 9001 is correctly implemented it "provide[s] the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties" (9000, 2005, pp.1). Thus, there is an inconsistency in the rationale of the ISO 9000 series. On the one hand, it declares that with the implementation of the clauses of ISO 9001, a framework for continuous improvement can be established. On the other hand, the current audit approach of compliance with ISO 9001 and ISO 19011 does not permit effective detection of improvements in the QMS.

Karapetrovic & Willborn (2000a) were the first scholars to detect this inconsistency, by pointing out that quality audits should be used for the primary purpose of continuous improvement and not only for compliance with the stated requirements. They also argue that audits directed at performance improvement, by far outweigh the benefits of audits for compliance purposes only (Karapetrovic & Willborn 2000b).

Also, in 2000, Najmi & Kehoe noticed that some problems that ISO 9000 CO were facing with their QMS may have been due to a lack of PM knowledge in the quality field. Hence, these academics attempted to connect the ISO 9000 QMS with the PM body of knowledge through developing a PM system framework for ISO 9000 certified organisations. However, the proposed framework is not properly linked with ISO 9001 clauses and referred to the 1994 version of the standard. This last fact did not permit their approach to be introduced into practice because it was published in 2000, the same year that the new version of ISO 9001 was published. Section 3.3 of this work discusses the Najmi & Kehoe approach to connect both the quality and PM bodies of knowledge in more detail.

The ISO/TC 176 and the IAF have been involved in different projects to try to help certified organisations towards better auditing practice. As discussed in Chapter 1, in 2003 these two bodies created the 'ISO 9001 Auditing Practice Group', an international committee of experts, with the aim of developing supportive audit guidance for the ISO 9001 standard. The first output of the group was the 'Sydney model' (2004), which is a framework that makes use of gap analysis to evaluate the effectiveness of QMS. The Sydney model proposes the identification of organisational objectives which have to be measured against organisational results. Hence, gap analysis is used to evaluate the differences between the expected outputs stated in the organisational objectives and the real results. However, the

main problem with the model is the pre-requisite to have *a priori* metrics to assess organisational objectives against ISO 9001 requirements, a pre-requisite that most CO do not accomplish because the ISO 9000 standards do not have this approach.

In 2004 the ISO 9001 Auditing Practice Group also published a set of documents addressing some common problems with the audit process (ISO & IAF, 2004a). The documents provide valuable guidance and examples of audit practice for organisations. Nevertheless, their focus was lost from the original effectiveness and improvement of the Sydney model to a focus just on compliance with ISO 9001 requirements.

The next important contribution to audit practice was stated by Biazzo (2005) who resumed the work of Karapetrovic & Willborn and Najmi & Kehoe and undertook a study in order to understand to what extent third party auditors focus on the performance of the QMS when they conduct external audits in order to detect improvements. The author developed a set of eight performance assessment dimensions which were evaluated by practitioners through a survey. Not surprisingly, Biazzo found that CB audit with a focus on performance only in two dimensions 'customer satisfaction management' and 'management of competences' which, as stated in section 2.4, are the other performance methods for assessing the QMS[8]. Nevertheless, the scholar concluded that "[t]he conceptual evolution of the ISO 9001 standard has intensified the problem of ceremonial conformity and made it necessary to move from the traditional conformance audit model towards the 'performance audit' model." (pp. 382).

Power & Terziovsky (2007) also advocate changing the current compliance approach to a performance based one in order to permit organisations to improve. They state that CO are looking for a more balanced approach to auditing in terms of compliance and continuous improvement. In their study the authors measured the perception of both auditors and auditees about how much focus on improvement was applied when conducting third party audits. Their results show a clear difference between the perception of both groups, with the managers of CO feeling that third party auditors conduct audits with too much emphasis on compliance auditing and not enough on continuous improvement.

Although the studies conducted by Biazzo (2005) and Power & Terziovsky (2007) were centred on third party audits, their results have important implications for internal audits, since both types of audits use the same audit criteria and are based on the same standards. The central difference between them is that the scope of internal audit can be readily expanded to include PM but this is not possible in third party audits (certification and surveillance) because these must necessarily focus on compliance with the ISO 9001 standard.

[8] What Biazzo identifies as 'management of competences' is part of the ISO 9001 PM method is 'management reviews'

More recently, Kaziliunas (2008) joined the conversation about changing the focus of internal audits. He provides an explanation about why, even if organisations are having problems with their audits, they apply the compliance approach. The author argues that "[o]rganisations continue with the conformity approach to auditing because certification bodies do the same. Auditors concentrate on what is easy and accessible, spending too much valuable time on details rather than on strategy and [the] larger picture" (pp. 72). Kaziliunas also suggests different approaches for better auditing, but he states that the most effective is the process-based approach where auditors seek to establish the results the organisation needs to achieve and examine the way that processes are managed to achieve these results and improve performance. Nevertheless, Kaziliunas (2008) does not provide audit criteria about how to conduct the performance assessment of processes in order detect improvements.

In recent years, scholars have advocated changing the current approach of internal audits from compliance to performance in order to better assess the performance of the QMS. As argued in this section, the results of the most recent studies regarding this issue support the need for this change.

2.2.2. The current trends to improve internal quality audits

As stated above, the conversation about improving audit practice has also included the development of different models, frameworks and guidelines. An important group of academics and practitioners have recently put forward some methods to help organisations move towards better auditing. In the following paragraphs these different approaches developed for the 2000 and 2008 versions of the ISO 9001 standard and their implications for performance auditing will be discussed.

Karapetrovic & Willborn (2001a) were perhaps the first academics to notice the need for improving the audit process for ISO 9001:2000. Their main concern was integrating different management systems into a systems audit. Hence, organisations would not allocate so many resources for conducting different audits and audit findings would have a greater impact for auditees due to being related to different disciplines (e.g. quality, health and safety and environment). This approach would also facilitate continuous improvement. The scholars propose a process for conducting internal audits with four main stages: audit determination and review; planning and design; resource allocation and deployment; and reporting and follow up. Hence, the results of the process, the audit findings, should lead to corrective and preventive actions which would permit the continuous improvement of the QMS. This proposal also includes conducting audits using the process-based approach of the 2000 version of the ISO 9000 core standards in order to have a system approach. Karapetrovic & Willborn's audit process represented an important advance in audit practice at that time, however, the authors did not provide any empirical data regarding the applicability of the framework and their approach was theoretical.

The same scholars also set out in another work a model for conducting individual self-audits, where process owners have to conduct continuous self-audits in order to evaluate the performance of processes (Karapetrovic & Willborn, 2001b). A problem with this approach is that the independence principle of auditing (ISO 19011, 2002) which states that auditors must not review their own work is not met. Hence, CO would find it difficult to implement this approach because in a third party audit a non-conformity would be identified for violating the independence principle.

In 2003, Ni & Karapetrovic updated the previous work of Karapetrovic & Willborn (2001b) regarding individual self-audits in the context of the ISO 19011 standard. Nevertheless, the independence principle of auditing was still not met in this approach.

Beckmerhagen *et al.* (2004) proposed a set of audit criteria to conduct effective internal audits. The authors discuss the risks of poor auditing, how to mitigate them and provide two examples in the nuclear industry about the importance of measuring and improving audit effectiveness. However, as with the previous proposals already discussed, the authors did not include empirical data to assess the proposed audit criteria.

From a practitioners' point of view, Berglund (2005), using the Sydney model, put forward a framework to audit the performance of a QMS in healthcare. The framework is intended to be used by organisations which have implemented balanced scorecards and other quality approaches apart from ISO 9001. A problem with this proposal is the limited number of organisations which will be able to fulfil these requirements.

Mors (2008) returned to the problem of integrating different management systems into a single audit. He provides a set of audit criteria for measuring the performance of an integrated management system for ISO 9001, ISO 14001 and ISO/TS 16949. The author notes that with the current audit criteria it is not possible to conduct an internal audit of an integrated system, due to the fact that ISO 14001 does not include a process-based approach. Hence, Mors developed some checklists for ISO 14001 using the process-based approach of ISO 9001 and ISO/TS 16949 in order to help auditors to conduct an integrated audit. This interesting approach aims to avoid the waste of resources in conducting each audit separately. Nevertheless, the audit criteria contained in the proposed checklists are too generic and the author does not provide more guidance on how to evaluate the performance of the integrated system to achieve continuous improvement.

Le Saux (2010) created a matrix to link the relationship between audit and metrics of performance. The author discusses four possible scenarios of outputs of an internal audit: QMS non compliant and ineffective; QMS compliant but ineffective, QMS non compliant but effective; and QMS compliant and effective. Le Saux argues that a rigorous analysis of audit performance versus QMS processes metrics adds new data

to the audit process and allows a repeatable improvement mechanism which leads to enhanced performance.

Wells (2010) proposed a quality dashboard to translate internal audit findings into terms that top management will be able to understand. The author argues that audit findings do not generate excitement and urgency in top management because they are typically expressed as non conformances with the standards and procedures. Audit findings, in the opinion of Wells, should be expressed in terms of money which is the metric that top management understand and is interested in. Hence, Wells provides an example of a global quality dashboard where some metrics are established. Nevertheless, the author does not provide any criteria about how to select effective metrics for the dashboard.

Bernardo *et al.* (2010 and 2011) also investigated the issue of integrating management systems into a single audit. They conducted a survey between different Spanish ISO 9001 and ISO 14000 certified organisations to analyse the application and level of integration of internal and third party audits. The authors found that organisations that exhibited a higher level of integration in their management systems also had integrated internal audits.

More recently, Alic & Rusjan (2010 and 2012) developed a theoretical framework for assessing the contribution of internal audits to the achievement of business goals. The authors argue that internal audit findings set the grounds for achieving business objectives when the ISO 9001 QMS is related to the balanced scorecard. Nevertheless, as with the Sydney model, certified organisations need to establish *a priori* a set of performance metrics aligned to the ISO 9001 clauses, a pre-requisite difficult to accomplish for many organisations, especially SMEs.

To summarise, due to the constant problems that organisations have with their internal audits, various scholars have proposed models, frameworks and guidelines aimed at improving the internal audit process. As stated above, there have been two main lines of research in this area:

- the integration of different management systems into a single internal audit for a better and more effective use of audit resources (Karapetrovic & Willborn, 2001a; Mors, 2008; Bernardo *et al.,* 2010 and 2011); and
- the incorporation of different performance models and metrics to make audits a more effective decision making tool for top management (Karapetrovic & Willborn, 2001b; Ni & Karapetrovic, 2003; Beckmerhagen *et al.* 2004; Berglund, 2005; Alic & Rusjan, 2010 and 2012; Wells, 2010).

The latter models, however, with the exception of the work of Alic & Rusjan (2010 and 2012), have not incorporated concepts from the PM body of knowledge in their proposals, as suggested by Najmi & Kehoe (2000). This omission has caused the respective models to have a lack of clear audit criteria to measure the performance of the QMS, making it more difficult to change the current compliance approach of internal auditing to a performance based one. And this is precisely the main

objective of this thesis, to provide an internal auditing framework to help ISO 9001 companies effectively measure the performance of their QMS.

2.3 Conclusions of the chapter

This chapter presented an introduction to the ISO 9000 family of international standards and reviewed the relevant literature relating to ISO 9001 and its internal audit process. Two main conversations regarding the problems faced by organisations when conducting audits and how to improve the audit process were discussed in depth. The literature review yielded two main conclusions:

- it is important to conduct a study to identify the current problems faced by certified companies when conducting ISO 9001 internal audits. Since the most recent study addressing this issue dates back to 2004 and there is evidence in the literature that organisations continue facing many problems with their internal audits, despite the fact that the ISO 9001 and ISO 19011 standards have been updated a few times in this decade; and
- PM concepts should be integrated into the body of knowledge of quality management in order to improve the internal audit process. There has been significant progress on this issue in two ways: discussing the need to change the current approach from compliance to a performance approach; and proposals of new models to help to improve audits. However, no research has connected both quality and PM bodies of knowledge in the context of the ISO 9000:2008 standard. That is, to propose the improvement of the internal audit process by creating audit guidelines focused on PM.

It was from these conclusions that the research gap and, subsequently, the research questions, stated in Chapter 1, were developed. However, the evident importance of PM to this research led to a further substantial investigation into the literature which aimed to examine the development and main concepts of the PM field related to ISO 9001 QMS. This review will be described in the following chapter.

CHAPTER 3
THE PERFORMANCE MEASUREMENT FIELD

This chapter aims to review the body of knowledge of performance measurement (PM), in order to address the first research objective of this work:

> "conduct a literature review which identifies the key concepts of both the QMS and PM bodies of knowledge together with relevant organisational theories".

Due to the fact that the PM body of knowledge is of great diversity (Neely *et al.*, 1995) and that the aim of this thesis is to develop an auditing framework to measure the performance of the ISO 9001 QMS, only the models, techniques and concepts related to PM systems will be discussed in this section.

Section 3.1 gives an introduction to the origins of PM as a body of knowledge and provides some important definitions. Section 3.2 defines a PM system and the elements that constitute it. Section 3.3 discusses the relationship between the PM body of knowledge and ISO 9000 standards. Finally Section 3.4 discusses the conclusions of this chapter.

3.1 Background

The interest in PM has importantly increased during the last 20 years, as organisations have understood that to improve their capabilities it is necessary to monitor, measure and control their environments (Taticchi *et al.,* 2010). However, as Franco-Santos & Bourne (2005) state, to implement an efficient PM system is not an easy task, it requires top management commitment, communication through all the levels of the organisation and the implementation of different strategies to motivate the collaboration of the personnel of the organisation. Nevertheless, even fulfilling all these conditions, there is no guarantee that the implemented system will be successful. In fact, some authors suggest that around 70% of attempts to implement PM systems fail (Bourne *et al.,* 2003; Franco-Santos & Bourne, 2005).

One of the reasons why implementing a PM system is a difficult task, is the diversity of PM system models extant. In fact, Neely (2005) points out that the most important authors in the field come from different backgrounds such as accounting, information systems and operations research. This causes people from different disciplines to try to answer different research questions using different approaches. Neely (2005) also concludes, "the resultant task of integrating the knowledge generated by such a diverse group of scholars to enable the development of a coherent and agreed body of knowledge for the performance measurement community would inevitably be a significant challenge" (Neely, 2005, pp. 1269).

Traditionally, quality experts have measured the performance of their QMS using quality cost (Crosby, 2004); quality control data (Deming, 2000); non-conformance (ISO 9000, 2005); and process capability index (statistical processes). In the context of ISO 9000, different standards addressing these topics have also developed, such as ISO/TR 10014:2006 guidelines for realising financial and economic benefits and ISO/TR 10017:2003 guidance on statistical techniques. However, these approaches are mainly oriented towards measuring the performance of processes and products instead of the QMS as an entity. This, as argued in Chapter 2, is causing different problems in the QMS and top management dissatisfaction. And this is precisely where the PM field became relevant to QMS because this body of knowledge may be able to provide strong foundations for incorporating performance metrics into the QMS.

In the following paragraphs, the PM field will be discussed and its connections with QMS will also be described.

The origins of PM

Bourne *et al.* (2003) reported that the PM field has its origins in early accounting systems, with the Medici system being a good example of how to maintain an accounting system without recourse to high-level techniques. In fact, financial measures have long been used as a way to assess performance in organisations. Johnson (1981), cited by Bourne *et al.* (2003), documented four main stages of management accounting developed in the USA between the 1850s and 1920s:

piecework to wages; single to multiple operations; individual production plans to vertical integrated business; and individual business to multi-dimensional firms.

After the First World War, some large companies, including DuPont and General Motors, developed more creative accounting tools, such as flexible budgets and returns on investment (Bourne *et al.,* 2003). Neely & Bourne (2000) argue that these techniques were widely adopted during the last century and hardly evolved in 80 years.

More recently, Taticchi *et al.* (2010) traced the modern origins of PM up until the 1980s, when the ´economic value-added model' and the 'activity based costing model' were developed as a result of the deficiencies in traditional accounting systems. These systems encouraged short term decision-making and were not always suitable for modern manufacturing; potentially damaging the economy of the organisations that implemented them (Bourne *et al.,* 2003). Kennerley & Neely (2002) argue that these early PM systems used only profits as the main performance measure and failed to consider what organisations have to manage in order to create those profits. Johnson & Kaplan (1987) were pioneers in highlighting these deficiencies and since the publication of their research more scholars have been interested in developing different PM models and techniques. Neely (2005) has classified the published modern PM literature into five broad phases:

- in the 1980's, a process of 'problem identification' recognising and discussing the weaknesses of measurement systems and their organisational impact;
- early 1990's, potential solutions were being proposed (e.g. balanced scorecard), search for frameworks;
- third phase, 'methods of application' involved the search for ways in which the proposed frameworks could be used;
- late 1990's, processes and methodologies for populating measurement frameworks were developed and discussed by researchers and practitioners; and
- recently, a call for more robust empirical and theoretical analysis of performance measurement frameworks and methodologies has begun. This phase is characterised by 'empirical investigation'.

Taticchi *et al.* (2010) have noted that nowadays scholars and practitioners are paying more attention to how companies can achieve their planned objectives through the measurement of their performance. They argue that PM systems need to enable companies to more effectively identify the relationships between their processes in order to translate PM system information into effective tasks. The authors also suggest that organisations do not face any problems in finding a right set of Key Performance Indicators (KPIs) for monitoring their performance; their difficulties arise when they try to identify the cause-effect relationship of the value of each indicator. This statement is very important for the ISO 9000 core standards because,

as reviewed in the previous chapter, the ISO/TC 176 committee has included for the first time in the 2008 version of the ISO 9004 standard the concept of KPIs, as a way of measuring performance. Thus, ISO 9001 certified organisations have to be aware of the problems that PM systems are facing regarding KPIs.

Some useful PM definitions

In their seminal work, Neely *et al.* (1995) state that PM is a topic which is often discussed but rarely defined. They argue that depending on the discipline, PM could have different connotations and definitions. Thus, they propose the following general definition to the concept:

> *"Performance Measurement* can be defined as the process of quantifying the efficiency and effectiveness of action"[9]
>
> (pp. 80)

The authors also define a 'performance measure' as:

> "a metric used to quantify the efficiency and/or effectiveness of an action"
>
> (pp. 80)

Whereas 'PM system' is defined as follows:

> "a set of metrics used to quantify both the efficiency and effectiveness of actions".
>
> (pp. 81)

Bourne *et al.* (2003) state that although the Neely *et al.* (1995) definitions are still valid, the concept of PM has changed and currently refers to a multi-dimensional set of performance measures for the planning and development of a business. This set includes financial and non-financial measures regarding internal and external contexts which are contrasted in current and future scenarios, to evaluate and predict organisation's performance. Moreover, these scholars also conclude that PM cannot be done in isolation because it is only relevant when a correct reference model exists and measures can be compared.

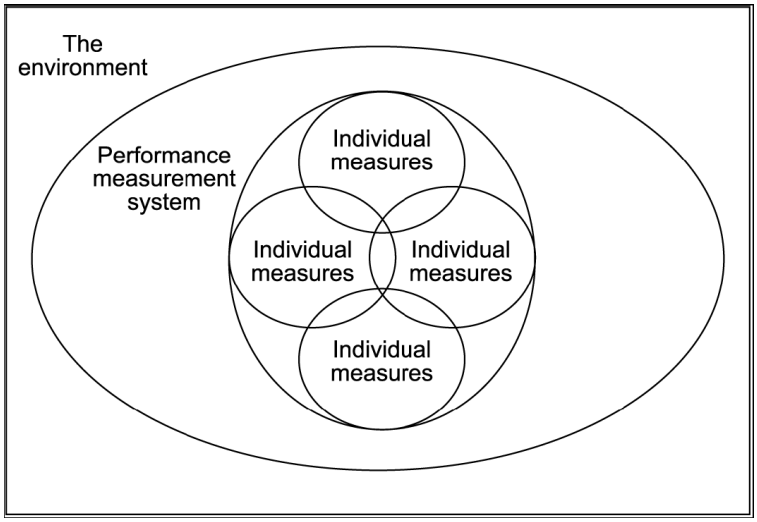
[9] It is important to note that the ISO 9000 family of standards has a strong focus on efficiency and effectiveness.

3.2 The PM System

Neely *et al*. (1995) argue that to better understand how PM interacts in organisations, it is possible to examine it at three different levels of scrutiny:

1. Individual performance measures;
2. The set of performance measures – the PM system as an entity; and
3. The relationship between the PM system and the environment within which it operates.

Figure 3.1 shows the relationships between these three levels.



Source: Neely *et al.,* 1995

Figure 3.1 A framework for PM system design

Hence, at the level of the individual measures, the PM system can be analysed by asking questions such as:

- "What performance measures are used?
- What are they used for?
- How much do they cost?
- What benefit do they provide?"

(Neely *et al.,* 1995, pp. 1229-1230)

The PM system level can be analysed by exploring issues such as:

- "Have all the appropriate elements (internal, external, financial, non-financial) been covered?
- Have measures which relate to the rate of improvement been introduced?
- Have measures which relate to both the long and short-term objectives of the business been introduced?
- Have the measures been integrated, both vertically and horizontally?
- Do any of the measures conflict with one another?"

(pp. 1230)

And the highest level, the system and its environment, can be analysed by assessing:

- "Whether the measures reinforce the firm's strategies;
- Whether the measures match the organization's culture;
- Whether the measures are consistent with the existing recognition and reward structure;
- Whether some measures focus on customer satisfaction; and
- Whether some measures focus on what the competition is doing."

(pp.1231)

The PM system developed by Neely *et al.* (1995) has become one of the most widely used PM frameworks for academics and scholars (Neely, 2005; Taticchi *et al.,* 2010). In the following paragraphs each PM level of this framework will be discussed.

3.2.1 The individual performance measures level

All PM systems consist of a set of individual performance measures (Neely *et. al*., 1995). Due to the diversity of scholars who have researched in this area, there are different models to categorise these measures, from Kaplan and Norton's (1992) balanced scorecard to Franco-Santos & Bourne's (2005) critical PM factors. However, Neely *et al*. (1995) generic categorisation is one of the most cited in the literature. These authors propose classifying individual performance measures into four types: quality, cost, flexibility and time. Table 3.1 provides the dimensions of these measures.

Quality	Time	Cost	Flexibility
Performance	Manufacture lead time	Manufacturing cost	Material quality
Features		Value added	Output quality
Reliability	Rate of production introduction	Selling price	New product
Conformance	Delivery lead time	Running cost	Modify product
Technical durability	Due-date performance	Service cost	Deliverability
Serviceability			Volume
Aesthetics	Frequency of delivery		Mix
Perceived quality			Resource mix
Humanity			
Value			

Source: Neely *et al.* (1995)

Table 3.1 The multiple dimensions of quality, time, cost and flexibility

3.2.2. The PM system as an entity

As far as the PM system as an entity is concerned, Neely *et al.* (1995) identified the following PM systems as the most important approaches in the literature:

- the PM matrix developed by Keegan *et al.(1989);*
- the PM questionnaire created by Dixon *et al*.(1990);
- CAM-I approach by Computer Aided Manufacturing International;
- nine- step process by Wisner & Fawcetts;
- Globerson's guidelines for PM system design;
- Maskel's seven principles of PM system design; and
- the balanced scorecard by Kapan & Norton (1992)

(Neely *et al*., 1995)

In a more recent review of the PM research published in 2005, Neely found that these models are still the prevailing approaches in the literature and they are used as the basis of new developments. He also argues that the PM research community is very dependent on this limited number of works and the balanced scorecard (BSC) is clearly the single concept that dominates the field.

In 2010 Taticchi *et al.* published a literature review following Neely's (2005) work. In their lists of the most cited PM works, the scholars include the 7 PM systems described above and, interestingly, they also add the European Foundation for Quality Management's (EFQM) Excellence Model[10] to the list. These scholars also found that the BSC is the most influential work in the PM body of knowledge.

The balanced scorecard

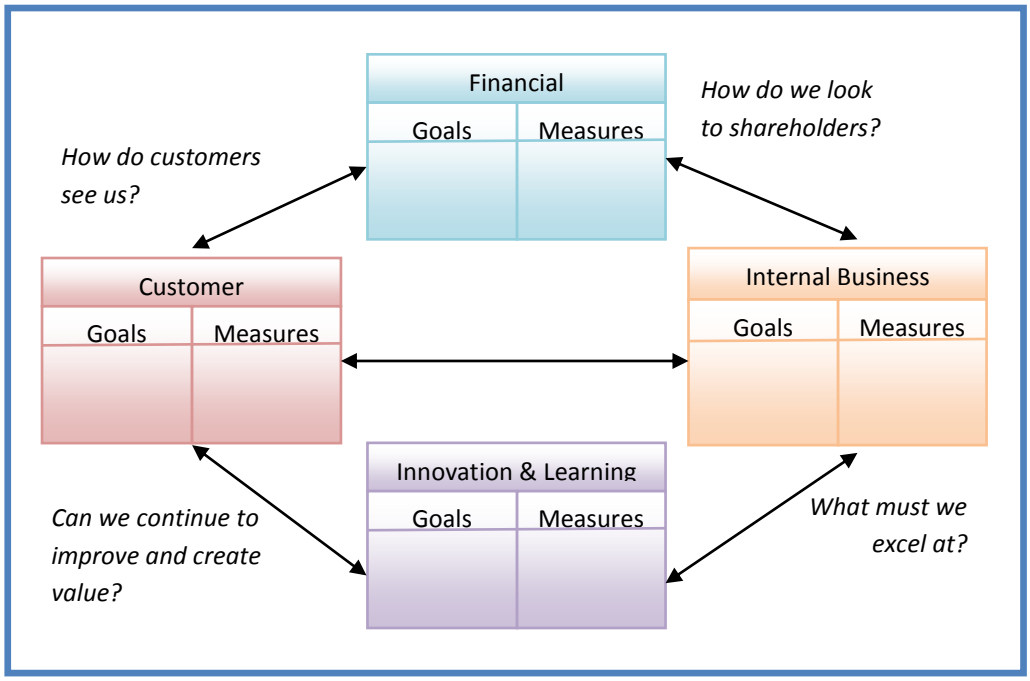
Part of the reasons why the BSC has been widely adopted by organisations is that it provides managers with information to answer the following questions:

- How do we look to our shareholders?
- What must we excel at?
- How do our customers see us? and
- How can we continue to improve and create value?

Hence, the BSC is a tool that permits PM to be linked with the strategy of organisations. For Kaplan & Norton (1992), managers should not have to choose between financial and operational measures, they should have a complete view of the business through four main dimensions: financial; internal business; customer and innovation; and learning perspective. Figure 3.2 shows the linkages of these performance measures.

[10] The business excellence models are discussed in Appendix M

It is important to highlight that despite the recent attention that the BSC has received in industry, there is not much literature relating the BSC with quality performance applications. In fact, the author was only able to find the Alic & Rusjan (2010 and 2012) study linking the BSC with ISO 9001 internal quality audits. This study was discussed in Chapter 2.



Source: Kaplan & Norton (1992)

Figure 3.2 The balanced scorecard

The business excellence models

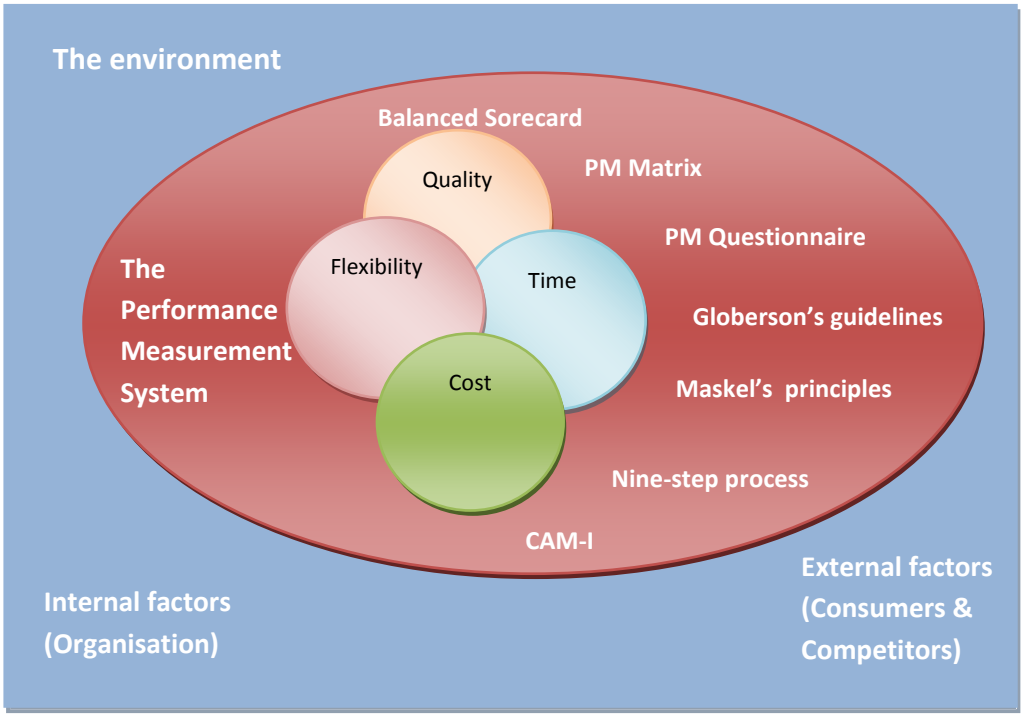
As stated above, Taticchi *et al.* (2010) found evidence denoting the EFQM excellence model as a PM system. Business Excellence Models (BEM) are self-assessment frameworks which allow organisations to measure their continuous improvement (Dale *et al.*, 2007e). The most recognised BEM are the Deming Application Prize in Japan, the Malcolm Baldrige National Quality Award (MBNQA) in the US and the EFQM in Europe. Although there are some differences between these models, they have some common elements and themes. There are many national and regional quality/excellence awards, however most of them are based on the Deming, MBNQA and EFQM models (Dale *et al.*, 2007e). Appendix M provides a description of these models as well as their assessment criteria.

One of the reasons why organisations see the EFQM model as a PM system may be due to the model's criteria providing a good assessment framework to determine the state of their improvement processes. In fact, Dale *et al.* (2007e) argue that the measurement of the progress of improvement on a daily basis and its comparison with scores from previous assessments is a confirmation to the management team

that real improvement and achievement have taken place. The quantification of performance in terms of numbers is important for senior management (Dale *et al.* 2007e) and this is may be why organisations see BEM as good tools to measure their performance. However as Davies (2008) states, implementing the EFQM is not an easy task for organisations and the integration of the EFQM model into the functions of the organisation is an essential element in its effective implementation.

3.2.3 The PM system and its environment

Regarding the PM system and its environment, Neely *et al.* (1995) argue that the environment has two fundamental dimensions: internal (measures related to the organisation) and the external (measures related to the market in which the organisation competes). Examples of internal measures are cost profiles, product profitability and past financial performance, whereas external measures are related to consumers and competitors. Figure 3.3 illustrates the PM system model proposed by Neely *et al.* (1995).

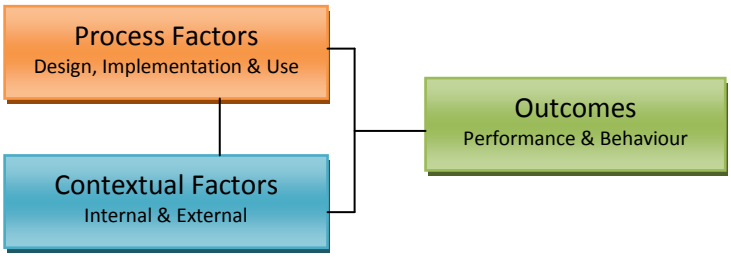


Adapted from Neely *et al.* (1995)

Figure 3.3 A framework for performance measurement design

In 2005, Franco-Santos & Bourne took a different approach to analysing PM systems, they also conducted a systematic literature review of the PM field but classify the articles using 'the Pettigrew change management framework' which permits a

relationship to be traced between the process factors used in the implementation of a PM system and the contextual factors and outcomes interacting in the PM system (see Figure 3.4).



Source: Franco-Santos & Bourne (2005)

Figure 3.4 The Pettigrew change management framework

The authors argue that *process factors* in a PM system can be categorised into factors relating to design, implementation and use.

Moreover, they explain that there are many factors that enable an organisation to effectively design a PM system, but the critical factors are: implementation of performance measurement frameworks and strategy maps; the effective development of measures and targets; the correct alignment and integration of the PM system with the business strategy; and a correct information structure.

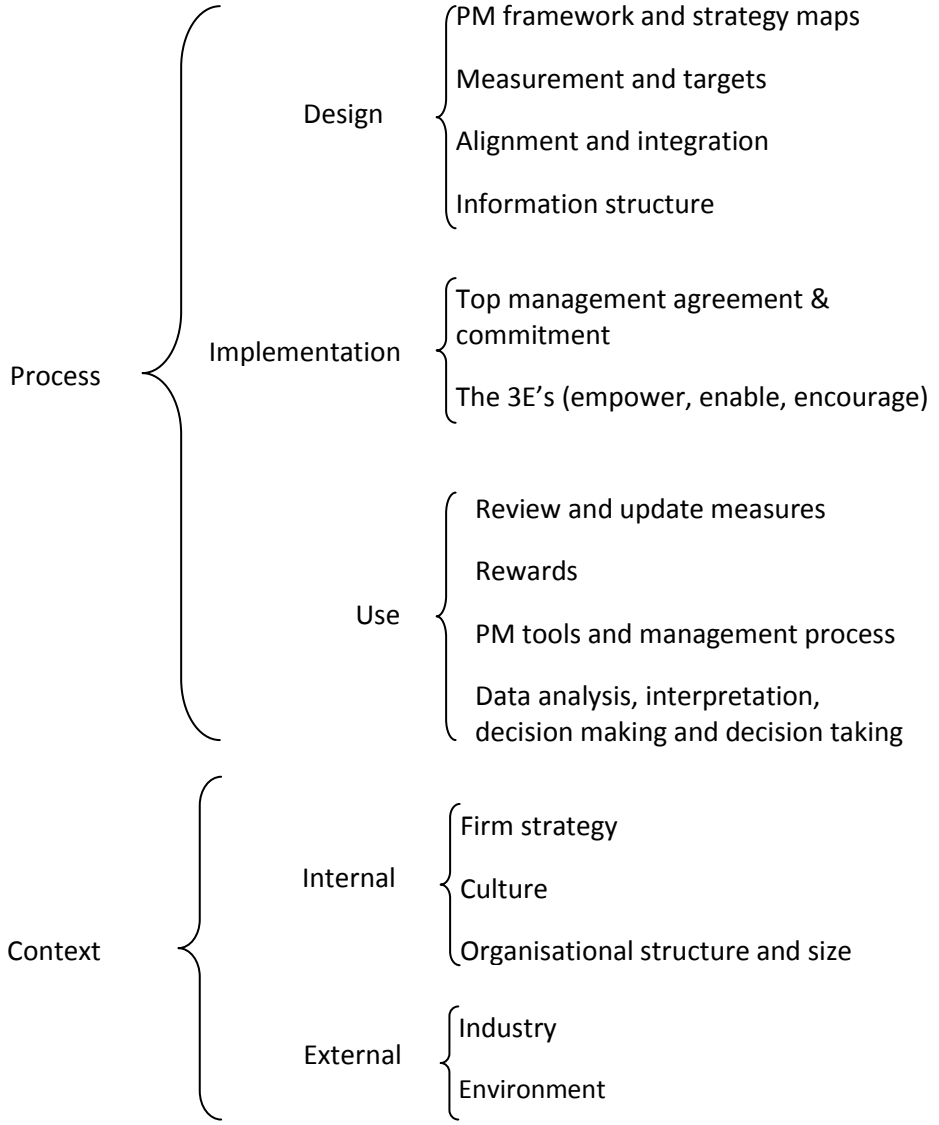
The researchers also suggest three critical factors for correctly implementing a PM system: top management agreement and commitment; communication; and the implementation of the 3 E's strategy[11] between people in the organisation.

As far as the effective use of PM system factors is concerned, Franco-Santos & Bourne (2005) state that the key factors that enable an organisation to better manage itself through measures are the systematic review and update of the measures; the implementation of rewards; the developing of tools and specific management processes that facilitate the use of the performance measures; and the establishment of the management cycle: data analysis, interpretation, decision-making and action taking.

The authors also argue that little attention has been paid in the literature regarding contextual factors; there are just a few scholars who have investigated this topic (e.g. Hoque & James, 2000). Pettigrew (1985), cited by Franco-Santos & Bourne (2005), categorises contextual factors as internal and external. The most important internal factors identified in the literature by Franco-Santos & Bourne are firm strategy; culture; and organisational structure and size; whilst the most important

[11] Empower, enable and encourage

external factors are industry characteristics and environment. Figure 3.5 presents a summary of the Franco-Santos & Bourne (2005) work.



Source: Franco-Santos & Bourne (2005)

Figure 3.5 The relationship of critical factors affecting a PM system

3.3 The relationship between the PM field and the ISO 9000 world

As discussed in Chapter 2, Najmi & Kehoe (2000) were the first scholars who noted that an ISO 9000 series QMS could be improved if some PM concepts were incorporated in the quality field. Hence, these academics attempted to connect the QMS and PM fields by developing a PM system framework for CO, using the work of Neely *et al.* (1995) as a basis.

For building their framework, Najmi & Kehoe (2000) administered a survey to quality managers in order to find out the most important QMS dimensions for a PM system based on the 1994 version of ISO 9000 standards. From the data, they established six dimensions: suppliers; customers; employees; management; processes; and quality information systems.

Najmi & Kehoe (2000) also identified three individual performance metrics: quality; time; and financial aspects. It should be noted that Najmi & Kehoe incorporated most of the individual measures classified as 'cost' by Neely *et al.* (1995) in the financial aspects. Similarly, they included 'flexibility' as an individual measure of time. Table 3.2 shows their individual performance measures.

Quality	Time	Financial
Incoming parts quality	Production lead time	Inventory turnover
In process quality	Cycle time	Production cost
Product quality	Flexibility	Cost of quality
Errors, defects, rework	On-time delivery	Sales growth rate
Failed failure under warranty	Product development timescale	Market share
Customer complaints		

Source: Najmi & Kehoe (2000)

Table 3.2 The individual performance measures for QMS

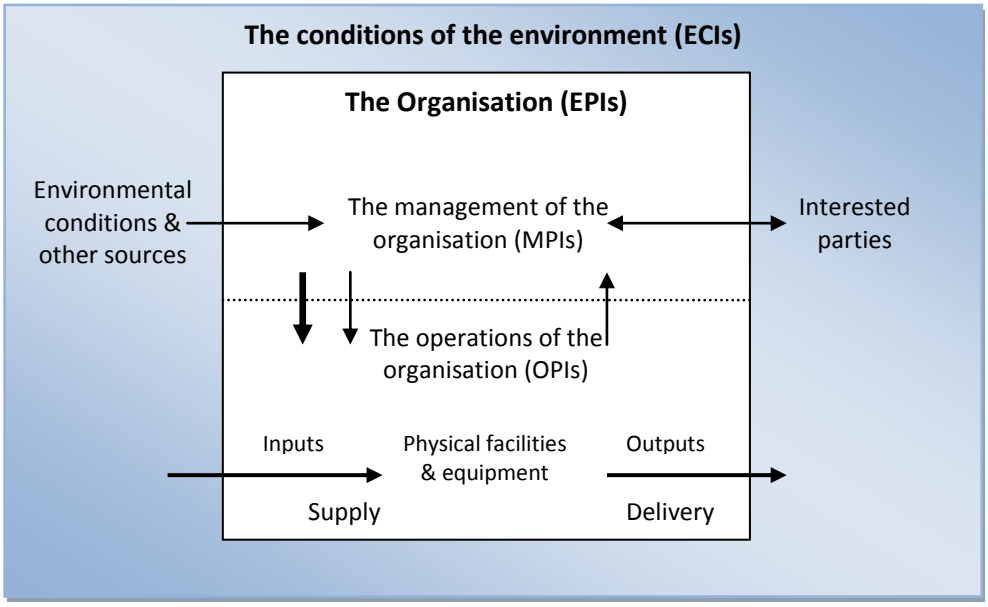
As with all research, the Najmi & Kehoe approach has some limitations. Firstly, there is no connection between the proposed set of measures of their framework and the ISO 9001 requirements. Thus, it is not clear how a company that is interested in maintaining its certification could use this framework. Secondly, the PM methods required to achieve the ISO 9001 certification (management reviews, customer satisfaction, and audits) are not related to the PM system developed by the authors. Finally, as discussed in Chapter 2, the ISO 9000 standards were radically changed in 2000 and this caused the Najmi & Kehoe framework to become obsolete almost immediately.

Measuring performance through ISO standards

In order to determine whether any other relevant PM standards have been developed, the British Standard Institution (BSI) data base was consulted on 29th May 2010. The BSI is recognised as one of the most prolific developers of standards in the world and its data base is one of the most complete and trustworthy sources of standards information.

A search was conducted with the key words: management -> systems -> performance -> measurement. Only one standard, ISO 14031 for environmental performance evaluation, was found which directly related to performance measurement of management systems. As ISO 14000 and ISO 9000 standards use ISO 19011 to assess their management systems, in the following paragraphs the evaluation model of ISO 14031 will be discussed due to its strong links with the ISO 9000 family.

The ISO 14031 standard, published by the Technical Committee for Environmental Management (ISO/TC 207), provides an interesting model to develop environmental performance indicators (see Figure 3.6).



Key

→	Information flows
→	Input and output flows related to the organisation's operation
➡	Decision flows
ECIs	Environmental conditions indicators
EPIs	Environmental performance indicators
MPIs	Management performance indicators
OPIs	Operational performance indicators

Source: ISO 17031

Figure 3.6 The interrelationships of an organisation's management and operations with the conditions of the environment

Smith (2010) explains that the ISO 14031 framework guides an organisation on how to select performance indicators in three categories: management performance indicators (MPIs); operational performance indicators (OPIS); and environmental conditions indicators (ECIs). Furthermore, the MPIs identify issues such as:

- implementation and effectiveness of environmental management programmes;
- management actions which influence the environmental performance of the organisation's operations, and possibly the conductions of the environment;
- efforts of particular importance to the successful environmental management of the organisation;
- environmental management capabilities of the organisation, including accomplishment of specific objectives, effective coordination, or problem-solving capacity;
- compliance with legal and regulatory requirements, and conformance with other requirements to which the organisation subscribes; and
- financial cost and benefits.

Regarding OPIs, the standard considers topics such as:

- inputs: materials, energy and services;
- supply of inputs to the organisation's operations;
- the design, installation, operation and maintenance of the physical facilities and equipment of the organisation;
- outputs: product design, services, wastes; and
- the delivery of outputs resulting from the organisation's operations

Finally, the ECIs are indicators concerned with the world, region and country on matters such as greenhouse emissions.

It is important to point out that some of these indicators will suffer considerable changes for the new version of the standard. In fact, almost all the qualitative indicators were eliminated from the draft of the standard during the TC/207 meeting in Leon in 2010 because, as stated by the chairman of the working group in charge of the revision of the standard, "they cannot be objectively measured".

ISO 14031 provides an interesting approach to the development of indicators for a management system, in this case an environmental system. However, it is far removed from the frameworks and techniques developed by scholars in the PM field and analysed above. ISO 14031 is only focused on identifying individual measures of performance and as argued above, a good PM system should include more dimensions. Nevertheless, this standard provides an interesting reference to develop a PM standard for the ISO 9000 family.

3.4 Conclusions of the chapter

This chapter aimed to provide a description of the most important PM concepts and techniques related to ISO 9000 QMS in order to incorporate them into the context of ISO 9001 audits. As argued in this chapter, PM is a field with great diversity and during the last two decades scholars have developed several different models, techniques and systems to help organisations measure their performance. For this reason, this chapter only included a review of the concepts related to PM systems which could be easily incorporated into the QMS world due to both areas being built around the systems approach.

Due to the fact that the PM system approach designed by Neely *et al.* (1995) is one of the most well-recognised approaches in the literature and has been previously used as a PM framework for the ISO 9000 QMS (Najmi & Kehoe, 2000), this system was discussed in detail. A good PM system, in the view of Neely *et al.* (1995), should include three levels of measurement: individual performance metrics; the set of PM measures (the PM system as an entity); and the PM system and its relationship with the organisations' environment. There are many types of individual performance metrics but those regarding quality, cost, time and flexibility are the most important for top management. Similarly, there are seven recognised techniques for establishing a set of PM measures in the literature. Nevertheless, the BSC has been the only technique which has been widely adopted in industry (Neely, 2005; Taticchi *et al.,* 2010). The relationship of the PM system and its environment was also discussed from the point of view of Neely *et al.* (1995) and also from Franco-Santos & Bourne (2005) who contextualise a PM system using the Pettigrew change management framework.

Finally, the relationship between the PM field and the ISO 9000 quality world was also addressed. There have been two attempts to connect the PM field with ISO standards:

- Najmi & Kehoe (2000) developed a PM framework for the ISO 9000 standards. However, their framework has two limitations: it is not linked with ISO 9000 clauses and refers to the earlier 1994 version of ISO 9000 standards. The first limitation made it difficult to implement for organisations and the second caused it to became obsolete almost immediately; and
- the ISO/TC 207 developed the ISO 14031 standard for environmental performance evaluation which provides of an interesting framework to assess an environmental management system. This standard provides an interesting reference to develop a PM standard for the ISO 9000 family.

CHAPTER 4
RESEARCH METHODOLOGY

The aim of this chapter is to describe the methodology used to address the research questions and objectives of this study. Section 4.1 explains the theoretical foundations and philosophical position underpinning this study. Section 4.2 describes the research design. Section 4.3 explains the first phase of the study "the identification and explanation of the current position", whereas Section 4.4 approaches the second phase "the development of a procedure for conducting ISO 9001:2008 audits to measure QMS performance". Finally, Section 4.5 provides the conclusions of the chapter.

4.1 Theoretical foundations and research philosophy

In developing research, the use of a particular methodology and methods characterise the assumptions about reality that the research is incorporating. But discussing assumptions is also discussing the theoretical perspective of the study (Crotty, 1998). In the following sections, the epistemology, theoretical perspective, methodology and methods used in the development of this research will be described.

Crotty (1998) argues that there are four basic elements in any research process:

- *methods:* the techniques or procedures used to gather and analyse data related to some research question or hypothesis;
- *methodology:* the strategy, plan of action, process or design lying behind the choice and use of particular methods and linking the choice and use of methods to the desired outcomes;
- *theoretical perspective:* the philosophical instance informing the methodology and thus providing a context for the process and grounding its logic criteria; and
- *epistemology:* the theory of knowledge embedded in the theoretical perspective and thereby in the methodology.

Hamlyn (1995), cited by Crotty (1998), states that epistemology deals with the nature of knowledge, its possibilities, scope and general basis. Epistemology is, therefore, the basis for both the theoretical perspective and the methodology which are chosen to address any research. There are several epistemologies, but *objectivism, constructionism* and *subjectivism* are the most recognised and used among scholars (Crotty, 1998). The other existent epistemologies are variations of these three worldviews (Crotty, 1998). *Interpretativism* is one of these variations and some thinkers have related it to constructionism. As Crotty (1998) argues, it is difficult to trace the boundaries between worldviews because authors use them in different contexts with different meanings. Thus, it is difficult to state with certainty, if interpretativism has roots with constructivism. Nevertheless, some thinkers have traced its origins to the German philosopher Max Weber (1864-1920), who suggested that human sciences are concerned with *Verstehen* (understanding) (Crotty, 1998; Bryman, 2008). Crotty (1998) indicates that Weber contrasts the interpretative approach (*Verstehen*, understanding) needed in human and social sciences with the explicative approach (*Erklären*, explaining), focused on causality which is found in the natural sciences. This way of understanding reality allowed other philosophers such as Wilhelm Dilthey, Wilhelm Windelband, and Henrich Rickert to create a distinction between qualitative and quantitative research methods arguing that natural and social reality are different and their investigation requires different methods (Crotty, 1998). However, Weber disagreed on this distinction and sustained that the one scientific method should apply to these two forms of science.

Nowadays, as Crotty (1998) notes, *interpretativism* has accepted that human and social sciences require different methods from those of natural sciences. The author states that many thinkers have recognised that the claims of *positivism* of certitude and objectivity cannot be sustained and findings in natural sciences are themselves social constructions and human interpretations. What currently is understood as *interpretativism* has different connotations such as hermeneutics, phenomenology, and symbolic interactionism.

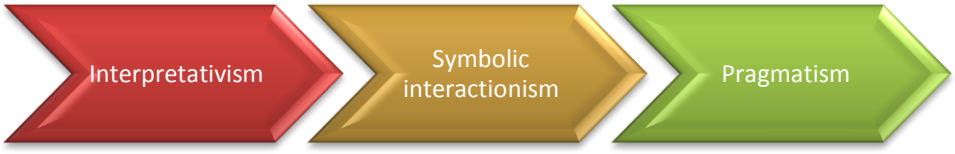


Figure 4.1 The epistemology and theoretical perspectives of this research

Symbolic interactionism "explores the understanding abroad in culture as the meaningful matrix that guides our lives" (Crotty, 1998, pp. 71). It is also the theoretical perspective which originates 'pragmatism' (see Figure 4.1). *Pragmatism* can be traced to the work of Charles Sanders Pierce, who was looking for a critical philosophy. The philosopher conceptualised pragmatism as a method for reflexion having the purpose to render ideas clearly (Crotty, 1998). Creswell (2009) argues that pragmatism arises out of actions, situations, and consequences rather than antecedent conditions. It is concerned with applications and solutions to problems. Pragmatist researchers emphasise the research problem and use all the available approaches to understand the problem instead of focusing on methods (Creswell, 2008).

This study was based on pragmatism due to its fundamental focus on business activity and the application of practical methods to solve problems. The ISO 9000 standards represent a practical approach for implementing QMS in organisations to solve their management problems. Because the study sought to develop an audit procedure for the ISO 9000 standards that helps practitioners to resolve the problems of effectively measuring the performance of QMS, a philosophical approach which is concerned with the solution of practical problems and that also provides some degree of freedom was necessary.

Research design

Regarding research design, there are three basic types: *quantitative, qualitative and mixed methods research* (Bryman, 2008; Creswell, 2009). Each one has different epistemological foundations and use different research strategies (Bryman, 2008).

Bryman (2008) points out that *quantitative research* is associated more with the natural sciences model. This type of research emphasises quantification in the collection and analysis of data that:

- "entails a deductive approach of the relationship between theory and research, in which the accent is placed on testing theories;
- It has incorporated the practices and norms of the natural scientific model and of positivism in particular; and
- It embodies a view of social reality as an external, objective reality."

(pp. 22)

On the other hand, as stated by Bryman (2008), *qualitative research* usually emphasises words rather than quantification in the collection and analysis of data that:

- "predominantly emphasizes an inductive approach to the relationship between theory and research, in which the emphasis is placed on the generations of theories;
- It has rejected practices and norms of the natural scientific model and of positivism in particular in preference for an emphasis on the ways in which individuals interpret their social world; and
- It embodies a view of social reality as a constantly shifting emergent property of individuals' creations"

(pp. 22-23)

Mixed methods research[12] is a relatively new research approach that has become popular amongst scholars during the last decade and combines quantitative and qualitative strategies of enquiry within a single project (Bryman, 2008). Bryman (2008) explains that the distinction between mixed methods research and other strategies is that mixed methods research combines methods that cross the two research strategies.

In the following sections, the research design of this study will be discussed. Because mixed methods research was chosen as the research method for both phases of the thesis: theory building method and theory testing; its philosophical grounds will be also examined. Finally, it will be stated why this method was chosen as the best option to address the research question of this study.

4.2 Research design

As previously stated, this study aimed to develop and test an audit procedure to help ISO 9001 certified organisations to measure their QMS performance. The research focused not only on the development of the descriptive theory but the development and testing of a practical tool and guidelines which can assist auditors to evaluate

[12] There are many terms used to refer to mixed methods research: integrating, synthesis, quantitative and qualitative methods, multi-method, and mixed methodology (Creswell, 2008).

QMS performance. In order to achieve the aims of the research, it is important to consider the following points when establishing the research design:

1. Establish a sound basis of knowledge concerning the current position of audit practice in ISO 9001:2008 certified organisations;
2. Include practitioner experience in developing the proposed audit procedure;
3. Test the validity and practicality of the proposed procedure in ISO 9001:2008 certified organisations; and
4. Involve the researcher when exploring the usability of the proposed procedure.

Due to these considerations, the research is divided into two main phases:

Phase 1 – The identification and explanation of the current position (research objectives 1 and 2)

This phase commences with a literature review presented in Chapter 1 and 2. For the empirical studies, a mixed methods approach involving both quantitative and qualitative methods was selected to provide the benefits of triangulation in terms of strong data reliability and validity. The quantitative method involved the development of two surveys which were administered to 272 participants. The analysis of these questionnaires provided data concerning the current state of the art of ISO 9001 audits and PM practices. The qualitative method chosen to triangulate was interviews, three different sets of semi-structured interviews were conducted with 25 ISO 9000 experts and practitioners, to establish the current position, influences, causation and trends. This phase provided the basis for theory building and developed some aspects of the final theory.

Phase 2 - The development of the procedure for conducting ISO 9001:2008 audits to measure QMS performance (research objectives 3 and 4)

This phase consisted of both theory building and theory testing. Using key outcomes from phase 1 (both theory and practice), a preliminary procedure for conducting ISO 9001 audits to measure QMS performance was developed. The proposed procedure was sent to 15 selected ISO 9001 experts, including internal auditors, quality managers, third party auditors, certification managers and TC/176 delegates, for a preliminary review. Using the experts' comments, the procedure was refined.

In the theory testing phase, an exploratory mixed methods research design was applied by combining a qualitative method (case studies) and a quantitative method (surveys at workshops) following the Creswell & Plano Clark (2007) design guidelines. Hence, the procedure was tested by conducting three in-depth case studies in organisations and a survey of 174 ISO 9001 experts. In each organisation, the study observed the application of the developed approach during a real internal

audit. The survey was conducted at six workshops, where ISO 9001 auditors were asked to provide feedback about the procedure, to support the findings of the case studies. Figure 4.2 illustrates the research design of this study.

In the following section, the first phase of the research design will be explained, paying special attention to the technique of triangulation of mixed methods research used in the study to identify and explain the current position.

4.3 The identification and explanation of the current position

The identification and explanation of the current position of the ISO 9000 audit process was exploratory in nature and was developed using the technique of triangulation which is part of mixed methods research. Creswell (2009) traces the origins of mixed methods research to 1959 when Campbell & Frisk used it in a study to validate psychological traits. Their study encouraged other academics to combine quantitative with qualitative research to neutralise or cancel the biases of a single method (Creswell, 2009). Creswell & Plano Clark (2007) argue that through mixed methods research, quantitative and qualitative data can merge into one large data base or the results can be used side by side to reinforce each other.

It is important to point out that the use of the term 'mixed methods research' has only recently been established between academics. Mixed methods research can also be found under the names: *mixed methodology, multimethod, quantitative and qualitative methods, synthesis and integrating* (Creswell, 2009).

Creswell (2009) also argues that mixed methods research has been popularised because all methodologies have limitations and the use of different methods in a project may neutralise them. Moreover, the author also states that researchers using it assume that collecting diverse types of data provides a better understanding of the research problem. Regarding its limitations, Bryman (2008) explains that the reason that the mixed method approach is not adopted more in academic studies is the epistemological criticisms the methodology has suffered during the last three decades. Two main arguments against this type of approach are explored by the author:

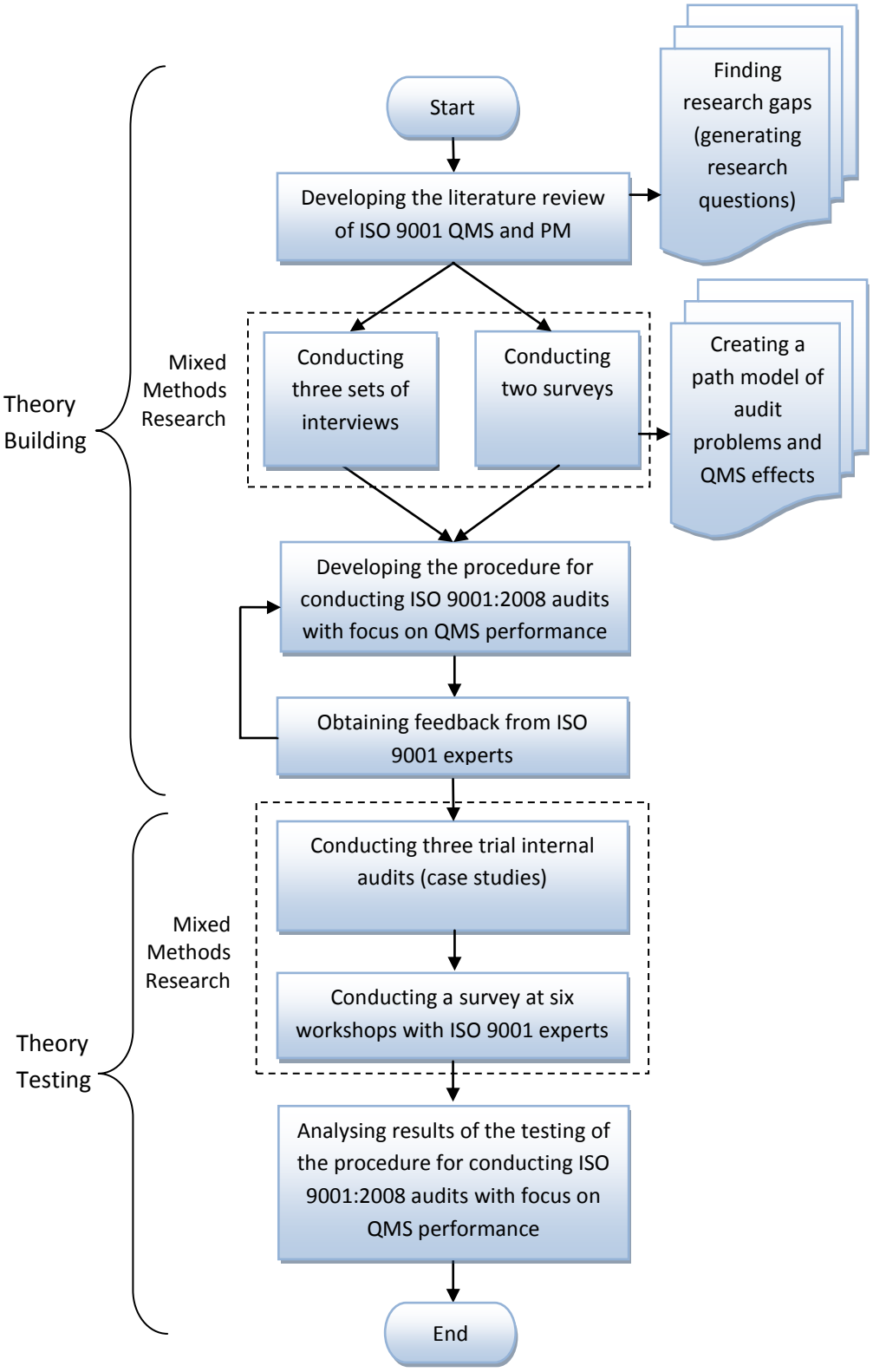


Figure 4.2 Flow diagram of the research design of this study

- mixed methods research does not have epistemological commitments; and
- quantitative and qualitative approaches are separate paradigms[13].

The first criticism implies that all research methods have to be associated with an epistemological basis and, as Bryman (2008) argues, when using mixed methods research it is not easy to fix a particular philosophical position. Moreover, Creswell (2009) indicates that pragmatism is the basis for mixed methods research, because it focuses its attention on the research problem in the social sciences and, then, uses pluralistic approaches to derive knowledge about the problem.

Regarding the second argument against the mixed methods approach, which conceives quantitative and qualitative research as incompatible paradigms, Bryman (2008) provides clarity in this debate arguing that "paradigms are incommensurable, it is by no means clear that quantitative and qualitative research are in fact paradigms" (pp.605). Furthermore, Bryman (2008) highlights that quantitative and qualitative methods are connected with distinctive epistemological philosophies but this connection is not fixed and ineluctable. The author indicates that research methods, unlike epistemology, are autonomous and that even when a leader method is stated to have been used in a study, the assumption of separate paradigms does not always apply.

Despite these criticisms, the use of mixed methods research has grown between academics during the last decade (Creswell, 2009). Nowadays, it is very common that editors of academic journals encourage the submission of papers using mixed method research.

Hammersley (1996), cited by Bryman (2008), has proposed three main uses for mixed methods research:

- *triangulation.* When researchers want to corroborate their quantitative or qualitative research using the other method;
- *facilitation.* One research strategy is employed to aid research using the other research strategy; and
- *complementarity*. When two research strategies are used in order that different aspects of an investigation can be fit together.

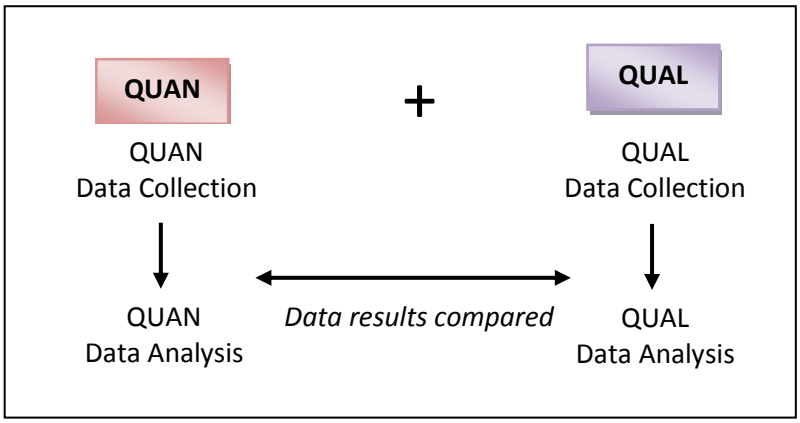
For this study, a 'triangulation' approach was used to identify the current state of the art of ISO 9001 audits, due to its strengths in providing strong reliability and validity to the results. Also a 'facilitation' approach was followed to test the

[13]Thomas Kuhn (1922-96) used the term 'paradigm' from his analysis of revolution of science. There is no consensus between academics about the concept (Crotty, 2008). However, Bryman provides a definition for the term, for him 'paradigm' is a "cluster of beliefs and dictates which for scientists in a particular discipline influence what should be studied, how research should be done and how results should be interpreted" (2008, pp. 605). It is important to point out that "'paradigms' are incommensurable, that is, they are inconsistent with each other because their divergent assumptions and methods" (ibid). Social Sciences are, as Bryman also explains, disciplines in which no paradigm has emerged as pre-eminent.

procedure for conducting ISO 9001:2008 audits with a focus on the performance of the QMS (Section 4.4. discusses this approach in greater detail).

Creswell (2009) argues that triangulation is probably the most used strategy of mixed methods research. Researchers may collect quantitative and qualitative information at the same time which can be compared later to check for divergences, differences or combinations. Moreover, the author indicates that this method generally uses separate qualitative and qualitative methods as a way to balance the weakness inherent in one method with the strengths of the other.

In triangulation, both quantitative and qualitative data are collected at the same time. Also, usually the weight given to the methods is the same (Figure 4.3). It is important to highlight that mixed methods research can also combine exclusively quantitative methods or qualitative methods. For example, Yin (2006) used experiments and surveys in a single project which are regarded as quantitative methods. Yin (2006) also argues that the dichotomy of mixed methods can apply to all methods and it is not necessary to have one that is qualitative and another that is quantitative in the same study.



Key:

+	Indicate simultaneous or concurrent forms of data collection
→	Indicates a sequential form of data collection
CAPITALISATION	Indicates that a method is emphasised

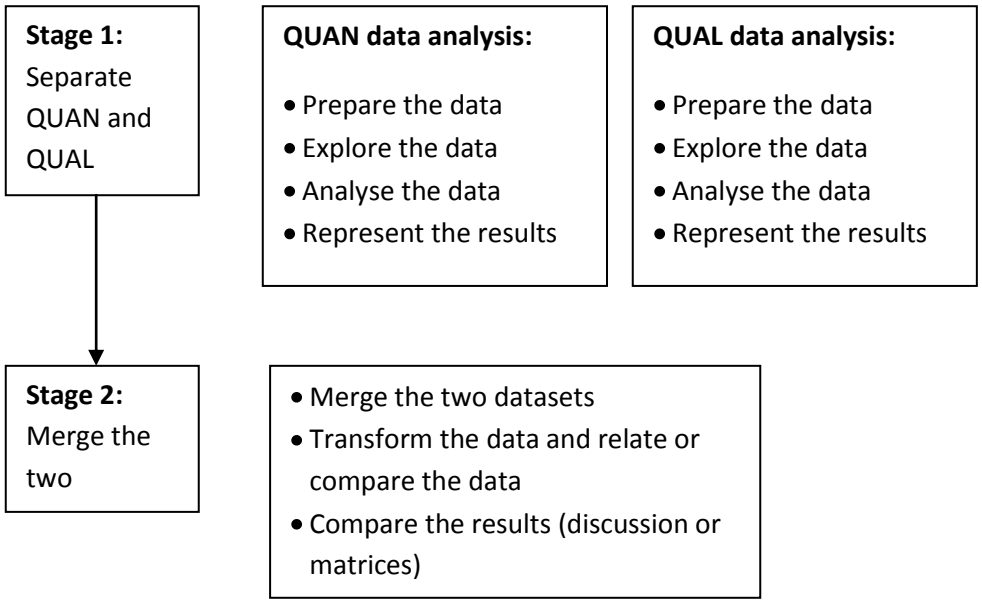
Source: Creswell (2009)

Figure 4.3 The triangulation design

Denzin (1978), cited by Jick (1979), defines triangulation as "the combination of methodologies in the study of the same phenomenon" (pp.291). The triangulation metaphor is from navigation and military strategy that uses multiple reference points to locate an object's exact position (Smith, 1975; Jack & Raturi, 2006). In geometry, multiple points allow for greater accuracy. Similarly, organisational researchers can improve the accuracy of their judgments by collecting different kinds of data bearing on the same phenomenon (Jick, 1979).

Although the use of triangulation in operations management (OM) research is relatively new (Jack & Raturi, 2006; Boyer & Swink, 2008), during the last decade scholars in the field have successfully used this approach to confirm their findings (e.g. Heikkila, 2002; Benders & Morita, 2004; Mangan *et al.*, 2004; Jack & Raturi, 2006). The point at which the perspectives converge is seen to represent reality (Jack & Raturi, 2006).

The procedures of mixed methods data analysis relate to the concurrent data analysis in a triangulation approach (Creswell & Plano Clark, 2007). In the concurrent approach the quantitative and qualitative analysis are kept separate (stage 1) to be merged later (stage 2) in order to develop a complete understanding of both datasets (Creswell & Plano Clark, 2007). As a result of merging the data, the researcher is able to answer: to what extent do the quantitative and qualitative data converge; how and why; to what extent do the same types of data confirm each other; and what similarities and differences exist across levels of analysis. Figure 4.4 shows the analysis procedure for a triangulation design when data collection was done concurrently.



Source: Creswell & Plano Clark (2007)

Figure 4.4 Concurrent data analysis procedures in triangulation

Creswell & Plano Clark (2007) suggest two techniques for merging quantitative and qualitative data: transform one type of data to make the qualitative and quantitative datasets comparable and then compare the datasets, or compare the data without transformation through a discussion or a matrix. In order to maintain the qualitative dataset for this study as accurate as possible, the second technique of comparing the data through a discussion or a matrix was used.

However, as happens with all research methods, triangulation has some limitations (Creswell, 2009):

- the effort and expertise required to study two separate methods at the same time;
- it is difficult to compare the results of two analyses using data of different forms; and
- sometimes it is unclear how to resolve discrepancies that arise when comparing the results.

As previously indicated, the triangulation technique was chosen for the theory building stage of the research because it provides high reliability and validity to the results. The methods selected to be mixed were surveys, which are generally recognised as a quantitative method, and semi-structured interviews that are a qualitative research method. Furthermore, surveys were selected as the research method because when conducting surveys it is possible to translate any concepts into a form which is measurable (De Vaus, 2002). Additionally, due to the fact that the ISO 9001 audit process falls on the expertise of internal and external auditors and that each audit they conduct is different, the use of semi-structured interviews was considered to gain enriched data, providing a better understanding of the current problems in the ISO 9001 audit process.

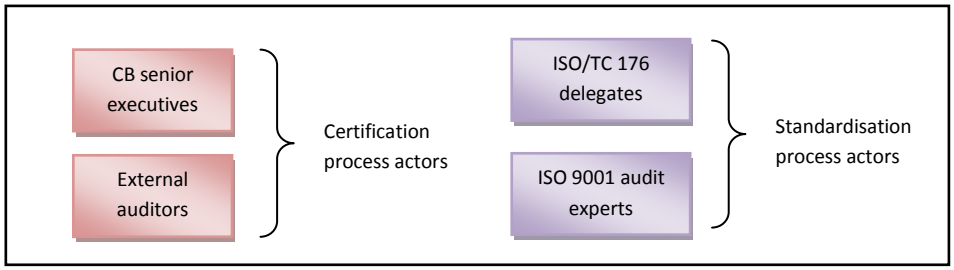
Thus, for this study, both sets of data were collected and analysed concurrently with equal weight. Then, the two data sets were merged by transforming interview data into quantitative data. The transformation was developed by classifying interview themes into the quantitative variables used in the surveys (Creswell & Plano Clark, 2007). Thus, a matrix using quantitative variables and qualitative themes was developed to facilitate the integration of both data types during the analysis (Creswell & Plano Clark, 2007).

4.3.1 The quantitative mixed method: surveys

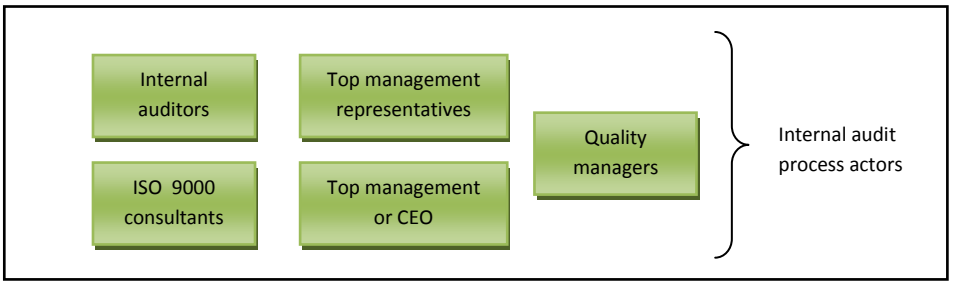
Creswell (2008, pp. 145) argues that "surveys provide a quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population. From sample results, the researcher generalizes or makes claims about a population". Meredith *et al.,* (1989) point out that the main strength of this method is its efficiency; surveys can be sent to a large number of people in a short period of time. Also, Boyer & Swink (2008) state that surveys can include measures designed to target specific factors which may not be directly observable and collect data directly from the individuals. As with all research methods, surveys also have some weaknesses. Meredith *et al.* (1989) point out that the main disadvantages of the method are the response rate, usually only a fraction of surveys are returned, and the difficulty in classifying open questions. Boyer & Swink (2008) highlight other concerns relating to survey research: respondents' interpretation of measures, potential lack of knowledge, bias and representation of unit of analysis. Despite

these weaknesses, surveys are one of the most popular research methods used by OM scholars and there are various techniques that help researchers overcome these weaknesses (De Vaus, 2002).

When using surveys it is necessary to identify the audience and the objectives of the surveys (De Vaus, 2002). CB and CO were determined as the audience of the surveys of this study, according to ISO 19011:2011. This classification was also consistent with the approach of Power & Terziovski (2007) of surveying both groups separately to cross information. Figure 4.5 shows the targeted audiences for each survey.



Certification bodies survey (CBS)



ISO 9001 certified organisations survey (COS)

Figure 4.5 Identification of the ISO 9001 audit actors by survey

Following the identification of the respondents, the objectives of each survey were stated. The aims of the first survey, identified as 'certification bodies survey' (CBS), were to:

- identify the problems that CB are facing when they conduct third party audits;
- determine the difficulties that CO have when they develop internal audits, from the point of view of third party auditors; and
- find out what are the most used PM techniques by CO for measuring QMS performance.

Regarding the 'certification organisations survey' (COS), the identified objectives were to:

- identify the problems that CO are facing when they conduct internal audits;
- find the difficulties that CO have when they receive certification or surveillance audits; and
- determine which PM models are used by CO to assess their QMS performance.

The certification bodies survey (CBS)

Following De Vaus (2002) guidelines about constructing questionnaires, the CB questionnaire was developed including 22 questions, 18 of which were closed and four were open questions. They were placed in four main sections: internal audit; external audit; performance measurement; and respondent. The CB questionnaire can be found in Appendix C.

Closed questions were chosen as the main format for the questionnaire because auditors, CB senior executives and standardisation experts are people with limited time and with this format they were able to answer the questionnaire in 10 to 15 minutes. In order to avoid the problem that the questionnaire did not include the desired answer in the list of options placed after the questions, an '*others*' option was included in each question to permit respondents to state their answers. In the same sense, each section of the questionnaire included an open question where the respondents could state their thoughts about the improvements that internal and external audits as well as performance measurement need.

Three different types of questions were used in the instrument: *knowledge*; *attitude*; and *attribute*. De Vaus, 2002 argues that *knowledge* questions seek to discover knowledge of particular facts, that is the accuracy of peoples beliefs; whereas *attitude* questions try to establish what they think is desirable; and *attribute* questions obtain information about the respondents' characteristics. Finally, a 1-5 numeric rating category was used as well as the 5 rating scale of Likert of *strongly agree; agree; neither agree nor disagree; disagree; and strongly disagree* items, following the guidelines for developing questionnaires of De Vaus (2002).

For the survey, two versions of the questionnaire, one in English and another in Spanish, were developed. The first version of the questionnaire was produced in English and reviewed by Dr. James D. Tannock from the University of Nottingham. Then, the Spanish version was created from the English document and reviewed by Dr. Nydia Lara Zavala from the National University of Mexico.

The pilot of the questionnaire was conducted during the period of 15th to 30th March 2010 by seven ISO 9000 experts, including CB senior executives, third party auditors and standardisation experts. During the review process, experts were encouraged to provide their suggested revisions of the instruments in terms of structure and content. Each expert looked at one questionnaire according to his/her interaction in the audit process. The evaluation of individual items included the examination of

variation; meaning; redundancy; scalability; non-response and acquiescent response set. As a result of this review, two questions were re-worded to ensure that respondents would understand the intended meaning of the questions and answers; some items were omitted to avoid redundancy and to ensure unambiguous interpretation by respondents; new variables were included in key questions; and the questionnaires were shortened. The results of the pilot testing can be found in Appendix C.

The certified organisations survey (COS)

The second questionnaire for ISO 9001 certified organisations was developed following the same considerations discussed for the CB questionnaire. For this survey, three versions of the questionnaire, in English, Spanish and Portuguese were developed. The first version of the questionnaire was produced in English and reviewed by Dr. James D. Tannock from the University of Nottingham. Then, the Spanish and Portuguese versions were created from the English document. The Spanish questionnaire was reviewed by Dr. Nydia Lara Zavala from the National University of Mexico and the Portuguese version was reviewed by Mrs. Joana dos Guimaraes Sá from the Portuguese Association for Certification (APCER).

The questionnaire was piloted during the period of 24th May to 21st June 2010 by 11 reviewers, including CB senior executives, quality managers, internal auditors and ISO 9001 consultants. The process for testing the questionnaire was the same as for the CBS. As a result of the pilot testing, three questions were re-worded to ensure that respondents would understand the intended meaning of the questions and answers; some items were omitted to avoid redundancy and to ensure unambiguous interpretation by respondents; new variables were included in key questions; and the questionnaires were shortened. The feedback from each reviewer can be found in Appendix C.

Chapter 5 addresses the specific data analysis and validation procedures conducted for these surveys in greater detail.

4.3.2 The qualitative mixed method: semi-structured interviews

Rubin & Rubin (1995) argue that qualitative interviewing is a research method that permits finding out what others feel and think about their worlds. Also, through this type of interview it is possible to understand experiences and reconstruct events where the researcher was unable to participate. Wengraf (2004) states that research interviews have two purposes:

1. Developing/constructing a 'model' of some aspects of reality that are expected to be in accordance with the facts about reality; and
2. Testing a constructed model to see whether it is confirmed or rejected by the facts.

(pp.4)

Bryman (2008) argues that the two main types of interviews in qualitative research are the unstructured interview and the semi-structured interview. He also explains that unstructured interviews tend to be very similar to a conversation because the researcher has complete freedom about what to ask the interviewee. Whereas, Kvale & Brinkmann (2009) define the semi-structured interview as:

> "an interview with the purpose of obtaining descriptions of the life world of the interviewee in order to interpret the meaning of the described phenomena"
>
> (pp. 3)

Bryman (2008) argues that in semi-structured interviews the researcher has a list of questions or specific topics to be covered but the interviewee has complete freedom about how to answer. Moreover, semi-structured interviews permit the researcher to include questions that are not included in the schedule in order to explore interviewee responses more deeply (Bryman, 2008).

Creswell (2009) identifies three advantages of using interviews:

- they are useful when participants cannot be directly observed;
- participants can provide historical information; and
- allows researcher control over the line of questioning.

Regarding its limitations, Creswell also identifies the following:

- provides indirect information filtered through the views of interviewees;
- provides information in a designated place rather than the natural field;
- researcher presence may bias responses; and
- not all people are equally articulate and perceptive.

As this study triangulated semi-structured interviews in combination with surveys, the limitations of interviews were overcome by the use of surveys.

Experienced researchers in quality interviewing recommend the use of an interview protocol before proceeding to conduct interviews (Rubin & Rubin, 1995; Bryman, 2008; Kvale & Brinkmann, 2009). In this research, the guidelines of Rubin & Rubin (1995) and Bryman (2008) were used in order to develop three different interview protocols for:

- third party auditors and CB senior executives;
- internal auditors, quality managers and ISO 9001 consultants; and
- standardisation experts.

For the interviews, two versions of the protocols, one in English and another in Spanish, were developed. The first version was produced in English and reviewed by Dr. James D. Tannock from the University of Nottingham. Then, the Spanish version

was created from the English document and reviewed by Dr. Nydia Lara Zavala from the National University of Mexico.

The pilot interview was conducted on 9th July 2010 with a senior executive of a CB. After the interview, question number five of the third party auditor protocol was modified because the wording was confusing.

It is important to state that all the interviewees received the interview protocol from the researcher by e-mail or in person a couple of days before the interview. The interview protocols and the list of experts who were interviewed can be found in Appendices D and B respectively. The specific data analysis and validation procedures used in this research can be found in Chapter 5.

Table 4.1 summarises the data sources and the data obtained from each research method used in the triangulation stage of this thesis.

Research method	Data sources	Data obtained
Certification bodies survey (CBS)	• CB senior executives • Third party auditors • Standardisation experts	91 completed questionnaires
Certified organisations survey (COS)	• Internal auditors • Top management representatives • Top management or CEO • Quality managers • ISO 9000 consultants	181 completed questionnaires
External audit process interviews	• Third party auditors • Managers of CB	8 interviews
Internal audit process interviews	• Internal auditors • Quality managers • ISO 9000 consultants	12 interviews
Standardisation process interviews	• Standardisation experts	5 interviews

Table 4.1 Summary of the surveys and interviews conducted for the triangulation stage

4.3.3 Construction of a path model to understand the relationship between audit problems and their impact on QMS performance

In order to address the third research question regarding how and to what extent internal audit problems are impacting the performance of the QMS of ISO 9001 CO, a statistical model was developed using the structural equations modelling technique of path analysis.

Asher (1983) explains that causal modelling, from which path analysis arises, attempts to resolve questions about possible causes of phenomena (effects) as the results of previous phenomena (causes). Hence, path analysis allows for empirical

estimation of the strength of each relationship described in a causal model (Hair *et al.,* 2010) as well as the overall quality of the model (Flynn & Saladin, 2001). Furthermore, Asher (1983) also argues that thinking causally about a problem and constructing an arrow diagram that reflects causal processes may often facilitate the clearer statement of hypotheses and the generation of additional insights into the topic at hand. Due to the fact that this research aimed to answer how and to what extent internal audit problems (causes) are impacting QMS performance (effects), causal modelling and path analysis were considered the best choices for addressing the research question.

Asher (1983) states that the use of path analysis is a straightforward and easy to learn process; but poor theory, unsatisfactory operational definitions, and other early steps in the research processes can frustrate the analysis. Researchers should begin using path analysis with a model in which they have substantial confidence (Asher, 1983). "Presumably, this confidence results from some theoretical or substantive reasoning about the linkages between the variables of interest" (Asher, 1983, pp. 10).

For this research, a causal model describing the effects on the QMS due to poor internal auditing was developed based on the theory discussed in Chapter 2. Then, the model was reviewed by three experienced internal and third party auditors, following the advice of Asher (1983). Finally, the resultant path model was statistically tested using SPSS version 18. Chapter 6 describes the path model used to address the third research question and explains how the statistical analysis was conducted.

4.4 The development of the procedure for conducting ISO 9001:2008 audits to measure QMS performance

As previously mentioned, the main objective of the research was to develop and test a procedure for conducting ISO 9001:2008 audits that complements ISO 9001:2008 and 19011:2011 to measure QMS performance. In order to achieve this objective, it was necessary to test and refine the procedure in a 'real' audit environment. Platts (1993) suggests the use of qualitative and quantitative research when testing processes and because a procedure is a detailed description of a process, this approach was followed. Hence, a mixed methods design consisting of two distinct stages, qualitative and quantitative, was conducted (Creswell & Plano Clark, 2007). Firstly, qualitative data (case studies) was collected and analysed and then quantitative data (surveys) was used to support the qualitative results from the first stage. The second, quantitative, stage built on the qualitative stage and the two phases are connected (see Figure 4.2).

The rationale for this mixed approach was that case study research (qualitative) investigates a contemporary phenomenon in-depth and within a real-life context (Yin, 2009), whereas quantitative data from the survey help to generalise qualitative data (Creswell & Plano Clark, 2007; Creswell 2009). Thus, case study research helped to profoundly examine 'how' and 'how well' the audit procedure was able to help

organisations to measure their QMS performance, while the survey addressed 'how many' ISO 9001 auditors agreed with the structure of the procedure and the PM concepts included in the document. The objective of this design was that results of the second method (quantitative) helped the first method (qualitative) by providing more strength to the results (Green et al., 1989 cited by Creswell & Plano Clark, 2007).

4.4.1 The qualitative research method: case study research

Eisenhardt (1989, pp. 534) has defined case study research as a "strategy which focuses on understanding the dynamics present within single settings". This research method can involve single or multiple cases and numerous levels of analysis. Yin (2009) indicates that "case study is used in many situations, to contribute to our knowledge of individual, group, organizational, social and political phenomena" (pp. 4). Quality audits are managerial tools which are used to measure QMS performance; they represent an important organisational phenomenon. Thus, case study research seemed appropriate to understand this organisational phenomenon in its real setting.

Moreover, case study research has been successfully used in OM research and quality management. In fact, Voss *at al*. (2002) state that "case research has consistently been one of the most powerful research methods in operations management, particularly in the development of new theory" (pp. 195). The authors explain that, in order to cope with the growing frequency and magnitude of changes in technology and managerial methods, scholars in OM have been using empirical methods in recent years. Moreover, "many of the breakthrough concepts and theories in management research, from lean production to manufacturing strategy, have been developed through field case research" (Voss *et al*., 2002, pp. 195). McCutcheon & Meredith (1993) recognise that the development of many important concepts in QMS such as '*just-in-time*' have been made possible through scholars' engagement with industry in field-based investigation.

Yin (2009) has also stated that the use of case study research is appropriate "when a 'how' or 'why' question is being asked about a contemporary set of events, over which the investigator has little or no control" (pp. 13). Similarly, Eisenhardt & Graebner (2007) underline that, case study research usually addresses the questions of 'what' and 'how' in unexplored areas particularly well. These conditions applied to the research question of the study formulated in the Chapter 1 due to:

- a contemporary event was addressed (measuring QMS performance using audits);
- relevant behaviour could not be manipulated because the investigator did not have control of the events (quality audits relied on the expertise of auditors which could not be controlled by the researcher);

- quality auditing was a relatively unexplored area (Karapetrovic & Willborn, 2000a); and
- it was a 'how' question.

Strengths and limitations of case study research

Simons (2009) has documented the most important strengths of case research, arguing that:

- using qualitative methods enables the experience and complexity of research;
- case studies can document multiple perspectives, explore contested viewpoints and demonstrate the influence of key actors and interactions between them;
- it is useful for exploring and understanding the process and dynamics of change;
- it is flexible, that is, neither time-dependent nor constrained by the method;
- it is written in accessible language, including direct observation of events, incidents and settings; and
- it has the potential to engage participants in the research process.

As with all research methods, case study research has advantages and disadvantages (Yin, 2009; Simons, 2009). According to Yin (2009) the following are its limitations:

- it is perceived to have a lack of rigor;
- produces little basis for scientific generalisation;
- case studies are too long and they result in massive, unreadable documents; and
- it is too subjective.

Regarding the first limitation, currently case study research is widely accepted in management research and its use in the OM field has been encouraged by prestigious scholars (see Boyer & Swink, 2008). Hence, the perception of scholars regarding this strategy of inquiry is changing.

As far was scientific generalisation is concerned, as Yin (2009) explains, case studies should not be conceived as a method of statistical but of analytical generalisation, because cases are not 'sampling units'. Hence, analytic generalisation should be used as a template to compare empirical results of case studies against theory. As Yin (2009) points out, "if two or more cases are shown to support the same theory, replication may be claimed" (pp. 38). In this research, multiple cases were used in conjunction with a survey to obtain both analytic and statistical generalisation.

In order to overcome the problem of case studies resulting in massive and unreadable documents, Yin (2009) suggests the use of protocols and structured

reports to conduct case studies. This approach was followed in this study and an example of the protocol regarding the pilot case study can be found in Appendix I, whereas Appendix J contains the report of the pilot case study.

Finally in order to avoid subjectivity, Yin (2009) also suggests using different sources of information. For this research different internal auditors were asked to provide feedback about the procedure and their opinions were contrasted. Also, the final reports of the case studies were reviewed by the audit team leader in order to triangulate the data.

The selected case studies

For this research, three in-depth case studies were performed in order to test the procedure for conducting ISO 9001:2008 audits with a focus on the performance of the QMS in a real environment. Organisations were selected to cover a broad spectrum of certified organisations. Hence, they were chosen by their size, type of certification, maturity of their QMS, and interest of the top management for collaborating in the research.

The case studies were conducted in three stages. Firstly, a group of internal auditors from the participant organisations were trained by the researcher regarding all the concepts of the procedure. Secondly, performance audits were conducted in the organisations following the procedure and ISO 9001:2008. Finally, semi-structured interviews were conducted with auditors separately to determine the suitability of the procedure. The description of the activities conducted for each case study and their results can be found in Chapter 8.

Quality tests for case studies

Yin (2009) explains that the research design has to represent a logical set of statements and its quality can be judged according to certain logical tests. Four tests have been commonly used to establish the quality of case study research (Yin, 2009). The following paragraphs discuss how these tests were conducted for this research.

Construct validity deals with identifying correct operational measures for the concepts being studied (Yin, 2009). Yin (2009) suggests three tactics for this test: *use multiple sources of evidence; establish a chain of evidence; and have key informants review the draft case study report*. In order to have a multiple sources of evidence, the researcher interviewed internal auditors separately after conducting the audits. Because an audit is a process which establishes a chain of evidence *per se*, internal auditors were reminded to state all of the different sources of information consulted during the on-site audit in their checklist. The sources of evidence included: previous internal and external audit reports; previous top management reviews; non-conformity reports; analysis of corrective, preventive and improvement actions; status of previous audit findings; reports regarding the follow-up of audit and top management review findings; results of customer satisfaction measurement; reports of processes capabilities; analysis of customer complaints; and evidence of processes

and QMS improvement, amongst others. Furthermore, the chain of evidence was also maintained through the participation of the group of internal auditors, who conducted the performance audits following a procedure and an audit plan. Finally, the team leader for each audit acted as key informant and reviewed the final draft of the case study reports for validation.

Internal validity is concerned with establishing a causal relationship amongst the different events in the study (Yin, 2009). There are four tactics for addressing the quality of this test: *do pattern matching; do explanation building; address rival explanations; and use logic models.* For this research the use of logic models was followed. In this case, the audit procedure contained the description of activities and tasks and acted as a logic model. The procedure was followed by the researcher and internal auditors to conduct each audit. This aimed to maintain the right cause-effect relationships according to the collected data.

Internal validity also relates to the participation of more than one researcher assessing the data. In the study, the internal auditors act on behalf of the researcher when applying the procedure, observing their appropriateness to the companies and their QMS.

External validity is the extent to which findings are generalisable beyond the immediate case study (Yin, 2009). McCutcheon and Meredith (1993) suggest the cross-analysis of multiple case studies to establish causal relationships. In this research, three case studies were conducted to address this issue. Through the comparison of results and outcomes, it is envisaged that some indication of generalisability was made possible.

Reliability deals with demonstrating that the operations of a study can be repeated with the same results (Yin, 2009). In the study, the application of the audit procedure guarantees the replication of the audit process in other or the same organisations. Thus, internal auditors were able to replicate the cases independently in order to assess the reliability of the proposed procedure. In addition, as suggested by Yin (2009) a case study protocol was developed as a tactic to address this test. The protocol contains all of the tasks that were performed in the case studies in greater detail and can be found in Appendix I.

4.4.2 The quantitative research method: survey

In section 4.3.1 the objective of conducting surveys, their strengths and weaknesses, and their use as a research method in OM were addressed. Hence, this section will only focus on describing how a survey was conducted in order to support the findings of the case study research.

Administering surveys at workshops is a common practice in OM (e.g. Dixon *et al.,* 1990; Biazzo, 2005). In a recent study of quality audits, Biazzo (2005) conducted a survey during two workshops to determine to what extent auditors were assessing

performance during ISO 9001 third party audits. For this study, he first introduced the audience to the most important concepts of the tool he wanted to test. Then, the audience was asked to evaluate the tool through a questionnaire. Biazzo (2005) states that the use of workshops allows researchers to evaluate the availability and interest of companies to participate in studies. Due to the similarities between Biazzo's study and this research, the approach of administering surveys at workshops was followed.

Hence, six one-day workshops with ISO 9001 experts to examine the proposed audit procedure were conducted between 17th August and 7th October 2011 at three different cities in Mexico (see Table 8.4 in Chapter 8). A personal invitation for attending the workshops was sent by e-mail to 485 experts. Hence, 211 experts including internal and third party auditors, consultants, standardisation experts, quality managers, certification managers, top management representatives and CEOs attended the workshops.

The workshops were structured in three main stages:

1. *Overall presentation of the research and results of the ISO 9001 audit survey*. During this stage the ISO 9001 experts were provided with the necessary background of the research;
2. *Discussion of each section of the procedure.* In this stage the researcher discussed each section of the procedure with the audience and provided them with practical exercises to understand the concepts addressed in the document; and
3. *Feedback of the procedure.* Attendees were asked at the end of the workshops to complete a feedback questionnaire.

174 completed questionnaires addressing the suitability of the audit procedure were collected at the workshops. The results of this survey are further discussed in Chapter 8.

4.5 Conclusions of the chapter

The objective of this chapter was to present the research methodology to address the research question and objectives of this study.

Section 4.1 provided a brief overview of the theoretical foundations and justification of the use of 'pragmatism' as a philosophy of reference for this thesis.

Section 4.2 described the research design and methods used for this study. This section also explained in depth the two phases of the research: *Identification and explanation of the current position* (research objectives 1 and 2) and *the development of the procedure for conducting ISO 9001:2008 audits to measure QMS performance* (research objectives 3 and 4).

In Section 4.3 the use of mixed methods research to address the first phase of the research was justified. This section also described the two research methods to be mixed in depth: surveys and semi-structured interviews.

Finally, Section 4.4 explained the methods used for the second phase of the research: case studies and surveys.

CHAPTER 5
THE CURRENT STATE OF THE ART OF ISO 9001:2008 INTERNAL AUDITS: A MIXED METHODS APPROACH

This chapter aims to accomplish the second research objective by establishing the current state of the art of internal ISO 9001 audit practice, including the awareness of PM knowledge in ISO 9001 CO. It is important to highlight that the intermediate research questions 1, 2 and 4 which originated from this research objective, are answered in this chapter. In order to meet this research objective, a mixed methods research approach, including the triangulation of two surveys and three different sets of interviews, was conducted in accordance with the research design proposed in Section 4.2.1 of Chapter 4.

Section 5.1 explains the quantitative research method used in the mixed methods approach. This section includes the description of the pilot surveys, samples, data analysis and a summary of results.

Section 5.2 describes the qualitative research method including the pilot interview and background to the interviews conducted. It also provides the feedback from the interviews and a summary of results.

Section 5.3 describes how the two methods were mixed and provides answers to the intermediate research questions 1, 2 and 4.

Finally, Section 5.4 provides the conclusions of the chapter.

5.1 The quantitative mixed method: surveys

As described in section 4.3.1, two different surveys were administered to ISO 9001 experts in order to better understand the current problems that the audit process is facing. The surveys were distributed to delegates of the ISO TC/176 and ISO/CASCO, members of the International Certification Network (IQNet) as well as National Member Bodies in the UK and Mexico. Additionally, two CB in Mexico and Portugal disseminated the surveys to their clients and auditors.

The surveys included questions that were common for both audiences and some specific to each group, following Power & Terziovski's (2007) approach. The questionnaires were divided into three main sections: internal audits, third party audits and PM. Nevertheless, due to time constraints, only the results of the internal audits and PM section are reported in this work.

In the internal audit section, the questionnaires included questions addressing:

- Which part of the internal audit process is presenting the most problems?
- What are those problems?
- What are the reasons for those problems?
- How they impact the performance of the QMS? and
- How the internal audit process might be improved?

The PM section addressed:

- What are the most used PM techniques for both groups? and
- What types of KPIs are important for ISO 9000 experts and should be included in the audit process?

The final version of the questionnaire used in both surveys can be found in Appendix C.

5.1.1 Survey instrument pilot testing

In order to test the validity and reliability of the variables identified in the literature review, the questionnaires were pilot tested by a process of academic/practitioner review with sixteen different ISO 9001 experts. The evaluation of individual items included the examination of variation; meaning; redundancy; scalability; non-response and acquiescent response set. Each expert looked at one questionnaire according to his/her interaction in the audit process. During the review process, experts were encouraged to provide their suggested revisions of the instruments in terms of structure and content. As a result of this review, two questions were re-worded to assure that respondents understand the intended meaning of the questions and answers; some items were omitted to avoid redundancy and to ensure unambiguous interpretation by respondents; new variables were included in key questions; and the questionnaires shortened. The results of the pilot testing can also be found in Appendix C.

5.1.2 Survey samples

Because much audit work requires confidentiality of information relating to certification, the surveys were distributed directly by the participant organisations (ISO/TC 176; ISO/CASCO; IQNet; and ISO National Body Members). These organisations distributed the questionnaires by email to ISO 9000 delegates; national quality experts; members of IQNet; and clients and auditors of CB. Respondents were asked by these organisations to send the completed questionnaires by email directly to the researcher. As a result, 181 completed questionnaires from the COS and 91 from the CBS were received. The demographic profile of the respondents is shown in Tables 5.1 and 5.2.

Time working in the quality field		Current job title		Location of organisation's headquarters		Organisation's presence in other places	
Years	%	Title[14]	%	Place	%	Place	%
1-5	7.7	CEO	8.8	Asia	4.6	Africa	16.08
6-10	18.7	Certification manager	18.7	Europe	64.3	Asia	9.09
11-15	29.7	Divisional manager	12.1	Americas	30.9	Europe	43.76
16-20	22.0	Third party auditor	60.4			Americas	20.07
More than 20	22.0	Other	35.2			Global	6.99

Table 5.1 Demographic profile of the Certification Bodies' survey (CBS) sample

Time working in the quality field		Current job title		Location of organisation's headquarters		Organisation's presence in other places	
Years	%	Title[15]	%	Place	%	Place	%
1-5	32.2	CEO	2.8	Asia	0.6	Asia	3.86
6-10	31.1	Quality manager	32.8	Europe	39.9	Africa	3.86
11-15	21.1	Divisional manager	7.2	Americas	59.7	Europe	37.67
16-20	8.9	Internal auditor	39.4			Americas	49.06
More than 20	6.1	Top management representative	28.3			Global	5.31
		Other	33.9				

Table 5.2 Demographic profile of the Certified Organisations' survey (COS) sample

In addition, to better understand the profile of the companies surveyed, a specific question regarding how long the organisations of the respondents had been working with ISO 9000 standards was included in the COS. Figure 5.1 shows that the survey sample was distributed homogeneously with 31% of the companies working with the ISO 9000 series for 6-11 years, 24% for 1-5 years, 23% for more than 15 years and 22% for 11-15 years.

[14] Because certification and divisional managers tend to also be third party auditors, respondents could answer more than one option.

[15] Due to quality managers tending to also be top management representatives and internal auditors, respondents could answer more than one option.

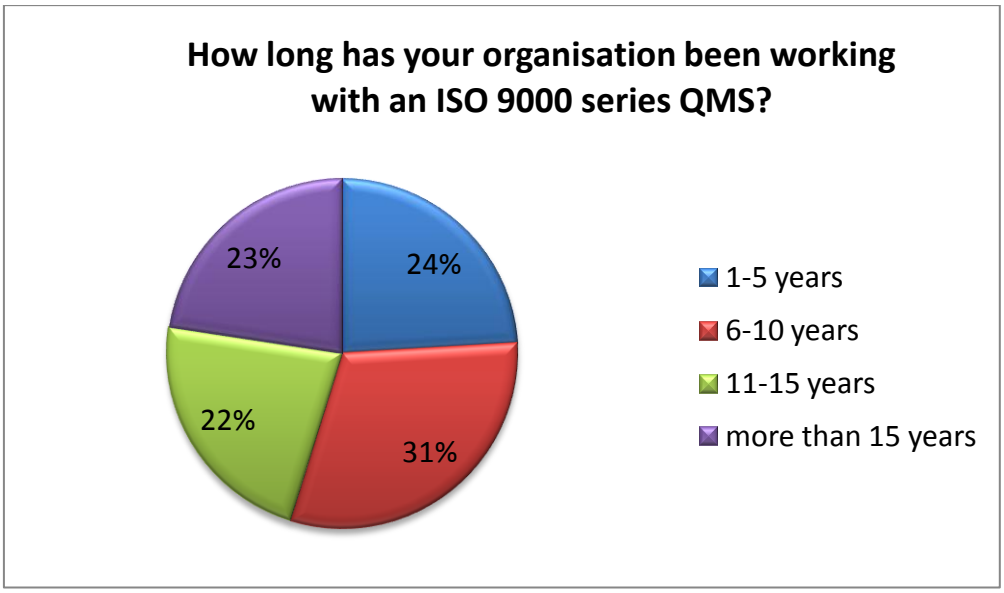


Figure 5.1 Organisations' time working with the ISO 9000 series

Moreover, respondents from the COS were also asked why their organisations decided to implement an ISO 9001 QMS. Table 5.3 shows that **top management desire to improve the organisations' capabilities** was stated as the most important reason for implementing a QMS with 81.8%, followed by **clients requirement to achieve the certification** with 26%, and **exporting products to international markets** with 16%. These results show a significant change in the motivations of organisations for implementing ISO 9001 QMS, from the traditional driver of client demanding the certification to a top management desire to improve the organisation through a QMS. These results are consistent with some recent studies that also highlight this change (van der Wiele *at al.*, 2005; Terziovski & Power, 2007) and may indicate that ISO 9001 QMS are increasingly perceived as a management tool by top management, helping to explain why the ISO 9001 certification has increased by more than 1 million companies in the last ten years.

Reason	%
We export products to international markets	16.0%
Clients require us to achieve the certification	26.0%
Top Management desire to improve our organisations' capabilities	81.8%
Our competitors had obtained the certification	5.5%
Other	22.7%

Table 5.3 Main reasons why CO decided to implement an ISO 9001 QMS[16]

[16] Respondents were able to mark any number of options

Also, in order to determine how many other approaches were used within the ISO 9001 standard, the COS included the question 'has your organisation implemented any other QMS or improvement approach apart from ISO 9001?' [17]. Figure 5.2 shows the results of this question, with the **ISO 14000 series** being the most widely used approach apart from ISO 9000 (42.3%). It is important to note that according to these results, ISO 9001 certified companies tend to use other ISO standards to compliment their management systems rather than other business improvement oriented quality approaches such as Six Sigma (10.3%), Business Excellence Models (8%) and TQM (5.3%).

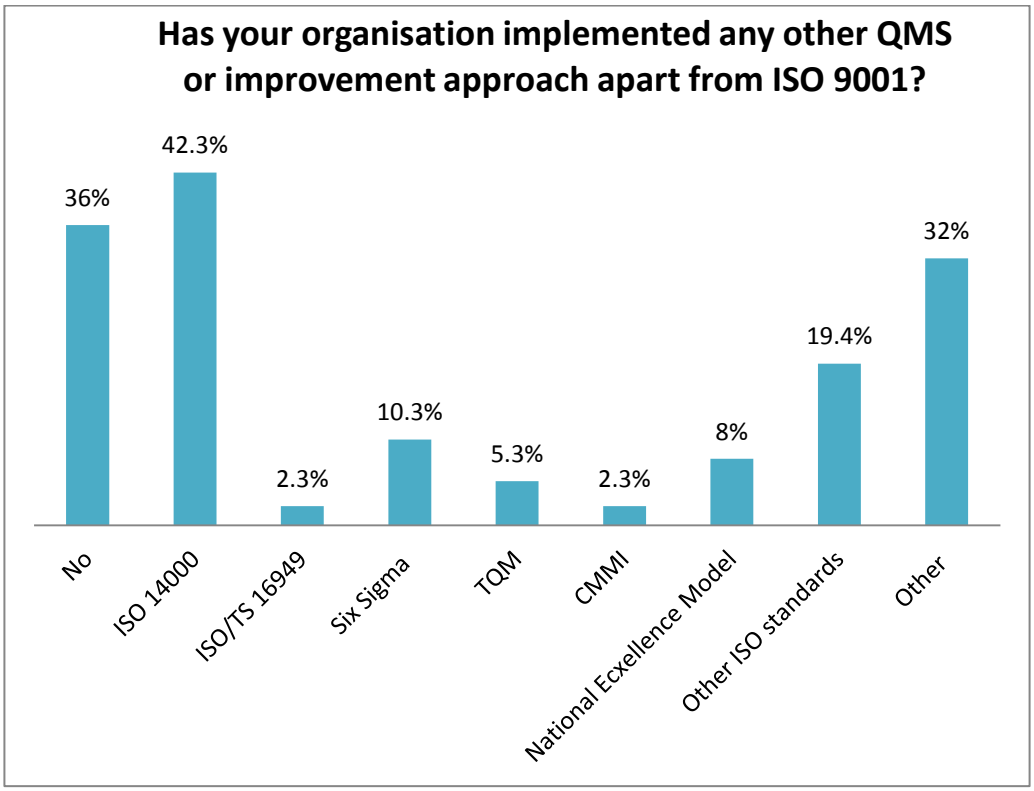


Figure 5.2 Improvement approaches implemented with the ISO 9001 standard

5.1.3 Data analysis

De Vaus (2002) states that four factors affect how survey data should be analysed:

1. The number of variables being examined;
2. The level of measurement of the variables;
3. Whether the data is used for descriptive or inferential purposes; and
4. Ethical responsibilities

Regarding the number of variables, there are three methods of analysis: univariate (one variable); bivariate (two variables); and multivariate (three or more variables) (De Vaus, 2002).

[17] Respondents could answer more than one option

The level of measurement of variables refers to how the categories of the variable relate to each other (De Vaus, 2002). There are three main levels of measurement: interval (also called continuous); ordinal; and nominal (also called categorical or qualitative) (De Vaus, 2002).

Finally, the choice of statistics is determined by the method of analysis, the level of measurement of the variables and complexity of the research questions (De Vaus, 2002). There are two basic types of statistics: descriptive and inferential. Descriptive statistics are those used to summarise patterns of responses in a sample (De Vaus, 2002). There are three broad ways in which descriptive analysis is conducted and presented: tabular; graphical; and statistical (De Vaus, 2002). Inferential statistics, on the other hand, provide an idea about whether the patterns described in the sample are likely to apply to the population from which the sample is drawn (De Vaus, 2002). There are two main types of inferential statistics: interval estimates and test of statistical significance (De Vaus, 2002).

For this research, a combination of bivariate and multivariate analysis was conducted with interval and ordinal levels of measurement. In this section, the bivariate analysis (descriptive statistics) conducted to describe the general results of the surveys will be discussed; whereas in Chapter 6 the multivariate analysis (path analysis) will be explained.

The statistical software analysis package SPSS (version 18) was used for all quantitative testing. Descriptive analysis was used within this study to describe the distribution of variables (De Vaus, 2002). This approach was particularly useful for addressing the intermediate research questions. De Vaus' guidelines for conducting descriptive analysis were followed to present the cross-tabulation tables and graphs. The most important descriptive analysis is discussed in the following sections. It is important to point out that other statistical tests could be used with the interval variables if the intermediate research questions were different. These tests would include: F-test; chi squared; test of significance of tau; test of significance of rho; test of significance of r; and regression (De Vaus, 2002).

Internal audits

In order to determine the current state of the art of the ISO 9001 internal audit process, it is necessary to identify the most important supporting documents used by organisations to conduct audits. Hence, any improvements in the audit process could be included in these documents.

Thus, experts from CO and CB were asked about the most used documents for conducting audits. The results, summarised in Table 5.4, indicate that **ISO 19011** is the document used the most for performing audits with 86.4% of respondents from the CBS and 81.2% from the COS using it. Surprisingly, the second most used document according to both surveys was the **ISO 9001 auditing practice group**

documents developed by the IAF and the ISO/TC 176 which obtained 33% in the CBS and 35.9% in the COS.

Documents	Certification Bodies	Certified Organisations
The ISO 19011 standard	86.4%	81.2%
The ISO 9004 standard	19.3%	22.1%
Other ISO 9000 family standards	25.0%	19.3%
ISO 9001 auditing practice group documents	33.0%	35.9%
Others	17.2%	16.0%

Table 5.4 The standards, methods, guidelines and tools that ISO 9001 CO use to conduct internal audits[18]

Regarding the stages or tasks of the audit process that present the most problems, experts of both groups pointed out that **generating audit findings**; **conducting the audit follow-up** and **preparing audit conclusions** are the most problematic tasks (the results of the mean are showed between brackets). Nevertheless from a close examination of the data, it can also be observed that CO face most of their problems during the stage of **conducting on-site activities** (see Table A.1 in Appendix A). This stage has seven tasks and four of them are in the top ten of the most problematic for organisations in both surveys: **generating the audit findings**; **preparing audit conclusions**; **collecting and verifying information**; and **establishing roles of the observers**. Hence, it can be concluded that more guidelines or supporting documents that address this stage of the audit process should be generated to help organisations to overcome these problems.

	Certification Bodies	Organisations
1	Generating audit findings (3.39)	Conducting the follow-up (2.96)
2	Conducting the audit follow-up (3.33)	Generating audit findings (2.25)
3	Preparing audit conclusions (3.25)	Preparing audit conclusions (2.24)
4	Establishing, implementing, monitoring and improving the audit program (3.06)	Collecting and verifiying information (2.05)
5	Collecting and verifying information (2.95)	Conducting document review (1.99)
6	Defining objectives, scope and criteria (2.88)	Selecting the audit team (1.87)
7	Preparing the audit plan (2.71)	Developing the audit programme (1.86)
8	Determining the feasibility of the audit (2.69)	Preparing and distributing the audit report (1.80)
9	Selecting the audit team (2.63)	Establishing roles of the observers (1.79)
10	Completing the audit (2.57)	Preparing work documents (1.76)

Table 5.5 The stages/tasks of the ISO 19011 internal audit process that present certified organisations with the most problems[19]

[18] Respondents were able to mark any number of options

In order to determine the current problems that CO face when conducting audits, a specific question including the problems identified in the literature review (see Table 2.1 in Chapter 2) was included in both surveys. Table 5.6 shows the results of the mean of both datasets, whereas Table 5.7 shows them separately.

Problems	Mean
Lack of follow-up of previous audit findings	3.54
Lack of ability to measure audit performance	3.49
Lack of ability to measure QMS performance	3.47
Lack of top management commitment	3.26
Internal auditors' competence	3.18
Lack of understanding of ISO 9000 standards	3.15
Lack of knowledge of audit practices	3.10
Bad audit plan	2.60

Table 5.6 Problems that organisations face when conducting ISO 9001 audits (mean of both surveys)[20]

Table 5.6 highlights that the main problem that CO face when conducting ISO 9001 audits, according to both surveys, is the **lack of follow-up of previous audit findings** with a mean of 3.54 out of a maximum of 5. This result may be explained by the fact that the ISO 19011 standard for conducting QMS audits does not provide guidelines for conducting the follow-up of the audit findings. In fact, the audit process described in ISO 19011 finishes exactly with this task (see Figure A.1 in Appendix A). Thus, the lack of clear follow-up guidelines may be causing these problems for organisations.

Also, it is important to note that the **lack of ability to measure audit performance** with a mean of 3.49 and the **lack of ability to measure QMS performance** with a mean of 3.47, were ranked the second and third most important problems for companies. These results show that PM is an important problem for organisations that do not know if their audits are conducted correctly and producing the right findings, and if their QMS is performing correctly.

Another interesting finding is that the **lack of top management commitment** was ranked fourth by experts with a mean of 3.26. This problem was mainly raised by experts in the CBS (see Table 5.7) and apparently opposes the findings of Table 5.3, which state that the main reason for achieving ISO 9001 certification is the desire of top management to improve the capabilities of the organisation. One possible explanation for this result may be that top management has a certain level of

[19] Mean scores on a 1-5 scale, where '1' indicates that the stage does not present 'any problem at all' and '5' indicates 'a lot of problems'
[20] Ibid

commitment when first deciding to implement an ISO 9001 QMS, but when the QMS is mature and the organisation is still not improving its capabilities as anticipated (see Table 5.9), top management become dissatisfied with the QMS (Power & Terziovsky, 2006). This dissatisfaction might influence their continuing commitment to support it and the associated internal audit process as Power & Terziovski (2006) argue.

Finally, it should also be noted that **internal auditors' competence** (3.18), **lack of understanding of ISO 9000 standards** (3.15) and **lack of knowledge of audit practices** (3.10) all obtained means above 3.0 which indicate that they are serious problems for organisations. Hence, it may be argued that the current ISO 9000 core of standards and the audit guidelines available are insufficient to provide good guidance about auditing. It may be that better or more comprehensive guidelines are needed to overcome these problems.

	Certification Bodies	Organisations
1	Lack of top management commitment (4.20)	Lack of follow-up of previous audit findings (3.37)
2	Internal auditors' competence (4.07)	Lack of ability to measure audit performance (3.27)
3	Lack of ability to measure QMS performance(4.00)	Lack of ability to measure QMS performance (3.19)
4	Lack of ability to measure audit performance (3.94)	Lack of understanding of ISO 9000 Standards (2.88)
5	Lack of knowledge of auditing practices (3.89)	Inconsistencies in audit findings between internal and external audits (2.85) (*)
6	Lack of follow-up of previous audit findings (3.88)	Lack of top management commitment (2.76)
7	Lack of understanding of ISO 9000 standards (3.69)	Internal auditors' competence (2.70)
8	Bad audit plan (3.30)	Lack of knowledge of auditing practices (2.69)
9		Bad audit plan (2.23)

Table 5.7 The reasons organisations face problems when conducting ISO 9001 internal audits[21, 22]

In order to find out how the problems in internal audits affect the performance of product/services, processes and the QMS, a question including the main impacts reported in the literature (see Table 2.2. in Chapter 2) was included in both surveys. Table 5.8 summarises the results of both datasets for this question, whereas Table 5.9 shows the mean results for each survey.

Effects	Mean
Organisations are not improving their capabilities as expected	3.55
Organisations are not detecting problems in their QMS processes	3.26
Organisations are not detecting all non-conforming products	3.23
Organisations' QMS is not performing correctly	3.12
Top Management is dissatisfied with the performance of the QMS	2.87

Table 5.8 Impacts on QMS performance due to audit problems (both datasets)[23]

[21] Ibid

[22] The CO survey contained one extra item (*)

[23] Mean scores on a 1-5 scale, where '1=strongly disagree, 2=disagree, 3=neither, 4=agree, 5=strongly agree and 6=don't know'

The statement that **organisations are not improving their capabilities as expected** received the highest score, with a mean of 3.55 out of a maximum of 5 in both surveys (see Table 5.8). It is important to analyse this result jointly with the result shown in Table 5.3 which states that top management is keen to implement an ISO 9001 QMS as a way to improve the capabilities of the organisation. Moreover, as also shown in Table 5.8, the perception that top management is dissatisfied with the performance of the QMS is also high, with a score of 2.87 out of a total of 5. From these results, it may be argued that problems with the internal audit process constitute a barrier to improving the capabilities of ISO 9001 organisations as expected by top management, hence causing their dissatisfaction. This result is similar to that of Power & Terziovsky (2006) regarding third party audits which states that top management is dissatisfied with the current results of certification and surveillance audits.

Problems with internal audits are causing other negative effects on the QMS. The second most important problem according to ISO 9001 experts is that **organisations are not detecting problems in their QMS processes** with a mean of 3.26, followed by **organisations are not detecting all non-conforming products** in third place with a mean of 3.23 and the **organisations' QMS is not performing correctly** with a mean of 3.12. These results echo the findings of the literature review in Chapter 2 (see Table 2.2). Hence, it may be concluded that despite the improvements to the ISO 9000 core of standards in 2000 and 2008, organisations are still facing problems with the assessment of their products/services, processes and QMS.

Impact	Certification Bodies	Organisations
Organisations are not detecting non-conforming products	3.55	3.07
Organisations' QMS are not performing correctly	3.85	2.73
Organisations are not detecting problems in their QMS's processes	4.09	2.83
Organisations are not improving their capabilities	4.10	3.27
Top Management is dissatisfied with the performance of the QMS	3.55	2.53

Table 5.9 Impacts on QMS performance due to audit problems[24]

As far as how internal audits can be improved, ISO 9001 experts who answered the COS considered the **involvement of the organisation personnel in the follow-up of the finding** as the best way to improve the internal audit process with a mean 4.37 of a maximum of 5 (see Table 5.10). This result was also consistent with the fact that the most important problem for organisations is the follow-up of audit findings (see Table 5.6). More interestingly, experts also agreed that **more methods, guidelines, tools and metrics to assure the quality of audits should be developed** which was

[24] Ibid

ranked second with a mean of 3.99. Also, the statement that **internal auditors should be more focused on performance than on compliance** received a high score of 3.93, reinforcing the view of Biazzo (2005) and Power & Terziovski (2006) about the need to change the current audit focus from compliance to performance.

Improvement	Score
The organisation personnel should be more involved in the follow up of the findings	4.37
Develop methods, guidelines, tools, metrics to assure the quality of the audits	3.99
Internal auditors should be more focused on performance than compliance	3.93
Certification Bodies should assess the competence of internal auditors	3.66
Develop more ISO 9000 family standards such as one for top management reviews	3.21
Improve the number of hours/auditors in order to deeply review the QMS	3.17

Table 5.10 Actions needed to improve ISO 9001 internal audits[25]

Performance measurement

As one of the objectives of this work was to incorporate some concepts from the PM field into the ISO 9000 world, both surveys were designed to provide insight about the current PM techniques, methods, concepts and metrics used by CO to support their QMS.

In order to determine the PM techniques most used by CO, a specific question including the most important techniques reported in the literature was added to both surveys (see Section 3.2 in Chapter 3). The results are shown in Table 5.11.

Some of the results regarding the use of these techniques by CO were unexpected, with **the performance measurement matrix** appearing as the most used PM technique with a mean of 2.81 out of a maximum of 5. It was followed by **the performance measurement questionnaire** with a mean of 2.51. In third and fourth place were the **dashboard** with a mean of 2.42, and the **BSC** with 2.38. As discussed in Chapter 3, previous studies have suggested that the BSC and the dashboard are the prevailing PM techniques in organisations (Neely *et al.,* 1995). Hence, these results were indeed surprising and may be due to strong dissemination of these techniques in the ISO 9000 world.

Nevertheless, when CB experts were asked about the most used PM techniques in certified organisations, the results showed alignment with the literature, showing the **BSC** as the most used PM technique with a mean of 2.59, followed by the **dashboard** with 2.44 and **the performance measurement questionnaire** with a mean score of 2.36.

[25] Ibid

PM Technique	CB	Organisations
Balanced Scorecard	2.59	2.38
Dashboard / *Tableau de bord*	2.44	2.42
The performance measurement matrix	2.30	2.81
The performance measurement questionnaire	2.36	2.51
CAM-I (Computer Aided Manufacturing International)	1.36	1.16
Nine-step process	1.48	1.24
Guidelines for performance measurement system design	1.64	1.86
Seven principles of performance measurement system design	1.47	1.45

Table 5.11 PM techniques used by certified organisations[26, 27, 28]

Respondents to both surveys were also asked about the competence of their audit staff to assess performance in addition to compliance. Figure 5.4 shows the results of this question regarding the CBS, whereas Figure 5.5 shows the results for the COS. In both surveys experts declared that their audit staff had the competence to assess performance in addition to compliance. Nevertheless, the opinion of CB experts was more optimistic with 73% of respondents answering positively in contrast with 59% of CO experts.

Figure 5.3 Current CB audit staff's competence of on assessing performance

[26] Mean scores on a 1-5 scale, where '1 indicates "Not used at all" and 5 "Used at great deal"
[27] Only 12 organisations from a total of 181 reported that they do not use PM techniques
[28] Up to 33% of respondents did not answer at least one of these items in the question, missing values were excluded from the calculation of the mean

Figure 5.4 Current CO audit staff's competence of on assessing performance

In order to determine what kind of performance metrics should be incorporated into internal audits, a specific question about the classification of Neely *et al.* (1995) was also included in both surveys.

Table 4.12 summarises the results of this question for both surveys, with **quality** being the most important performance measure in the COS, with a mean of 4.19 out of a maximum of 5. This finding may indicate that the current ISO 9001 requirements for quality management are not enough for organisations to provide customers with perceived 'good quality' products. Hence, specific quality KPIs should be included in the requirements of the standard. It should also be noted that the measure of **flexibility** was ranked as the second most important measure with a mean of 4.01; followed by **time** with 3.76; **finance** with 3.68; and **cost** with 3.63. The high value of these means may also highlight the need to re-consider the ISO 9001 requirements with these four types of KPIs.

As far as the CBS is concerned, the most valuable individual performance measure for CO, according to CB experts, was **cost** with a mean of 3.55 out of a maximum of 5. The second most important measure was **quality** with a mean of 3.54, followed by **finance** with 3.47, **flexibility** 3.30, and **time** with 3.16. As well as in the COS, the means of all the performance measures were high and may indicate that the ISO 9001 standard should include targeted KPIs regarding these measures.

Type of Measure	Certification Bodies	Organisations
Time	3.16	3.76
Cost	3.55	3.63
Flexibility	3.30	4.01
Quality	3.54	4.19
Finance	3.47	3.68

Table 5.12 Mean of individual performance measures[29, 30]

Finally, respondents of both surveys were asked if their organisations would use an audit framework that included specific individual performance measures. Figures 5.6 and 5.7 summarise the results of these questions, with 85% of the experts of the CBS stating that their CB would be interested in using one and 56% of the CO experts pointing out that their companies would be prepared to pay for the service.

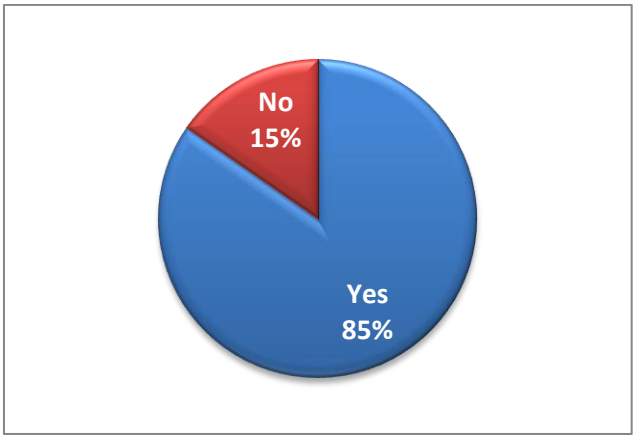


Figure 5.5 Results for the question "Do you think that your Certification Body would be interested in using an 'Audit+' framework for ISO 9001 which includes targeted performance measures?"

[29] Mean scores on a 1-5 scale, where '1=strongly disagree, 2=disagree, 3=neither, 4=agree, 5=strongly agree and 6=don't know'

[30] The response rate per item varied between 142 to 151 from a total of 181, missing values were excluded from the calculation of the mean

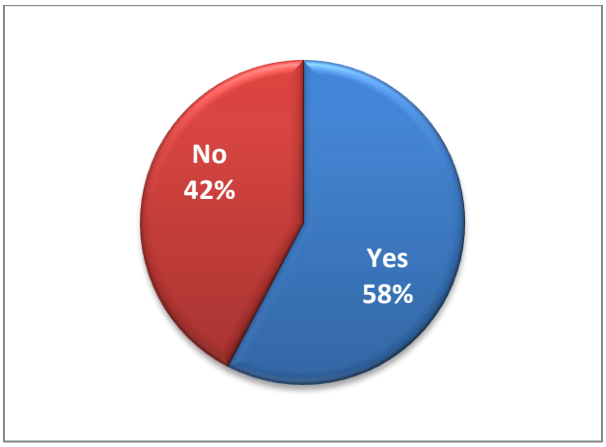


Figure 5.6 Results for the question "Do you think that your organisation would be prepared to pay for an 'Audit+' service for ISO 9001 which includes targeted performance measures?"

Summary of the findings

The results of the surveys highlighted that PM of both the QMS and the audit process are important concerns of CO and CB. The lack of PM guidelines to assess the QMS during internal audits is contributing to the failure of organisations to detect problems in their products/services and processes and improvements in the QMS, which is contributing to a degree of top management dissatisfaction. Hence, the survey results supported the view that changing the current compliance approach of the ISO 9001 audit to a performance oriented one (Biazzo, 2005; Power & Terziovski, 2007) would be beneficial. Moreover, the results also indicated that both CO and CB would be interested in incorporating performance measures and concepts within their auditing processes.

5.2 The qualitative mixed method: semi-structured interviews

This section explores the perspective of internal and third party auditors, managers of CB and CO, standardisation experts, consultants and CEO's on the current internal audit practice and PM of ISO 9001 QMS. Issues and difficulties found in the audit process were analysed and potential suggestions for improvement were discussed. There was some overlap and difficulty in placing interviewees unambiguously into a single category, however the method of analysis used ensured that all views were represented.

5.2.1 The interviewees perspective

This section aims to address the intermediate research questions 1, 2 and 4 from a qualitative perspective. For this purpose, 25 semi-structured interviews were

conducted between July – December of 2010 and March 2011. Table 5.13 shows the number of interviews conducted for each groups of experts.

Interviewees	Number of interviews conducted
Third party auditors and managers of CB	8
Internal auditors, quality managers and ISO 9000 consultants	12
Standardisation experts	5

Table 5.13 Classification of interviews

The interviewees belong to different types of organisations and contexts, reflecting the wide scope of the ISO 9001 certification. The vast majority of the interviews were conducted with auditors that are based in Mexico. Nevertheless, most of them belong to multinational companies. The working experience of interviewees with ISO 9001 QMS varies between 9 and 32 years. Tables B.1, B.2 and B.3 in Appendix B describe the interviewees by working background and national origin.

An interview protocol containing all of the questions for the interview was initially sent by e-mail to the interviewees. Themes associated with the questions that would emerge were also explored, the same for further suggestions and additional comments related to the topic. The three interview protocols used in this section can be found in Appendix D.

The questions covered four main areas: issues perceived in the internal audit process; difficulties encountered during third party audits; suggestions of potential improvements to internal and external audits; and the current use of PM techniques within ISO 9001 QMS, awareness and application in CO and CB.

The interview protocol for standardisation experts also included the topic of the PM system of the ISO 9000 core of standards as well as the main challenges to the ISO 9000 family.

For space reasons, only a bullet-point summary of the key findings of each set of interviews is presented in this section. Also, for space reasons, this section does not include a data analysis of the questions concerning third party audits. Tables 5.14 - 5.16 summarise the findings from the interviews. The complete content analysis of these sets of interviews can be found in Appendix E.

TOPIC	FEEDBACK FROM INTERVIEWS
Problems in internal audits	• 'poor' competency of internal auditors; • CO do not use internal audits as a management tool, they use them as an administrative verification/proof exercise that they have to do; • lack of guidelines and focus on PM present in the ISO 9000 standards; • companies' strategy is separate from the QMS; • CO measure their performance according to the number of audit findings: the less they have, the better performance is. This is contradictory, because companies should seek to have many findings during audits in order that their systems will be able to improve; • 'poor' root cause analysis to overcome audit findings; • lack of criteria to measure audit performance; • 'poor' consultancy (due to the fact they are in charge of training internal auditors when QMS is implemented); • irrelevant audit findings for auditees and top management; • incomplete audit programs (the audits are not performed according to the programme); and • ISO 9000 standards are not well understood
Reasons for these problems	• the 'checklist' view of standards, ignoring the CO need for improvement actions (compliance focus); and • internal auditing is not perceived as a valuable/learning exercise
Impact of problems on QMS performance	• lack of commitment from top management; • companies do not obtain benefits from the QMS; • 'poor' auditing which causes an incorrect performance measurement of the QMS and this does not allow the QMS to improve; and • because audits do not add value to organisations, top management is questioning why a QMS is needed
Suggestions for improving the audit process	• create a clearer set of criteria for the PM of the QMS; and • emphasise the continuous improvement focus of ISO 9001 standards;
PM techniques used in CO	• the BSC; • Six Sigma; and • solutions developed in-company.

Table 5.14 Feedback from interviews with external auditors and CB managers

TOPIC	FEEDBACK FROM INTERVIEWS
Problems in internal audits	• 'poor' competency of internal auditors (auditing qualities and management skills); • lack of auditors' experience in implementing QMS and auditing; • 'poor' audit training; and • lack of added value from audits for auditees
Reasons for these problems	• lack of awareness of the importance of quality and audit activities (some auditors are appointed because they 'do not have enough work'); • auditors training courses with too much emphasis on compliance auditing; • different approaches within the ISO 9000 family [ISO 9000 standards uses the process-based approach and ISO 19011 is focused on compliance and quality assurance); • the 'checklist' view of standards, ignoring CO need for improvement actions (compliance focus); and • the standards are not clear and explicit, have errors
Impact of problems on QMS performance	• QMS is not improving as expected; and • lack of commitment from top management and organisations personnel with the QMS
Suggestions for improving the audit process	• focus on business performance in addition to compliance; • involve top management in the audit objectives; • create a clearer set of criteria for the PM of the QMS; and • create clear guidelines for measuring services;
PM techniques used in CO	• the BSC; and • dashboards with QMS' KPIs

Table 5.15 Feedback from interviews with internal auditors, quality managers and ISO 9000 consultants

TOPIC	FEEDBACK FROM INTERVIEWS
The meaning of 'performance' in the ISO 9000 standards	• ISO 9001 is 'meeting customer requirements and achieving customer satisfaction'; and • ISO 9004 is 'to satisfy all relevant third parties'
PM methods for assessing ISO 9001 QMS	• customer satisfaction; • audits; and • management reviews
Reasons for the different approaches of ISO 9001 & ISO 9004	• ISO 9001 is based on effectiveness because the ISO/TC 176 has not found a clear way to assess efficiency. ISO 9004 has an approach of sustained success and improvement but it is not a certifiable standard. Hence, ISO 9004 is focused on improving the organisation as a whole, whereas ISO 9001 is about the effectiveness of QMS, is about one part of the organisation, a subsystem
Problems in internal audits	• organisations are not obtaining much value from their audits; • auditors' lack of competence and experience; • auditors' lack of knowledge of risk management and process management; and • lack of top management commitment
Reasons for these problems	• organisations do not treat the QMS and ISO 9001 certification seriously, auditing is a routine exercise; • if external auditors try to add value, they raise many non-conformities and companies do not like it[31]; • CB are not paid enough for conducting the type of audits that are needed for the 2000 version and organisations are not willing to pay for a better audit; • lack of attention of the ISO/TC 176 committee about the problems in the audit process; • lack of attention to human factors in the standards; and • third party auditors should also speak the language of business and not only the standards one;
QMS problems due to bad audits	• CO are not taking advantage of their QMS; • QMS is not providing good feedback that will serve to improve processes; • top management dissatisfaction and frustration; and • auditors are not able to deliver the full potential of the standard
Suggestions for improvement	• change the current compliance focus of auditing to the improvement approach; • develop more audit criteria to assess QMS performance based on the business of the organisation; • develop more audit criteria based on industry sectors; • provide better training to auditors; and • audit with a focus on processes instead of clauses
PM techniques used in the audit process	• self-assessment tools; • Business Excellence Models criteria; • statistical process control; • statistical software; and

[31] CO usually conduct internal audits based on how CB perform third party audits. Hence, some problems in third party audits may affect internal audits as well.

	• the BSC
Inclusion of an academic proposal in the ISO/TC176	• academics should join the ISO/TC 176 committee as national delegates
Challenges of the ISO 9000 family	• ISO 9001 needs to evolve into a performance oriented tool which helps organisations to improve; • increase the competence of the ISO/TC 176 committee in general management; • prove the relevance of ISO 9001 and ISO 9004 to managers; and • increase the speed of the standardisation process, it is very slow

Table 5.16 Feedback from interviews with ISO/TC 176 experts

5.2.2. Summary of the findings

The interviews with experts in many ways echoed the literature review findings. The problems found in internal audits are mostly related to the lack of focus and guidelines for the measurement of QMS performance found in the ISO 9001 standards. This issue tends to promote a limited view of the audit process, based on compliance rather than on PM and continuous improvement. For this reason, in the opinion of experts, CO are not able to identify important benefits emerging from the audit. As a result, the commitment of top management to the QMS and auditing process is also adversely impacted.

A framework to assess the performance of ISO 9001 QMS was proposed by interviewees to address these problems and difficulties. A clearer set of PM for ISO 9001 QMS criteria should be included in such a framework. A continuous improvement approach to QMS should be emphasised, according to the experts, in the framework and audit criteria.

Although, some PM tools such as the BSC were mentioned, the auditors indicated that only the minimum PM requirements associated with the standards are currently employed in the audit process. Those were considered insufficient to highlight the importance of audits to monitor and improve QMS.

5.3 Merging the two methods

In order to accomplish the second objective of this study and answer the first, second and fourth intermediate research questions using quantitative and qualitative results, a data transformation of the interviews was conducted and the results were then merged with the survey dataset.

Creswell & Plano Clark (2007) point out that the basic idea of data transformation is to convert one form of data into another form so that it can be easily merged. These authors also state that "unquestionably, it is easier to transform qualitative data into numeric counts (quantitative data) than vice versa. Transforming qualitative data

involves reducing themes or codes to numeric information, such as dichotomous categories" (Creswell & Plano Clark, 2007, pp. 138).

Qualitative data transformation techniques may include counting codes, counting themes or both (Creswell & Plano Clark, 2007). Counting codes is a popular data transformation technique; however Creswell & Plano Clark (2007) argue that counting codes is problematic with participants who are highly verbal or keep repeating ideas. In the case of counting themes, this may include: the frequency of themes within a sample; the total themes associated with a phenomenon; or the percentage of people selecting or endorsing multiple themes (Creswell & Plano Clark, 2007). Nevertheless, no matter how the qualitative data is transformed, it must be considered that the counts may not be an accurate representation of the themes and this has to be kept in mind during the analysis and interpretation of the transformed data (Creswell & Plano Clark, 2007). Moreover, "[the] quantitative database contains data from more people and hence any direct comparison between the qualitative and quantitative databases would give an unbalanced analysis of the participant views" (pp. 139).

For the analysis of this mixed methods research, the Creswell & Plano Clark (2007) approach of counting the total number of themes associated with a phenomenon, in this case the audit process, addressed by experts during the interviews was used. Hence, all the topics that emerged unprompted during each interview were classified by theme and then were contrasted with the original variables of the survey. That is, in each case where an expert was noted as addressing a theme, this reflects a significant mention of the topic as being important in the relevant context. To implement this approach, comparison matrices, following the McEntarffer (2003)[32] approach, were developed for each intermediate research question to show how both sets of data merged.

Discussion regarding the current problems in ISO 9001 internal audits – first intermediate question

In order to answer the first intermediate research question regarding the current problems that CO are experiencing when conducting audits, matrix 5.17 was created to match quantitative variables with qualitative themes.

It is important to observe that both data sets converged in all the internal audit problems covered in the surveys. In fact, for each problem, different experts from each group addressed the theme, with one exception: standardisation experts did not recognise the importance of the **lack of follow-up of previous audit findings**. This problem was the least mentioned by interviewees, with only 3 mentions, although it was the most important problem addressed by internal auditors in the COS. One of the reasons for the difference in the perceptions between experts may

[32] Cited by Creswell & Plano Clark (2007)

be that the 'lack of follow-up of previous audit findings' is not an obvious problem such as 'internal auditors' competence' for example. In fact, in the new version of ISO 19011, the 'conducting audit follow-up' stage (clause 6.7) was left almost with no guidance. Meanwhile, the standard dedicates the entire section 7 and Annex A to auditors' competence. This is an indication that the ISO/TC 176 does not consider follow-up as a major problem and perhaps explains why standardisation experts did not address the topic during the interviews and the external auditors in the CBS ranked it as the sixth most relevant topic. As expert C8 explained "there is a lack of attention of the ISO/TC 176 committee about the problems in the internal audit process" (it should be remembered that the ISO 19011 standard is for conducting both internal and external audits). Perhaps, another reason why standardisation experts did not address this problem may be the size of the group which consisted of only 5 experts, being the smallest of the three groups of interviewees.

Competence of internal auditors was the problem that received the most mentions by interviewees, with 16 of the 25 experts addressing it. This problem also had a mean of 4.07 out of a maximum of 5, quite high, in the CBS (see Table 5.6). It was, in fact, the second most important issue of concern to external auditors. However, it was ranked as the sixth problem in the COS with an average of 2.7 out of a maximum of 5 by internal auditors. The latter result may be due to a natural bias that could exist when internal auditors self-evaluate their own competence and that of their colleagues. Hence, it may be concluded that the competence of internal auditors is still an issue of considerable relevance to the audit process, as suggested in the literature review (Chapter 2).

Interestingly the **lack of ability to measure QMS performance** was the second most addressed problem by interviewees with 10 out of 25 interviewees mentioning it. It is important to highlight that this problem was ranked third in both surveys which makes it one of the most important problems in the internal audit process according to both research methods. Moreover, there is a natural connection between poor **internal auditors' competence** and the **lack of ability to measure QMS performance** because if internal auditors are not able to correctly measure QMS performance, they are likely to be considered as not competent enough.

Interviewees also considered the **lack of top management commitment** as a relevant problem in internal audits, with 8 out of 26 experts addressing it. It should be noted that this was considered the most important problem in the CBS by external auditors, with a mean of 4.2 out of a maximum of 5. Nevertheless, this topic was not of great importance for internal auditors who ranked it fifth in the COS with a mean of 2.76. As with internal auditors' competence, the difference in the perceptions of internal and external auditors in both surveys may be due to a natural bias that exists when internal auditors are asked to evaluate their own top management's commitment. It is also important to remember that 28% of the respondents of the COS are internal auditors as well as top management representatives (see Table 5.2).

The problem of a **lack of understanding of ISO 9000 standards** was mentioned by 5 interviewees and it was ranked fourth in the COS with a mean of 2.88 and seventh in the CBS with a mean of 3.69. The results of both research methods indicates that this is a relatively important problem, especially for standardisation experts who may be interested in addressing this issue in the 2015 version of the core of the ISO 9000 standards.

Also, the problem of a **bad audit plan** received 5 mentions by interviewees and was ranked eighth in both surveys. However, the mean values were quite high with 3.30 in the CBS and 2.23 in the COS, which also indicate this is a problem of concern by internal and third party auditors. Hence, improvements are needed in the current guidelines for developing good audit plans and programmes in the current 19011:2011 standard.

The **lack of knowledge of audit practices** was addressed by 4 experts during the interviews and was ranked fifth in the CBS with a mean of 3.89 and seventh in the COS with a mean of 2.69. Also, both means were also quite high and indicate that the ISO/IAF documents for better auditing are not enough to provide the basis of good audit practice or they are not well known/understood by auditors. Standardisation experts and internal auditors were particularly critical during the interviews about the 'poor competence' of some internal auditors. They specifically mentioned that internal auditors have a **lack of knowledge regarding risk and process management; audit training; and experience in implementing QMS** which is affecting the final audit outcome. External auditors also mentioned that **bad consultants** are a frequent problem in the internal audit process. Normally consultants train the personnel of organisations to conduct audits and act as lead auditors during the first audit. Hence, it is very important for organisations to count on good, experienced consultants.

Moreover, the **lack of ability to measure audit performance** also received 4 mentions by interviewees. Indeed, it was ranked second in the COS with a mean of 3.27 and fourth in the CBS with a mean of 3.94. The results of both research methods suggest this is a problem of concern for ISO 9000 experts.

Quantitative results rankings			Qualitative results			
CBS [33]	COS [34, 35]	Internal audit problems	Total	External auditors	Internal auditors	Standardisation experts
6	1	Lack of follow-up of previous audit findings	3	A3,A6	B17	--
4	2	Lack of ability to measure audit performance	4	A2,A5	B1	C1
3	3	Lack of ability to measure QMS performance	10	A2	B1, B5,B6,B7,B8,B17,B19	C1,C4
1	5	Lack of top management commitment	8	A4,A5	B6,B7,B8,B9	C1,C4
2	6	Internal auditors' competence	16	A1,A5,A6	B5,B6,B7,B8,B9,B10,B17,B18,B19,B20	C2,C7,C8
7	4	Lack of understanding of ISO 9000 standards	5	A3,A8	B1,B10	C7
5	7	Lack of knowledge of audit practices	4	A6,A7	B10	C2
8	8	Bad audit plan	5	A7	B2,B5,B18	C2
Other (problems addressed during the interviews)			CO do not use internal audits as a management tool; Companies' strategy is separate to QMS; Companies incorrectly measure their QMS performance: the less audit findings they have, the better the performance is; 'Poor' consultants; Irrelevant audit findings.		Lack of auditors' experience in implementing QMS and auditing; and 'Poor' audit training; and Lack of added value for auditees from audits.	Organisations are not getting much value from their audits; and Auditors' lack of knowledge of risk and process management.

Table 5.17 Comparison matrix of quantitative vs. qualitative data regarding the current problems that the ISO 9001 internal audit process is facing

[33] Ranked from the highest to the lowest median

[34] Ibid

[35] The survey contained an extra item which was ranked 5 'inconsistencies in audit findings between internal and external audits'. This item was omitted from this analysis because it was only included in one of the two surveys.

As mentioned above, other internal audit problems emerged during the semi-structured interviews which have not previously been considered very important in literature or by experts in the pilot surveys. Notably, **organisations are not getting much value from audits** was mentioned by different experts in the three groups of interviewees. Interestingly, the group of external auditors considered that some audit findings are 'irrelevant' and the group of internal auditors that there is a 'lack of added value for auditees from internal audits'. Hence, the internal audit process is being seriously questioned by ISO 9000 experts for not providing organisations with sufficient value. This finding supports the theory discussed in Chapter 2.

Different third party auditors addressed the issues of **the strategy of organisations being separate to the QMS** and **organisations not using audits as a management tool,** as important problems in internal auditing. These two problems may imply that CO are not using their QMS as a management tool which can help to improve the performance of the organisation as claimed in the ISO 9000 standard.

Finally, external auditors also pointed out that **companies are not measuring their QMS performance correctly** because they measure it in terms of having the least possible number of audit non-compliance findings. ISO 9001 organisations should look for internal audits that review their QMS more deeply and provide the greatest number of audit findings to identify possible improvements to the QMS. A QMS audited in such a manner would be predictive rather than reactive and more able to anticipate errors and problems in processes and products.

Discussion regarding the impacts on the QMS due to 'poor' internal audits – second intermediate research question

In order to answer the third intermediate research question regarding the effects that poor internal auditing is having on QMS performance, matrix 5.18 was created to match up the findings from the quantitative and qualitative datasets.

Some groups of interviewees did not address all of the effects of the poor internal auditing included in the surveys. Indeed, experts A1, B4, B6, B18, B20, C2 and C4 addressed other impacts which were not considered in the literature and pilot surveys. This suggests that the QMS is presenting more problems than the ones originally identified by scholars and practitioners and hence included in the surveys.

Also, one of the reasons why some impacts of auditing deficiencies were not addressed by a particular group of interviewees may be due to an association effect between different impacts. For example, interviewees may have considered that 'organisations' QMS is not performing correctly' and/or 'organisations are not improving their capabilities as expected' is due to 'organisations are not detecting problems in their QMS processes' and/or 'organisations are not detecting all non-conforming products'.

The effect of **organisations' QMS is not performing correctly** received the most attention from interviewees, with 9 mentions. It was also the third most important impact in the CBS with a mean of 3.85 out of a maximum of 5 and the fourth in the COS with a mean of 2.73. The high value of the means and the significant number of mentions in the interviews that this impact obtained from both research methods suggest that CO are facing considerable problems with their QMS performance. These companies are clearly not gaining all of the benefits of ISO 9001 implementation.

As far as the impact of **organisations are not improving their capabilities as expected** is concerned, it was the second most mentioned impact by interviewees and was also ranked first in both surveys with a mean of 4.10 in the CBS and 3.27 in the COS. Chapter 2 argued that the implementation of a QMS based on ISO 9001 can help to improve the capabilities of the organisation through achieving and exceeding customer satisfaction. The results of both research methods show that this objective is not necessarily being accomplished. It may be the case that in some organisations, the implementation of the QMS is still immature and the QMS has not yet shown its full potential. But it may also be because some companies have a poor implementation of the ISO 9001 standard and for this reason the organisations' capabilities are not improving. Another reason may be the lack of general process improvement focus of the standards, especially of ISO 9001, which may be failing to provide organisations with the necessary tools to improve their capabilities.

The third most mentioned effect by interviewees was **top management is dissatisfied with the performance of the QMS**, with four mentions. Interestingly, this effect was the least important in both surveys, however its means were relatively high with 3.55 in the CBS and 2.53 in the COS. As with the case of the above variables, this effect cannot be analysed in isolation from the other variables. If the main impacts of poor internal audits are a QMS which is not performing correctly and therefore organisations are not improving their capabilities as expected, it is not surprising that top management is dissatisfied with the performance of the QMS. As mentioned in section 5.2, the main reason why organisations are obtaining the ISO 9001 certification is the 'desire of top management to improve the capabilities of the organisation' (see Table 5.2). If this is not happening, top management would naturally become dissatisfied with the QMS.

Quantitative results ranking			Qualitative results			
CB[36]	CO	Effects of poor internal auditing	Total	External auditors	Internal auditors	Standardisation experts
1	1	Organisations are not improving their capabilities as expected	5	A3	B1,B19	C1,C4
2	3	Organisations are not detecting problems in their QMS processes	3	--	B9,B17	C4
4	2	Organisations are not detecting all non-conforming products	1	A7	--	--
3	4	Organisations' QMS is not performing correctly	9	A4,A5,A6,A7	B2,B5,B8,B10 ,B17	--
4	5	Top management is dissatisfied with the performance of the QMS	4	A8	--	C1,C4,C8
Others (effects addressed during the interviews)			Companies do not have enough benefit from the QMS; Bad internal audits cause an incorrect performance measurement of the QMS and this does not allow the QMS to improve; and Because audits do not add value to organisations, top management is questioning why a QMS is needed.		QMS are not improving as expected; and Lack of commitment from top management and organisations personnel with the QMS.	Organisations are not taking advantage of their QMS; Internal audits are not providing good feedback that will serve to improve processes; and Auditors are not able to deliver the full potential of the standard.

Table 5.18 Comparison matrix of quantitative vs. qualitative data regarding the impacts on the QMS due to problems in internal audits[37]

[36] The effects 'organisations are not detecting all non-conforming products' and 'top management is dissatisfied with the performance of the QMS' resulted in the same mean of 3.55. Hence both effects were ranked 4th.

[37] Experts A1, B4, B6, B18, B20, C2 and C4 provided other impacts which were not included in the survey. These experts were not considered in the calculation of the percentage of the qualitative dataset

The variable **organisations are not detecting problems in their QMS processes** was ranked the fourth most important effect by interviewees with three mentions. However, it was second in the CBS with a mean value of 4.09 and third in the COS survey with a mean of 2.83; both means are high which implies that this effect is of considerable concern to ISO 9000 experts, despite not being highly cited by interviewees. As pointed out above, this may be due to an association effect where the effects of 'organisations' QMS is not performing correctly' and 'organisations are not improving their capabilities as expected' are perceived by interviewees as core effects of poor internal auditing, caused by 'organisations are not detecting problems in their QMS processes'.

The effect '**organisations are not detecting all non-conforming products'** was considered the least important effect by interviewees with only one mention. However, it was ranked second in the COS and fourth in the CBS. Hence, for this variable, the research methods did not converge. However, the results of the surveys were surprising because, as reviewed in Chapter 2, the ISO 9001 standard has a strong emphasis on controlling product compliance with client requirements. Hence, it may be the case that the current standard is not sufficient to help organisations detect all non-conforming products as standardisation experts believe.

As mentioned above, interviewees addressed other undesirable effects of poor internal auditing, which were not stated in the literature nor in the pilot surveys. Notably, external auditors pointed out that **bad internal audits cause an incorrect PM of the QMS and this does not allow the QMS to improve**. Similarly, standardisation experts remarked that **internal audits are not providing good feedback that will serve to improve processes** and **auditors are not able to deliver the full potential of the standard**. External auditors also remarked that **organisations are not taking advantage of their QMS** as an outcome of poor internal auditing. Equally, standardisation experts agreed that **companies do not have benefits from the QMS,** whereas internal auditors indicated that **QMS are not improving as expected**. Finally, internal auditors pointed out that poor internal audit practice is also causing **lack of commitment from top management and the personnel of organisations** and external auditors mentioned that **because audits do not add value to organisations, top management is questioning the need for a QMS**.

It is clear from the analysis of the merging of both datasets, that there are more undesirable effects in the QMS due to poor internal auditing than have been previously reported in the literature. They do not only involve poor quality of products and poor performance of the QMS's process, they are also related to the performance of the QMS as a whole and, in some cases, the performance of the entire organisation. These undesirable effects are creating dissatisfaction and reducing commitment among top management and the personnel of organisations. The latter is not a minor issue, as an organisation´s staff have to work with the QMS on a daily basis and top management have to provide the necessary resources to maintain it. Hence, if the QMS is not providing them with all the advantages it

should, they will be tempted to stop using and maintaining it as a business system, relegating it to a more ceremonial role.

Discussion regarding the current PM techniques used by CO – fourth intermediate question

Regarding what are the most widely used PM techniques by CO, Table 5.19 shows the results of the data transformation of the interviews regarding this topic.

Interestingly, only eight experts mentioned one of the PM techniques listed in the surveys. The **BSC** was mentioned by seven experts whereas the **dashboard** was mentioned by only one. These results correspond with the CBS where these PM techniques were ranked first and second. However, they were ranked fourth and third respectively by organisations in the COS behind the performance measurement matrix and the performance measurement questionnaire (see Table 5.12). Also, as shown in Table 5.19, only three experts from CO declared that their companies use the BSC, whereas the other interviewees mentioned that they only use the requirements of ISO 9001 and KPIs. Hence, it may be concluded from the results of the COS and interviews that CO do not use PM techniques as much as CB and standardisation experts believe.

Experts	Balanced scorecard	ISO 9001 requirements	KPIs	Not used at all	Others
Third party auditor and certification managers	A2, A7	A1, A2, A3	A4, A6, A8	A3, A4, A5, A6	Six Sigma (A2) Dashboard (A7)
Internal auditors, quality managers and consultants	B1, B2, B19	B5, B9, B10, B20	B1, B2, B4, B7, B8, B17, B18, B19	B6	--
Standardisation experts	C1, C7, C8	C2, C7, C8	C2, C7	C4, C8	European Business Excellence Model (C2)

Table 5.19 PM techniques and models used by CO according to interviewees

5.5. Conclusions of the chapter

In order to accomplish the second research objective of this work, this chapter provided a review of the current state of the art of the ISO 9001 internal audit process. The chapter aimed to answer three intermediate research questions associated with this objective: what are the current problems that organisations face when conducting audits; how these problems affect the performance of product/services, processes and the QMS; and what are the PM techniques most used by certified organisations. From the mixed methods study conducted to answer these questions, the key conclusions may be summarised as:

- 'the lack of follow-up of internal audits', 'poor internal auditors' competence' and 'the lack of ability to measure QMS performance' are the most important problems for certified organisations when conducting internal audits;
- 'organisations are not improving their capabilities as expected' resulted in being the most important effect due to 'poor' internal auditing. Experts in both research methods found this effect of vital importance;
- experts in both research methods also agreed that poor internal auditing is causing 'organisations are not detecting problems in their products and processes' as well as 'QMS not performing correctly';
- 'top management is not satisfied with the performance of the QMS'; and
- 'the BSC was the PM technique most known by experts in both research methods, but it was not the most used PM technique by CO

The next chapter will analyse the relationships between the problems in the internal audit process and their effects on the performance of the QMS in greater detail, using the qualitative survey data with path analysis to present a model to relate internal audit problems to the impacts of the performance of the QMS and the organisation.

CHAPTER 6
A PATH MODEL TO UNDERSTAND THE RELATIONSHIP BETWEEN AUDIT PROBLEMS AND THEIR IMPACT ON QMS PERFORMANCE

In Chapter 2, eight main problems in the internal audit process were identified from the literature (see Tables 2.1 and 2.2) and in Chapter 5 the current validity of these problems was empirically tested using mixed methods research. This chapter aims to address the third intermediate research question regarding how and to what extent these problems impact the performance of products, services, processes and the QMS.

To address this question, a path model showing the linkages between audit problems and their potential effects on the performance of products/services, processes and the QMS, was developed and tested using path analysis.

Section 6.1 describes the hypotheses tested in the path model and the methodology used. Section 6.2 explains how the data analysis of the model was conducted. Section 6.3 illustrates the results of the proposed path model and Section 6.4 provides the conclusions of the chapter.

6.1 Research hypotheses and methodology

The third intermediate question addresses how and to what extent the internal audit problems identified in Chapter 5 are affecting the performance of the QMS. In order to tackle this question, all of the likely relationships between any two variables obtained from the literature (see Table 2.1) that were also identified and tested in Chapter 5 (see Table 5.18) were included in a postulated path diagram (Figure 6.1 – Audit problems) which included arrows indicating the author's *a priori* logical assumptions of causation. The resulting 43 hypotheses were tested using path analysis (Hair *et al.,* 2010). This technique was chosen because it is a "procedure for empirical estimation of the strength of each relationship (path) … [it] calculates the strength of the relationships using a correlation or covariance matrix as input" (Hair *et al.,* 2010, pp. 681). Hence, path analysis enables the decomposition of the bivariate correlations between the audit problems in the path diagram, to understand to what extent and how they are related (Hair *et al.,* 2010).

Kingsolver & Schemske (1991) and Mitchell (1992 and 1993) emphasise two main applications of path analysis: exploratory data analysis and formal hypothesis testing (statistical adequacy of a proposed causal model). The feature that distinguishes formal hypothesis testing is the presentation of a formal path model that is not derived from a data set that is itself the object of the path analysis (Petraitis *et al.*, 1994).

Moreover, Stage *et al.* (2004) state that one of the strengths of path analysis is that it allows the researcher to draw a set of hypothesised relationships that can be translated directly into the equations needed for the analysis. Lea (1997) notes that in some situations, one can use path analysis to test two or more causal hypotheses, although it cannot absolutely establish the direction of causality. A causal path between two variables is given a direction by the researcher, on the basis of theory (Stage *et al.,* 2004). The results of the analysis can provide support for the hypothetical relationships expressed within the model. Also, path analysis is most useful when the researcher has a clear hypothesis to test, or a small number of hypotheses, all of which can be represented within a single path diagram (Stage *et al.,* 2004). Asher (1983) states that a large number of hypotheses can be tested when they are supported by theory. The use of path analysis in social science research has allowed researchers to gain understanding and insight into important issues (Stage *et al.*, 2004). Path analysis is not a means to accurately demonstrate causality between variables. It is a method for tracing the implications of a set of causal assumptions that the researcher is willing to impose on a system of relationships (Nie *et al.*, 1975).

The following hypotheses tested were related to direct relationships between the variables:

> **H1.** *Lack of knowledge of ISO 9000 series of standards* is positively related to *lack of internal auditors' competence*;

H2. *Lack of knowledge of auditing practices* is positively related to *lack of internal auditors' competence*;

H3. *Lack of knowledge of ISO 9000 series of standards* is positively related to *bad audit plan*;

H4. *Lack of knowledge of auditing practices* is positively related to *bad audit plan*;

H5. *Lack of knowledge of ISO 9000 series of standards* is positively related to *lack of ability to measure audit performance*;

H6. *Lack of knowledge of auditing practices* is positively related to *lack of ability to measure audit performance*;

H7. *Lack of internal auditor's competence* is positively related to *lack of ability to measure audit performance*;

H8. *Lack of knowledge of auditing practices* is positively related to *lack of follow-up of audit findings*;

H9. *Lack of ability to measure audit performance* is positively related to *lack of follow-up of audit findings*;

H10. *Bad audit plan* is positively related to *lack of follow-up of audit findings*;

H11. *Lack of ability to measure QMS performance* is positively related to *lack of follow-up of audit findings*;

H12. *Lack of ability to measure QMS performance* is positively related to *lack of top management commitment;*

H13. *Lack of ability to measure audit performance* is positively related to *lack of top management commitment*;

H14. *Lack of ability to measure audit performance* is positively related to *lack of ability to measure QMS performance*;

H15. *Lack of internal auditor's competence* is positively related to *lack of ability to measure QMS performance*;

H16. *Lack of understanding of ISO 9000 series of standards* is positively related to *lack of ability to measure QMS performance*; and

H17. *Lack of knowledge of auditing practices* is positively related to *lack of ability to measure QMS performance*.

H18. *Lack of follow-up of audit findings* is positively related to *organisations are not detecting problems in their QMS processes*;

H19. *Lack of ability to measure QMS performance* is positively related to *organisations are not detecting problems in their QMS processes*;

H20. *Lack of understanding of the ISO 9000 series of standards* is positively related to *organisations are not detecting problems in their QMS processes*;

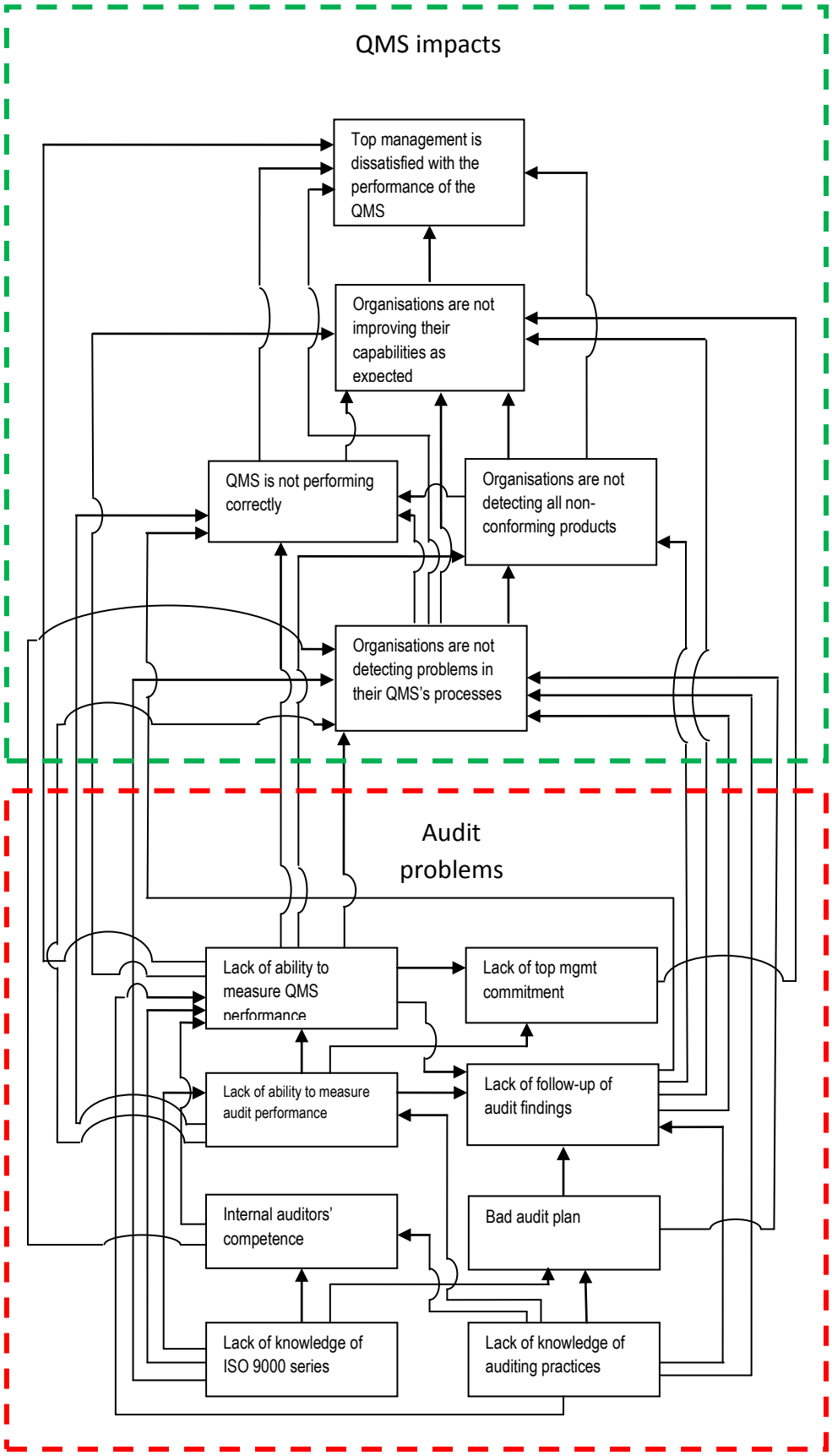


Figure 6.1 Postulated path diagram of relationships between audit problems and their impacts on the QMS

H13. *Lack of ability to measure audit performance* is positively related to *lack of top management commitment*;

H21. *Lack of knowledge of auditing practices* is positively related to *organisations are not detecting problems in their QMS processes*;

H22. *Lack of internal auditor's competence* is positively related to *organisations are not detecting problems in their QMS processes*;

H23. *Lack of ability to measure audit performance* is positively related to *organisations are not detecting problems in their QMS processes*;

H24. *Bad audit plan* is positively related to *organisations are not detecting problems in their QMS processes*;

H25. *Organisations are not detecting problems in their QMS processes* is positively related to *organisations are not detecting all their non-conforming products*;

H26. *Lack of follow-up of audit findings* is positively related to *organisations are not detecting all their non-conforming products*;

H27. *Lack of ability to measure QMS performance* is positively related to *organisations are not detecting all their non-conforming products*;

H28. *Organisations are not detecting problems in their QMS processes* is positively related to *QMS is not performing correctly*;

H29. *Lack of ability to measure QMS performance* is positively related to *QMS is not performing correctly*;

H30. *Lack of follow-up of audit findings* is positively related to *QMS is not performing correctly*;

H31. *Organisations are not detecting all their non-conforming products* is positively related to *QMS is not performing correctly*;

H32. *Lack of ability to measure audit performance* is positively related to *QMS is not performing correctly*;

H33. *Lack of top management commitment* is positively related to *organisations are not improving their capabilities as expected*;

H34. *QMS is not performing correctly* is positively related to *organisations are not improving their capabilities as expected*;

H35. *Organisations are not detecting all their non-conforming products* is positively related to *organisations are not improving their capabilities as expected*;

H36. *Lack of ability to measure QMS performance* is positively related to *organisations are not improving their capabilities as expected*;

H37. *Lack of follow-up of audit findings* is positively related to *organisations are not improving their capabilities as expected*;

H38. *Organisations are not detecting problems in their QMS processes* is positively related to *organisations are not improving their capabilities as expected*;

H39. *Organisations are not detecting problems in their QMS processes* is positively related to *top management is dissatisfied with the performance of the QMS*;

H40. *Lack of ability to measure QMS performance* is positively related to *top management is dissatisfied with the performance of the QMS*;

H41. *Organisations are not improving their capabilities as expected* is positively related to *top management is dissatisfied with the performance of the QMS*;

H42. *Organisations are not detecting all non-conforming products* is positively related to *top management is dissatisfied with the performance of the QMS*; and

H43. *QMS is not performing correctly* is positively related to *top management is dissatisfied with the performance of the QMS*.

As stated above, the preparation of the postulated path diagram drew upon the literature (see Chapter 2) and also the author's professional experience as an auditor, quality manager and ISO national committee member. The proposed relationships and causation directionality were then independently reviewed by three experienced practitioners and standardisation experts and the model refined according to their comments. Figure 6.1 shows this diagram which aims to present an initial theory of linkage and causation assumptions between variables, to be tested by path analysis using the data of the surveys discussed in Chapter 5. The only exogenous variables in the proposed model were *lack of knowledge of auditing practices* and *lack of understanding of ISO 9000 standards*, leaving 11 dependent variables.

The description of how the pilot surveys were conducted, the data preparation for the analysis and the demographic profile of respondents were discussed in Section 5.1. Hence, in the following paragraphs only the path analysis will be discussed.

6.2 Data analysis

As stated in Chapter 2, no previous studies addressing the relationships between audit problems and QMS impacts were found. Hence this was an exploratory, rather than a confirmatory analysis.

As discussed above, in order to test the proposed hypotheses, the technique of path analysis was used. This is a form of structural equations modelling (Ullman, 1996; Hair *et al*., 2010) and allows for empirical estimation of the strength of each

relationship described in the postulated path model (Hair *et al.,* 2010). It represents the correlation between any two variables as the sum of the compound paths of the relationships connecting the points. Hence, path analysis breaks a postulated relationship model into a set of multiple regression models, one for each independent variable (Flynn & Saladin, 2001). The standardised regression coefficients are decomposed into their effects to allow detailed assessment of potential specification error. Hence, path analysis is "a method for determining the overall quality of a causal model, as well as for detailed assessment of specification error in specific relationships between variables" (Flynn & Saladin, 2001, pp. 628). Thus, this technique enables the decomposition of the bivariate correlations of the internal audit problems described in the path diagram to understand to what extent and how they are related (Hair *et al.,* 2010).

Bryman & Cramer's (2009) approach for path analysis using structural equations was used to calculate the path coefficients and for the correlation and regression analysis. The total number of responses was 272. The number of cases used in the regressions was between 248 and 260. As the sample size was greater than 200 and the missing data was below 10%, the analysis was conducted using a pairwise approach (Hair *et al.*, 2010). The degrees of freedom of the model were established as 46, and the model was determined to be 'over-identified' (Shah & Goldstein, 2006).

For the data analysis, the path correlations were established to >0.3 (Pallant, 2007) and a regression analysis was then conducted for each hypothesis. All the data was screened for normality, linearity, homoscedasticity, independence of residuals, multicollinearity and singularity. All the variables were established to be normal and otherwise acceptable, except for the variables 'organisations are not detecting problems in their QMS's processes', 'QMS is not performing correctly' and 'organisations are not detecting all non-conforming products' which presented multicollinearity, with Mahal values of 24.3, 20.5 and 16.3 respectively. The specific case that created the problem (one in each equation) was eliminated from the data, and a new correlation and regression analysis was then conducted (Pallant, 2007).

Next, in order to simplify the model prior to decomposition, any paths that were not statistically significant at the 0.05 level or less were eliminated (19 in total). For the refined model, the direct, indirect and spurious effects for each path were calculated, together with their sum, which indicates the model fit. Indirect effects are typically due to mediating variables; these can be seen in several of the linkages. Spurious effects can exist between a pair of variables because of another variable that influences both. These are not meaningful effects, but are tabulated for the variables otherwise related (directly or indirectly). The sum of all effects for each path was compared with the original correlation, to determine whether the model was well-specified (Asher, 1983). For such a model, the implied correlation should ideally be equal to the sum of all the path effects, the difference being the measurement error. Asher (1983) suggested an arbitrary rule, that differences greater than 0.10 suggest a model revision may be needed.

6.3 Results

The hypotheses H1, H3, H9, H13, H15, H17, H18, H21, H22, H23, H27, H30, H32, H33, H35, H36, H37, H40, and H42 were rejected, as these were not significant at <0.05 level. A total of 11 regression models were analysed, corresponding to the 11 dependent variables. Each remaining relationship was statistically significant at <0.05 level, having R^2 values from 0.237 to 0.613, the average R^2 value being 0.399 (see Table 6.1).

Figure 6.2 illustrates the simplified model and Table 6.2 shows its decomposition. The right hand column in Table 6.2 shows the difference between the implied correlation and sum of the path effects. There were twelve differences between the sum of the paths and the implied correlations that exceeded Asher's criterion for measurement error, although the average difference was only 0.05. Only two paths exceeded this criterion in the first section of the model, for the audit problems; which indicates a good fit. However, in the second part of the model, the impacts of the audit problems on QMS performance show evidence of measurement error. This is unsurprising, as the other PM methods to measure the QMS, management reviews and customer satisfaction measurement, will also impact the performance of the QMS.

The revisited path analysis model (see Figure 6.2) indicates that there is no single primary cause for internal audit problems at ISO 9001 CO and also that there are several important impacts on QMS performance. The model shows a network of mediating variables, indicating interlinked audit problems. Several of these have managerial implications that are described below.

Table 6.1 Path analysis of audit problems and their impacts on QMS performance

Dependent variable	Independent variable	Standardised path coefficient	t	Probability (p<.05)
Internal auditors' competence	Lack of knowledge of audit practices	.567	8.543	.000
Bad audit plan	Lack of knowledge of audit practices	.638	8.761	.000
Lack of ability to measure audit performance	Lack of understanding of ISO 9000 standards	.149	2.060	.040
	Lack of knowledge of audit practices	.306	3.747	.000
	Internal auditors' competence	.204	2.995	.003
Lack of follow-up of audit findings	Lack of knowledge of audit practices	.213	3.160	.002
	Bad audit plan	.143	2.341	.020
	Lack of ability to measure QMS performance	.403	5.229	.000
Lack of top management commitment	Lack of ability to measure QMS performance	.541	7.018	.000
Lack of ability to measure QMS performance	Lack of ability to measure audit performance	.597	12.415	.000
	Lack of understanding of ISO 9000 standards	.224	4.028	.000
Organisations are not detecting problems in their QMS processes	Lack of ability to measure QMS performance	.219	2.569	.011
	Lack of understanding of ISO 9000 standards	.161	2.047	.042
	Bad audit plan	.156	2.267	.024
Top management is dissatisfied with the performance of the QMS	Organisations are not detecting problems in their QMS processes	.185	2.784	.006
	Organisations are not improving their capabilities as expected	.220	3.301	.001
	QMS is not performing correctly	.286	3.779	.000
QMS is not performing correctly	Organisations are not detecting problems in their QMS processes	.318	5.881	.000
	Lack of ability to measure QMS performance	.251	3.441	.001
	Organisations are not detecting all non-conforming products	.215	4.241	.000
Organisations are not detecting all non-conforming products	Organisations are not detecting problems in their QMS processes	.276	4.179	.000
	Lack of follow-up of audit findings	.269	3.842	.000
Organisations are not improving their capabilities	QMS is not performing correctly	.259	3.548	.000
	Organisations are not detecting problems in their QMS' processes	.246	3.852	.000

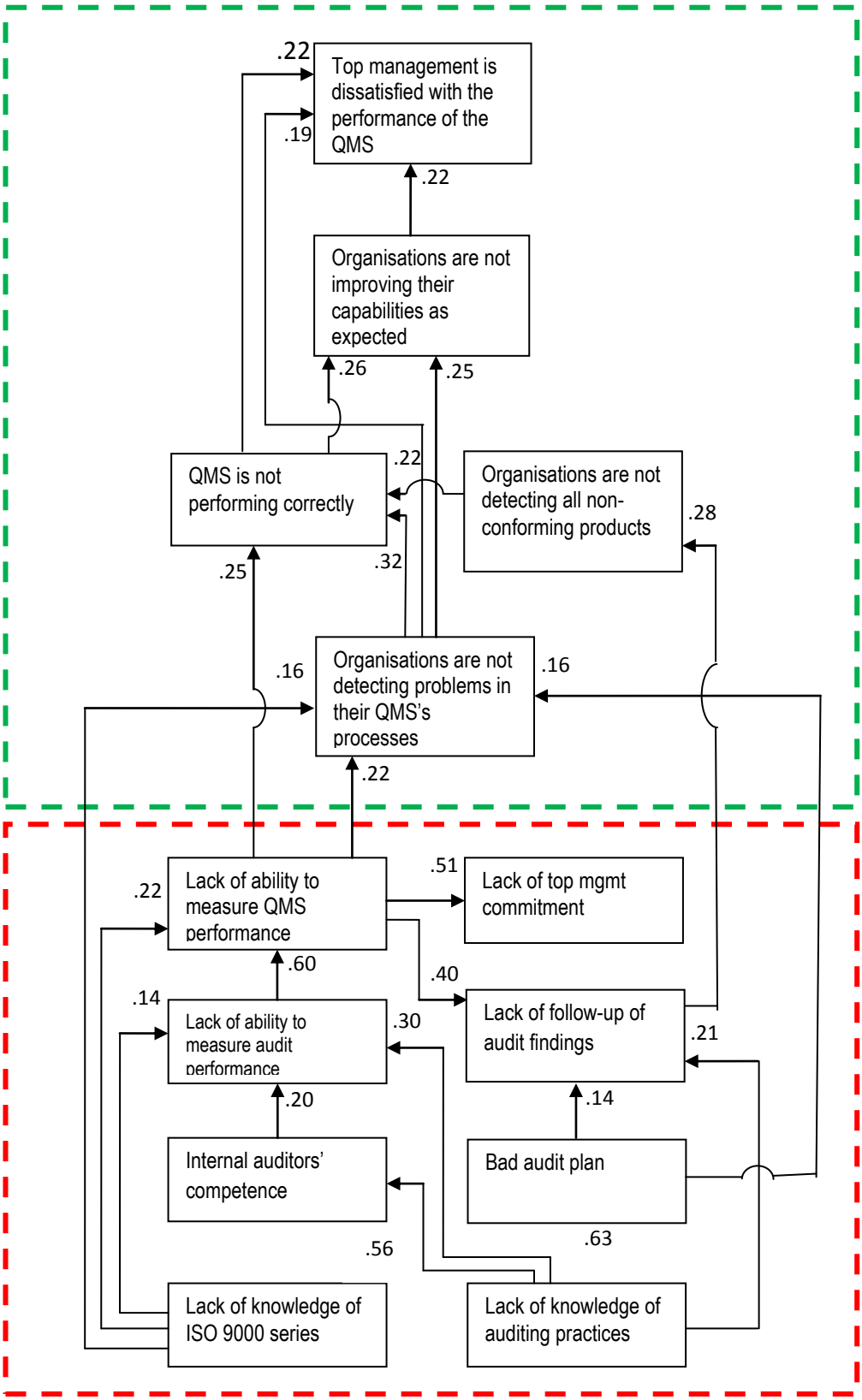


Figure 6.2 Revisited path diagram of the relationships between audit problems and their impacts on QMS performance

Table 6.2 Decomposition for each path illustrated in Figure 6.2

Dependent variable	Independent variable	Direct effect	Indirect effect	Total effect	Spurious effect	Sum of paths	Implied correlation	Difference
Internal auditors' competence	Lack of knowledge of audit practices	.567	0	0.567001	0.0771224	0.6441235	.647	0.003093011
Bad audit plan	Lack of knowledge of audit practices	.638	0	0.637538	0.013164	0.6507023	.563	0.08735798
Lack of ability to measure audit performance	Lack of understanding of ISO 9000 standards	.149	0	0.148917	0.1774389	0.3263559	.466	0.139285468
	Lack of knowledge of audit practices	.306	0.1155887	0.4212	0.0956354	0.516835	.541	0.024392038
	Internal auditors' competence	.204	0	0.20386	0.2272575	0.4311172	.478	0.046480945
Lack of follow-up of audit findings	Lack of knowledge of audit practices	.213	0.1799243	0.392967	0.0310469	0.4240139	.506	0.081503661
	Bad audit plan	.143	0	0.143199	0.2236285	0.3668275	.417	0.049980463
	Lack of ability to measure QMS performance	.403	0	0.402544	0.1382688	0.5408125	.567	0.025987051
Lack of top management commitment	Lack of ability to measure QMS performance	.541	0	0.541143	0	0.541143	.577	0.036112211
Lack of ability to measure QMS performance	Lack of ability to measure audit performance	.597	0	0.597434	0.0905582	0.6879925	.745	0.057406673
	Lack of understanding of ISO 9000 standards	.224	0.0889681	0.312838	0.0714335	0.3842714	.548	0.163795987
Organisations are not detecting problems in their QMS processes	Lack of ability to measure QMS performance	.219	0	0.219125	0.1996144	0.4187393	.509	0.089851588
	Lack of understanding of ISO 9000 standards	.161	0.0685506	0.229481	0.0511731	0.2806542	.474	0.193398701
	Bad audit plan	.156	0	0.156237	0.0580655	0.214303	.424	0.209911124
Top management is dissatisfied with the performance of the QMS	Organisations are not detecting problems in their QMS processes	.185	0.1837969	0.368839	0	0.3688392	.496	0.126717006
	Organisations are not improving their capabilities as expected	.220	0	0.220474	0.1377978	0.3582716	.513	0.154789562
	QMS is not performing correctly	.286	0.0571286	0.343227	0.1001269	0.4433534	.555	0.111223489
QMS is not performing correctly	Organisations are not detecting problems in their QMS processes	.318	0	0.317994	0.1225417	0.4405356	.613	0.172097989
	Lack of ability to measure QMS performance	.251	0.1561642	0.407599	0.0429924	0.4505915	.598	0.147608801
	Organisations are not detecting all non-conforming products	.215	0	0.214843	0.1631478	0.3779909	.496	0.118212071
Organisations are not detecting all non-conforming products	Organisations are not detecting problems in their QMS processes	.276	0	0.275994	0.1356403	0.4116341	.414	0.001977868
	Lack of follow-up of audit findings	.269	0	0.269019	0.0594138	0.3284332	.412	0.083955592
Organisations are not improving their capabilities	QMS is not performing correctly	.259	0	0.259118	0.1235454	0.3826629	.589	0.206566914
	Organisations are not detecting problems in their QMS' processes	.246	0.0977623	0.344055	0.0734592	0.4175145	.556	0.138281121

Implications for practice

As far as the exogenous variables are concerned, **lack of knowledge of auditing practices** resulted closely linked to 'internal auditors' competence' (56%) and exerted a significant influence on three other important dependent variables: 'bad audit plan' (63%), 'lack of ability to measure audit performance' (30%) and 'lack of follow up of audit findings' (21%). On the other hand, **lack of understanding of ISO 9001 standards** also showed a lesser, but still significant, influence on several variables. The postulated path (Figure 6.1) to 'poor internal auditors' competence' was eliminated because its probability was not significant. However, the variable shows important linkages with 'lack of ability to measure audit performance' (14%), 'lack of ability to measure QMS performance' (22%) and 'organisations are not detecting problems in their QMS' (16%).

Hence, poor **internal auditors' competence** was mainly explained within the model by 'lack of knowledge of auditing practices', accounting for 56% of the effect. Also, the variable has linkages only with the variable of 'lack of ability to measure audit performance' (20%). These results clearly show that better knowledge of the ISO 9000 standards is not as important as knowledge of auditing practices, as regards auditor competence. The managerial implication is that training in auditing practice, rather than ISO 9001 itself, is particularly important for internal audit success and training efforts in their organisations should reflect this.

The variables **lack of follow-up of audit findings**, **lack of ability to measure audit performance**, and **lack of ability to measure QMS performance** which were the foremost concerns of certified companies according to the surveys (see Table 5.6 in Chapter 5) presented interesting linkages.

Regarding the **lack of follow-up of audit findings,** which was the most important concern for CO and CB experts in the surveys, this variable was significantly influenced by 'bad audit plan' (14%), 'lack of knowledge of audit practices' (21%) and interestingly, by 'lack of ability to measure QMS performance' (40%). However, it only exerts influence on the variable 'organisations are not detecting all their non-conforming products' (28%). This result may indicate that even if auditors consider this activity central for concluding the internal audit process, it is not as relevant as they believe for the performance of the QMS.

Meanwhile, **lack of ability to measure audit performance** is influenced by 'poor internal auditors' competence' (20%), 'lack of understanding of ISO 9000 standards' (14%) and 'lack of knowledge of auditing practices' (30%). This variable only impacts on the variable of 'lack of ability to measure QMS performance' (60%).

Finally, **lack of ability to measure QMS performance** is influenced by 'lack of understanding of ISO 9000 standards' (22%) and, as pointed out above, by 'lack of ability to measure audit performance' (60%). It is important to note that 'lack of ability to measure QMS performance' appeared as a central variable to the audit problems model, with four important impacts: 'lack of follow-up of audit findings'

(40%); 'lack of top management commitment' (51%); 'organisations are not detecting problems in their QMS processes' (22%) and 'QMS is not performing correctly' (25%). These results also have important implications for top management. Firstly, managers should focus their efforts on improving the measurement of QMS performance (i.e. to effectively detect process problems), which will help the QMS to perform correctly. Secondly, inadequate PM of ISO 9001 QMS performance measurement will provoke problems in the follow-up of audits findings, generating spurious or inaccurate findings with little value for auditees, who do not see the point in conducting the follow-up. Finally, organisations should focus on performance measurement, because if senior management do not find the system metrics useful or reliable, this will adversely impact their commitment to the auditing process and the QMS.

Also, the model suggested that **organisations are not detecting problems with their QMS processes** because of 'bad audit plan' (16%) and 'lack of understanding of ISO 9001 standards' (16%), together with 'lack of ability to measure QMS performance' (22%). Further, this variable has a direct effect on 'QMS is not performing correctly' (32%) and 'organisations are not improving their capabilities as expected' (25%). A further direct effect appears on 'top management is dissatisfied with the performance of the QMS' (19%). Interestingly, the postulated path of this variable with 'organisations are not detecting all non-conforming products' was eliminated because its probability was not significant. These results indicate that proper detection of problems with QMS processes is central not only for the system to perform properly, but for organisations to improve their capabilities and to elicit top management satisfaction with the performance of the system.

QMS is not performing correctly resulted in the most important effect caused by poor internal auditing. This problem is significantly influenced by 'lack of ability to measure the QMS performance' (25%); 'organisations are not detecting all non-conforming products' (22%) and 'organisations are not detecting problems in their QMS processes' (32%) – in total 79% of the effect. This result highlights the importance to managers of establishing a comprehensive PM system including all three levels of scrutiny required by the ISO 9001 standard: products, processes and the QMS.

'Organisations are not detecting problems in their QMS processes' and 'QMS is not performing correctly' significantly impacted the final variables in the model: **organisations are not improving their capabilities** (25% and 26% of the effect respectively) and **top management is dissatisfied with the performance of the QMS** (19% and 22% of the effect respectively). This last variable is also 22% directly impacted by 'organisations are not improving their capabilities as expected', making a total effect explained within the model of 63%. These findings may be of value to top management, to help them address their sense of dissatisfaction and properly direct their responses.

Finally, it should be noted that all the above findings are particularly relevant for auditors, quality managers and standardisation experts because the ISO will shortly launch a new 'High Level Structure for management systems (MS)' which will standardise the use of audits as the primary PM method for several important MS standards outside of the quality area. The new version of the ISO 19011 auditing standard is also expanding its applicability to MS. Thus, more organisations will potentially face similar audit problems in a wider range of MS operational contexts.

6.4 Conclusions of the chapter

This chapter presented a path model of the relationships between internal audit problems and their effects on quality performance and the performance of the QMS. The path analysis technique applied to this model allowed for the quantification of these impacts from the eight different variables related to poor internal auditing.

Clear evidence was found of a network of interlinked audit problems, which together influence the performance of the QMS and the organisation. The impacts on the QMS and the organisation are significant, but the eight internal audit problems in the model are clearly not the only influences, as evidenced by the model decomposition and the measurement errors identified. Nevertheless, the path analysis and model have advanced the understanding of internal auditing, providing useful implications for management. It also presents opportunities for further investigation, which would use evidence concerning certification and surveillance audits to establish additional sources of influence on the QMS and the organisation.

CHAPTER 7
PROPOSAL OF A PROCEDURE FOR CONDUCTING ISO 9001:2008 AUDITS WITH A FOCUS ON QMS PERFORMANCE

Chapters 5 and 6 discussed the current problems faced by organisations when conducting internal audits, as well as the effects of these problems on the performance of the QMS. The aim of this chapter is to discuss a procedure for conducting audits with a focus on measuring the performance of the QMS, which contributes towards eliminating these problems. Thus, this chapter aims to accomplish the third research objective of this work:

> "Develop a procedure for conducting ISO 9001 audits with a focus on the performance of the QMS".

Section 7.1 discusses the reasons for developing the procedure. Section 7.2 describes the structure of the procedure and its content whilst Section 7.3 discusses the comments received from experts. Finally, Section 7.4 provides the conclusions of the chapter.

7.1 Rationale for the development of the procedure

It is a requirement of ISO 9001:2008 that organisations establish and maintain a documented QMS (clause 4.1). Generally, the arrangement of QMS documentation follows either the processes of the organisation or the structure of the ISO 9001 standard, but it can also follow a combination of both (ISO/TR 10003, 2001). In the context of an ISO 9001:2008 QMS, it is very important to develop and maintain the appropriate documentation for the system because it provides a framework for all of its users about the organisation's processes, their interactions and the responsibilities of the personnel working with the QMS.

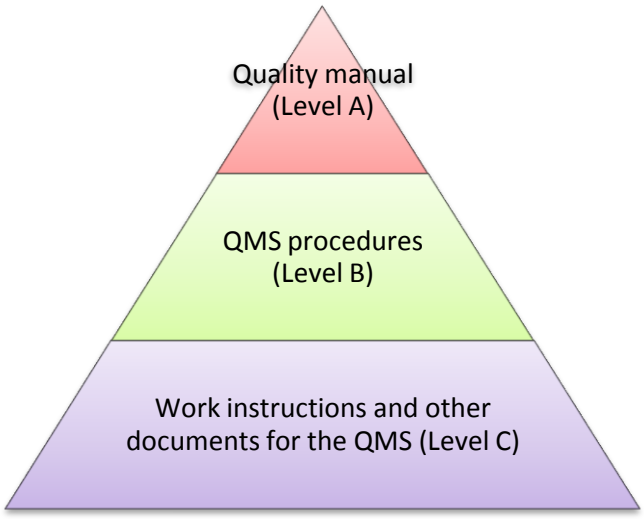
The extent of the QMS documentation will differ from one organisation to another due to the size of the organisation; type of activities; complexity of processes and their interactions; and the competence of personnel (ISO/TR 10013, 2001). The QMS documentation usually includes: quality policy and its objectives; quality manual; documented procedures; work instructions; forms; quality plans; specifications; external documents; and records. In 2001 the ISO/TC 176 committee launched the ISO/TR 10013 standard in order to help organisations to develop their QMS documentation. The ISO/TR 10013 standard suggests a hierarchy of 3 levels for QMS documentation: quality manual; QMS procedures; and work instructions and other documents for the QMS (see Figure 7.1). This structure should facilitate the distribution, maintenance and understanding of the QMS documentation (ISO/TR 10013, 2001).

Document contents

A: Describes the QMS in accordance with the stated quality policy and objectives

B: Describes the interrelated processes and activities required to implement the QMS

C: Consists of detailed work documents.



Source: ISO/TR 10013:2001

Figure 7.1 Typical QMS documentation hierarchy

The quality manual is unique for each organisation and is the basis for the QMS documentation. According to ISO/TS 10013, it should include the scope of the QMS; the details of any justification for exclusions; the documented procedures or

reference to them; and a description of the processes of the QMS and their interactions.

Documented procedures "generally describe activities that cross different functions" (ISO/TR 10013, 2001, pp. 5) and in most cases include the following sections: purpose; scope; responsibility and authority; description of activities; records; appendices; review, approval and revision; and identification of changes.

Finally, work instructions "generally apply to tasks within one function" (ISO/TR 10013, 2001, pp. 5). There are many ways of developing instructions and they should be tailored to the needs of the personnel who are going to use them; the complexity of the work; the methods used; the training undertaken; and the competence of the personnel (ISO/TR 10013, 2001).

The ISO 9001:2008 standard devotes all of section 4.2 to documentation and it is mandatory for CO to comply with all of the requirements of this clause. The standard also requires that organisations maintain a quality manual (clause 4.2.2) and six documented procedures: control of documents (clause 4.2.3); control of records (clause 4.2.4); internal audits (clause 8.2.2); control of nonconforming products (clause 8.3); corrective actions (clause 8.5.2); and preventive actions (clause 8.5.3). There are no specific requirements for other types of documents such as work instructions.

Hence, a small organisation may find it appropriate to include the description of its entire QMS within a single quality manual, including all of the documented procedures required by ISO 9001. Large multinational organisations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation (ISO/TR 10013, 2001).

As discussed in Chapter 5 and 6, in order to reduce the various problems that are occurring in the QMS due to poor internal auditing, a set of audit guidelines for measuring the performance of the QMS needs to be developed. Due to it being mandatory for CO to establish an internal audit procedure, it was concluded that the best way to introduce this new set of guidelines to quality experts would be precisely by the use of a procedure. Hence, personnel would be familiar with the structure of the document and organisations could easily include it in their documented QMS.

7.2 The procedure

Two ISO 9000 standards were followed in order to develop the audit procedure with a focus on the performance of the QMS (Audit+). Firstly ISO/TR 10013:2001 was used to provide the document with the proper structure for a procedure. Secondly, ISO 19011:2002 was followed in order to incorporate all of the required activities of an internal audit into the Audit+ procedure, as auditors are familiar with them. Also,

a background section and a bibliography were included in the Audit+ procedure to introduce ISO 9000 auditors to the PM body of knowledge which they will generally not be familiar with. Figure 7.2 describes the structure followed by the Audit+ procedure, which can be found in full in Appendix F.

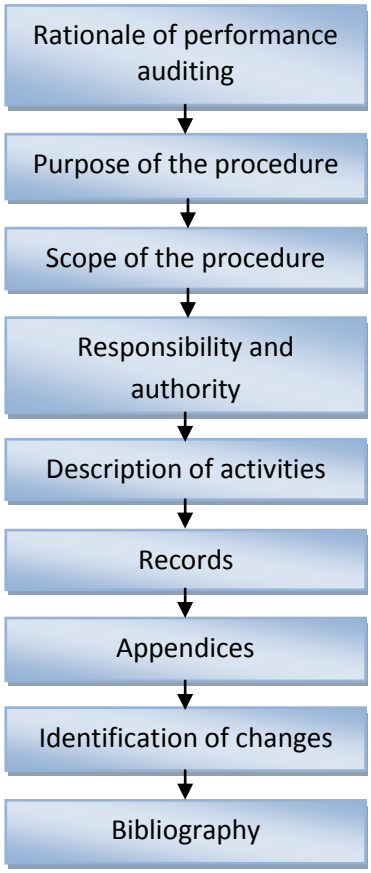


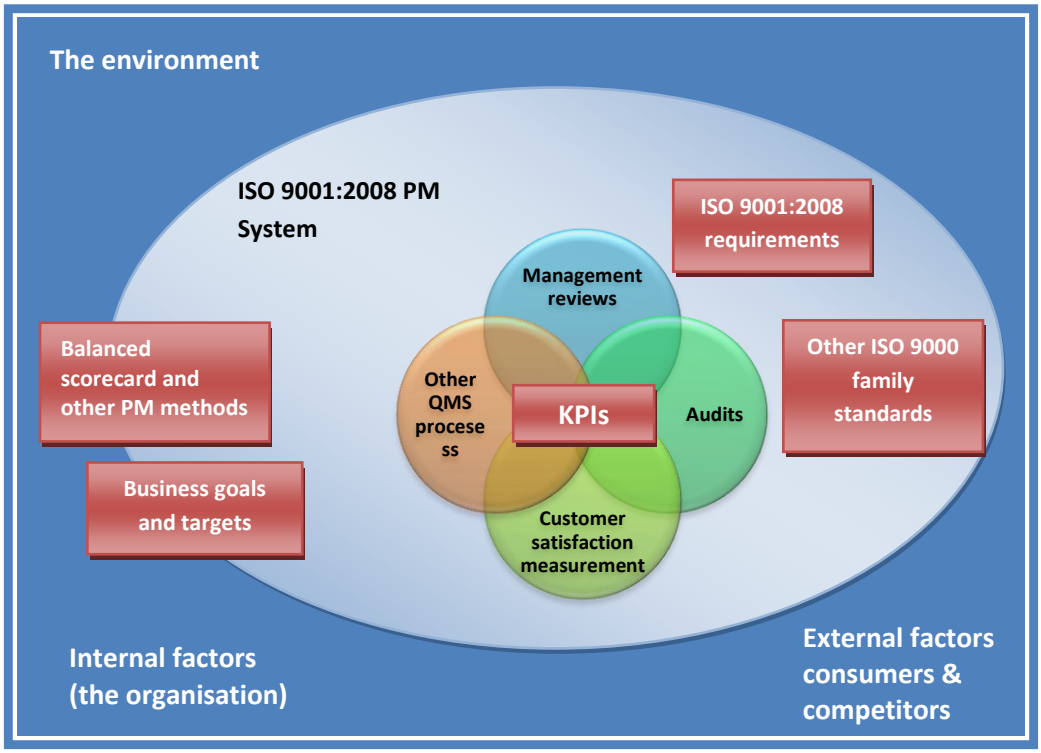
Figure 7.2 Structure of the procedure for conducting ISO 9001:2008 audits with a focus on performance (Audit+)

7.2.1 Rationale of performance auditing

This section introduces the three levels of scrutiny of the ISO 9001:2008 standard, describes the PM methods for ISO 9001 QMS and provides the necessary PM definitions for understanding the focus of the procedure. All of these concepts were taken from the literature review described in Chapters 2 and 3.

The section also includes a framework for PM based on ISO 9001:2008 (see Figure 7.3) adapted from Neely *et al.* (1995). As in the Neely *et al.* model, the QMS PM methods are in the centre of the framework, in this case: management reviews, audits and customer satisfaction measurement. These PM methods are usually implemented in companies as processes and interact with other processes of the QMS such as corrective actions or control of non-conforming products. All the processes are part of the QMS but because the framework is focused on PM, a distinction between PM processes and the other processes of the QMS was made in

the model. Both sets of processes (PM and QMS) as well as their interactions are measured by KPIs which also appear at the centre of the diagram. The ISO 9001:2008 PM system also includes the other requirements of the standard, which are mandatory for organisations, and other standards. The business objectives and other PM methods such as the BSC, typically internal factors of the organisation, may also be part of the PM system. This is the reason why these two subjects appear sharing both the PM system and the internal factors of the organisation in the diagram. Finally, the PM system is shown in the model as part of a bigger entity: the environment of the organisation.



Adapted from Neely *et al.* (1995)

Figure 7.3 The framework for performance measurement of ISO 9001:2008 QMS

In order to make all of the new concepts of PM easy to understand for quality experts, a performance triangle composed of four sub-triangles incorporating the most important concepts was created for the procedure (see Figure 7.4). The triangle was designed to address the three levels of scrutiny of the ISO 9001:2008 standard. Hence, the first sub-triangle relates to the first level of 'products/services' and includes the four individual measures of performance stated by Neely *et al.* (1995): quality, cost, time and flexibility. The second sub-triangle addresses the evaluation of processes in three dimensions: effectiveness, efficiency and adaptability, and is based on the work of Rohleder & Silver (1997). The third sub-triangle refers to the ISO 9001 PM methods for assessing the QMS: management reviews, audits and customer satisfaction measurement. Finally, the central sub-

triangle exemplifies how the correct measurement of the three levels of scrutiny may lead to the improvement of the whole QMS.

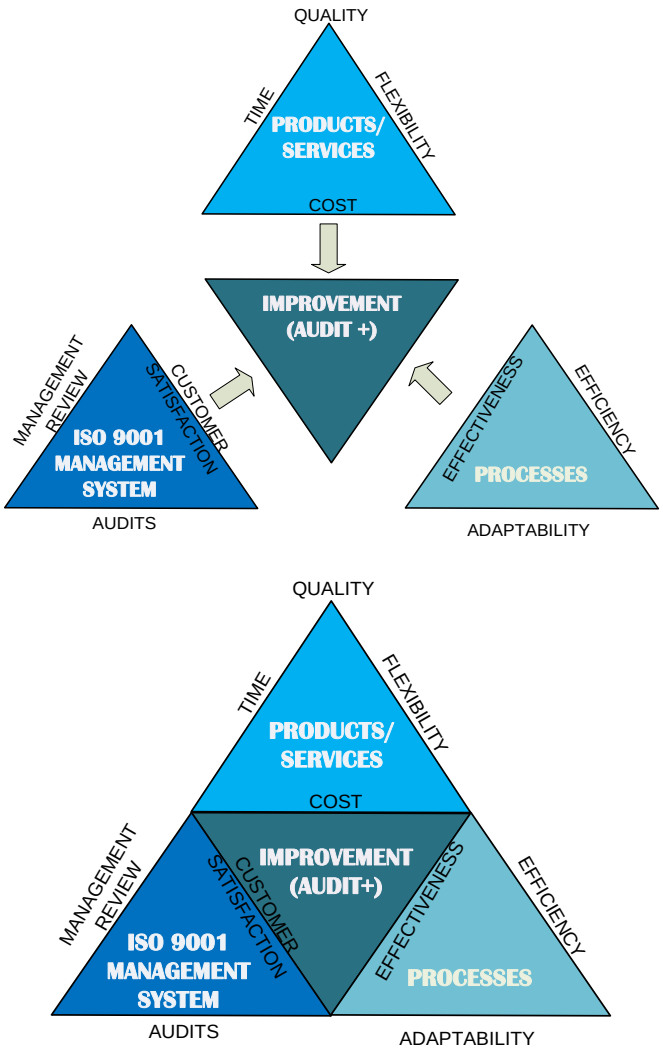


Figure 7.4 Performance Auditing Triangle (Audit+ Triangle)

7.2.2 Purpose of the procedure

According to the suggestions of the ISO 9000 experts interviewed during the theory building phase, the purpose of the procedure was established only for internal audits (see Section 5.3), since ISO 17021 states that the aim of third party audits is only to assess compliance. However, in order to not limit the scope of application of the guidelines, the procedure states that CB may conduct a third party assessment using its guidelines when organisations request it.

7.2.3 Scope of the procedure

Due to the fact that organisations may need to audit the whole QMS or only specific processes (Ni & Karapetrovic, 2003), the scope was set to include both approaches. Hence, all clauses of the document may be followed during an audit or the order can be altered.

The procedure is intended to be used by companies which have a level of maturity of 1-4 according to ISO 9004:2009. The use of the procedure is not recommended for companies that have a maturity level of 5, as they should already have implemented improvement processes for their QMS.

7.2.4 Responsibility and authority

This section describes the responsibilities and authorities of all those functions involved in the procedure: audit team leader; audit team; top management; top management representative; follow-up group of experts; and auditee.

7.2.5 Description of activities

This section describes the activities needed to conduct an internal audit with a focus on the performance of the QMS. It is divided into 4 subsections following the Deming cycle: planning the Audit+, doing the Audit+, checking the Audit+ and acting on the Audit+. This section of the procedure was designed around the Deming cycle in order to maintain the same structure as the ISO 9000 core of standards (Karapetrovic & Willborn, 2001; Mors, 2008). In this way, practitioners who implement it will be familiar with its structure. This section also includes a subsection describing all of the necessary inputs to start applying the procedure as well as the outputs expected from its use.

Planning the Audit+

The planning stage of the audit relates to all those previous activities needed to conduct the on-site audit. This stage starts with the appointment of the audit team by top management who have to take into consideration which auditors have the competence to assess business goals and targets in addition to compliance with ISO 9001. As discussed in Chapter 5, experts remarked that a potential problem for a QMS is its detachment from the strategy of the organisation (see Table 5.18). Hence, it is important to review the connection between the organisational strategy and the QMS during the audit. Thus, competent auditors with knowledge about the organisation in addition to the clauses of ISO 9001 are needed.

The first activity for the audit team is to identify the processes which will be audited (Ni & Karapetrovic, 2003; Mors, 2008). Also, in order to have a wide perspective about how these processes interact with the internal factors of the organisation as

Neely *et al.* (1995) suggest, the audit team is required to identify the business processes which interact with the QMS processes to be audited (Wells, 2010). To assist auditors in the development of this task, the procedure includes the Armistead *et al.* (1995) definition of business processes. Moreover, to determine the possible degree of inspection that the processes should require, the procedure also suggests identifying which processes can be categorised as 'artistic' according to the guidelines developed by Hall & Johnson (2009). The rationale of this approach is that mass processes will require less inspection than mass customisation, artistic or nascent process which are not fully standardised.

The second main activity of the stage is developing a customised checklist to assess the QMS and business processes. As remarked in Chapter 2 and by experts during the interviews (see Tables 5.15, 5.16 and 5.17), one of the main reasons why the internal audit process is having problems is that auditors only focus on ISO 9001 clauses and fail to include an improvement approach (Ni & Karapetrovic, 2003; Biazzo, 2005). One of the suggestions of experts to generate this improvement approach is to focus on processes in addition to ISO 9001 clauses (see table 5.17) when auditing, and one of the easiest ways to do this is by the development of a customised checklist. Hence, clauses 5.5 – 5.8 are devoted to developing a checklist with a focus on processes as well as on compliance with ISO 9001 requirements.

The procedure suggests analysing processes in terms of elements, activities, tasks, inputs and outputs following the guidelines of Armistead *et al.* (1995). In this way, auditors will be able to conduct a first analysis of which activities or tasks are not adding value to the process. The Rohleder & Silver (1997) approach for determining the added value of processes is also suggested in the document. The next step in building the checklist is to identify and assess the KPIs of the processes (Wells, 2010). In order to perform this task, the procedure suggests the use of the Neely *et al.* (1995) approach of classifying individual performance measures in terms of cost, time, flexibility and quality and to analyse their targets. The procedure also highlights that the Neely *et al.* (1995) classification is the minimum set of metrics that organisations should have and that a good measurement scheme should also include customer feedback, internal operations, finances and improvement/learning needs (Kaplan & Norton, 1992). The document also notes that when other management systems are implemented in conjunction with the QMS, it is important to include other types of KPIs in this classification (e.g. environmental). Finally, the audit team is requested to identify the ISO 9001:2008 clauses that apply to each activity or task in order to maintain the objective of the organisation to comply with the standard.

The next step in this phase is to include the revision of the design, implementation and use of the PM processes of the QMS (Franco-Santos & Bourne, 2005) in the audit plan, in the case that those processes are included in the scope of the audit.

The planning phase finishes with the assignment of the work that each auditor will have to conduct during the on-site audit and with the audit team leader contacting the auditees to agree the dates and times of the on-site audit (ISO 19011, 2002).

Doing the Audit+

This phase relates to the on-site audit when auditors, based on the audit plan and checklist, collect and verify information to generate the audit findings. The phase starts with an opening meeting, conducted by the audit team leader.

The next activity is to conduct the on-site assessment in order to verify the effective implementation and performance of the QMS and business processes. To achieve this, the procedure suggests assessing the processes internally (process elements, activities, tasks, KPIs) and externally (their interaction with other QMS processes and with the business goals and targets). This task can be done using the Rohleder & Silver (1997) guidelines which suggest reviewing processes internally so that auditors can focus on all the possible sources of waste, whereas for checking them externally auditors should consider three possible dimensions: effectiveness, efficiency and adaptability. During this activity, KPIs must also be assessed against their established goals or targets.

As pointed out above, when assessing the PM processes of the QMS it is important to also review its design, implementation and use. The procedure includes guidelines suggested by Franco-Santos & Bourne (2005) to conduct this evaluation.

The stage ends by recalling that the on-site audit should be seen as an important learning exercise for the auditees, this point was stressed by the experts during the interviews at the theory building stage (see Table 5.15). Thus, clause 5.21 suggests that auditors ensure that each auditee fully understands the findings of the audit and the need to solve any problem identified.

Checking the Audit+

The objective of this phase is to prepare the audit report. The phase begins by reminding the audit team that in order to have a comprehensive measure of performance of the QMS, it is necessary to evaluate the performance of processes internally and externally (Neely *at al.* 1995). Hence, the audit team should evaluate how the interaction between all the processes (QMS and business) in the scope of the audit is occurring in order to have a complete evaluation of the performance of the system.

In order to classify the audit findings, the procedure advises following the criteria used by the CB that granted the ISO 9001 certification. In this way, the results of the internal audits will not create conflicts with future third party audits and confusion will be avoided between organisation's personnel.

In the ISO 9001:2008 context there are four types of audit findings: *conformities, non-conformities, observations* and *opportunities for improvement* (ISO 19011, 2011). The procedure recommends that *conformities* with ISO 9001 are not stated in the audit report in order to not create a long report to top management. As far as *non-conformities* are concerned, there are no clear audit criteria regarding how to grade non-conformities in the ISO 9000 standards and CB usually use the definition of non-conformity as the "non-fulfilment of a requirement" (ISO 9000, 2005, pp.13) to state them. Meanwhile, *observations* are usually considered by CB as failures in implementation or maintenance in the QMS processes, but the ISO 9000 core of standards do not provide criteria about the assessment of observations. Finally, *opportunities for improvement* are those findings that increase "the ability to fulfil quality requirements" (ISO 9000, 2005, pp.9). The Audit+ procedure includes 'performance findings' as an extra type. These findings will be those that are not failures to fulfil the requirements of the ISO 9001 standard, but that are affecting the QMS and may create potential problems for the QMS in the future.

In order to state the audit findings in an easy-to-understand way, the procedure advocates ordering them following the classification of the checklist by element, activities and tasks. Also, the document advises that audit findings should also be summarised according to the ISO 19011:2002 guidelines (e.g. indicating location, functions, etc.). An example of an Audit+ report for this internal assessment is provided in Table 7.1.

Audit+ elements	Finding 1	Finding 2
Process	Customer service	Customer service
Process element	Sales	Sales
Activity	Management of customer accounts	Management of customer accounts
Task	Assign order number	Process order
Input	Client call	Client requirement
Output	Purchase order number	Purchase order number
ISO 9001:2008 requirement	7.2.1, 7.2.2, 7.5.3	7.2.1, 7.2.2, 7.5.3
KPIs	Not applicable	Number of attended calls per person The performance of the KPIs was satisfactory
Type of measure	Not applicable	Quality
Audit finding	The task is not adding value to the process. Revision by the owner of the process is recommended	This activity is not correctly interacting with the shipping process which is causing delays in supplying goods to clients. It is not affecting KPI performance or ISO 9001 requirements but it is affecting customer satisfaction
Type of audit finding (Performance and/or ISO 9001:2008 and/or other applicable regulation)	Performance audit finding	Performance audit finding

Table 7.1 Example of an Audit+ report - Internal process assessment

The audit report should also include a special section regarding the findings of the KPIs. It is recommended in the procedure that the audit team classify the KPIs by types of measure (quality, time, cost and flexibility) so that top management will easily understand them.

Finally, the stage ends with the closing meeting conducted by the audit team leader.

Acting on the Audit+

This phase of the Audit+ process deals with the follow-up of the audit findings. It is important to point out that the ISO 19011:2002 standard does not include this phase in its audit process. Nevertheless, some studies argue that this phase is the most important part of the internal audit process (Russell & Regel, 1996; Terziovski & Power, 2007). Also, the insights from experts during the theory building phase of this research suggested the importance of audit follow-up (see Table 5.18), as did the path analysis based on the survey data in Chapter 6 of this thesis.

The procedure starts this phase by proposing that top management or its representative appoints a 'follow-up group of experts' who will review the audit findings and determine which actions are needed in order to resolve them. Traditionally, the owners of the processes are in charge of resolving the audit findings, however because to organisations reported that they are facing problems with the audit follow-up (see Table 5.18), the creation of a group of experts to help top management to conduct the follow-up is proposed.

The next step in this phase is determining the root-cause of audit findings. The procedure suggests consulting the work of Dale *et al.* (2007) to choose the most suitable problem-solving methodology. When the root-causes have been defined, an action plan to solve them should be proposed to top management. The Audit+ procedure also notes that the audit findings should lead to corrections, corrective and preventive actions, improvement initiatives and/or process re-engineering.

The action plan has to be reviewed by the audit team leader in order to check that the proposed actions cover all the audit findings. When the action plan is approved by the audit team leader, top management will have to appoint a leader from the group of experts who will be in charge of conducting the action plan follow-up until all of the audit findings have been declared closed.

Finally, the procedure also addresses the importance of monitoring each action of the action plan until they stabilise (Rohleder & Silver, 1997). Moreover, it recommends that a specific task regarding the revision of the actions taken to resolve the audit findings be included in the next audit of the organisation.

7.2.6 Records

This section of the procedure lists the different records that should be created and maintained as part of the evidence of the audit.

7.2.7 Appendices

The procedure includes three appendices to provide more information to auditors regarding some PM concepts. Appendix F.A explains the process categorisation created by Hall & Johnson (2009) which is mentioned in clause 5.4. Appendix F.B provides the individual performance measures classification of Neely *et al.* (1995) that is used in clause 5.6. Finally, Appendix F.C explains the ISO 9000 PM system in greater detail and reviews the three PM methods for assessing the QMS.

7.2.8 Identification of changes

This section maintains traceability between the different versions of the Audit+ document. It also includes the following sub-sections: description of the change, release date and author of the changes.

7.2.9 Bibliography

As pointed out above, a bibliography section is not common in a procedure. Nevertheless due to the PM concepts being new for most quality auditors, this section was included in the document in order to provide some useful references for auditors. The bibliography section follows the Harvard system of citation.

7.3 Experts' feedback

The first version of the Audit+ procedure was reviewed by 15 international ISO 9000 experts. In order to provide the experts with a framework for reviewing the document, a specific feedback form was sent to them by e-mail so they could state their comments. This form can be found in Appendix G. A total of 106 comments were received from experts. Table H.1, in Appendix H, includes all comments received, with the exception of comments relating to syntax and spelling, which were omitted for reasons of space.

7.4 Conclusions of the chapter

This chapter has described the design of Audit+, a procedure for conducting ISO 9001:2008 audits with a focus on the performance of the QMS. It was developed to address the third objective of this research regarding how ISO 9001:2008 certified organisations can measure their performance using internal audits.

The procedure incorporated both the PM concepts discussed in Chapter 3 and the recommendations of ISO 9000 experts presented in Chapter 5, into the context of ISO 9001 internal audits. Thus, the document aims to provide internal auditors with a PM framework for assessing QMS performance.

This chapter has also discussed the background, rationale and justification for each section included in Audit+. Also, the most important concepts in the clauses of the document were explained.

Chapter 8 discusses in detail the results of the testing of the Audit+ procedure in three internal audits and presents the results of a survey conducted with 174 experts regarding Audit+.

CHAPTER 8
TESTING THE AUDIT+ PROCEDURE

In order to answer the research question: "How can ISO 9001:2008 certified organisations better measure their QMS performance using audits?", Chapter 7 described the procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS (Audit+). This chapter describes the testing of the procedure. Hence, this chapter aims to answer the fourth research objective:

> "Validate the procedure by means of trial internal audits using the proposed document in actual company audits and by a survey of ISO 9001 experts"

Section 8.1 discusses the approach used to test the Audit+ procedure. Section 8.2 describes the three in-depth case studies conducted to test the procedure in real internal audits. Section 8.3 provides the analysis of a survey administered to 211 ISO 9001 auditors to learn their opinions about the procedure. Finally, Section 8.4 presents the conclusions of the chapter.

8.1 Approach to testing

As outlined in Chapter 4, the testing of the Audit+ procedure was done by its application in three organisations and its generalisation was assessed by a survey.

8.1.1 Case study approach

The case studies were sponsored directly by the top management of the participant organisations. An initial presentation explaining the aims of the research, the Audit+ procedure and the expected outcomes of the Audit+ was conducted with the CEOs of the organisations who previously had expressed their interest in participating in the research. After their support was gained, another similar presentation was conducted with the internal audit teams.

The aim of the testing was to determine whether the Audit+ procedure did provide a practical PM guide for internal auditing. As discussed in Chapter 4, in order to investigate this, the Platts (1993) criteria for process evaluation were followed: feasibility (could the process be followed); usability (how easily could the process be followed); and utility (was the process useful). The Platts (1993) criteria have been used by several scholars in OM (e.g. Cáñez, 2000; Tan, 2002, Borges, 2010) and for this reason were appropriated for this research. Hence, case data was collected according to these criteria.

Feasibility

As suggested by Platts (1993), testing feasibility is a straightforward matter; simply following the process as laid down can demonstrate its feasibility. However, this demonstration was restricted to the particular organisation in which the procedure was conducted and to the particular audit team working with it. By repeating the procedure in different organisations with different audit teams, greater confidence in the more general feasibility of the procedure was achieved.

Usability

Testing the usability of the Audit+ procedure represented most of the work performed during the case studies. In order to test it, two main issues were addressed: the identification of problems in each section of the procedure; and the way in which each section of the procedure was structured (Platts, 1993). Hence, the procedure was tested and refined by its application. Some elements of the procedure were described in detail, for example, the structure of the Audit+ checklist and in these cases the usability could be assessed by noting what problems encountered. Other elements of the procedure were less well defined, for example, the Audit+ report and in these cases the testing was more of a mutual discovery with the company to determine tasks that appeared to be usable (Platts, 1993).

Utility

When the case studies were completed, an attempt was made to judge the success of the Audit+ procedure. Two possible ways of doing this were identified. Firstly, at a practical level, it was possible to compare the outcomes of the Audit+ with previous

internal audits and to identify the number of improvement opportunities stated. This was the direct output of the Audit+ procedure. Secondly, at a subjective level, the users were interviewed to establish their reactions to the procedure. However, as Platts (1993) highlights, this approach has the problem that it is not always possible to identify if the interviewee is telling the truth. Platts (1993) suggests two main reasons why interviewees tend to rationalise success:

1. The interviewee and interviewer had worked together over an extended period and thus personal relationships had evolved; and
2. The interviewees were being asked to comment on a procedure to which they had committed themselves and which had been instigated by top management.

In order to overcome these problems, the Platts (1993) guidelines about interviewing by both direct and indirect questioning (where answers could be cross checked) were followed. Hence, direct questions asked specifically about the usefulness of the procedure, indirect questions addressed specific issues (e.g. the performance measurement triangle) and the interviewees were also asked for suggestions for improvements. In this way, information used to both improve the procedure and to infer its usefulness was obtained. The interviews were semi-structured allowing the interviewees freedom to comment on any aspect of the process; this seemed most likely to elicit frank views. The interview protocol can be found in Appendix D.

8.1.2 Investigating the wider applicability of Audit+ by a survey

The case studies provided a detailed assessment of the application of the Audit+ procedure and demonstrated its feasibility, usability and utility. In order to investigate the wider applicability of the procedure, a survey exercise was conducted with 212 ISO 9001 experts in six workshops. This stage aimed to obtain data which could be compared with the results of the case studies. Hence, the specific objectives of this stage were to:

1. Seek specific feedback from potential users regarding the applicability of the Audit+ procedure and the way in which it was structured;
2. Assess the effectiveness of the procedure, if possible relating it to the QMS processes of the companies; and
3. Seek general feedback on the content, the perceived feasibility, usability and utility of the suggested procedure and any potential improvements to the document

In this way, the results of the survey could be linked to the findings of the case studies and provide evidence to support the more general applicability of the procedure. The criteria of feasibility, usability and utility developed for the assessment of the case studies were again applicable. A questionnaire including

specific questions regarding each criterion was administered during the workshops and can be found in Appendix L.

8.2 Case studies

8.2.1 Background of the selected case studies

As stated in Chapter 4, in order to test the Audit+ procedure in a real environment, three in-depth case studies were conducted. The case studies were designated as Cases X1, X2, and X3, with X1 being the pilot case study. The companies are anonymous by their request. The information on the companies' profile consists of: type of organisation (SME, medium, large or multinational); industry sector; scope of the audit; and QMS maturity level.

Case X1

X1 is an international company dedicated to providing logistics services which include maritime and air transportation. The company is an Italian family business with 32 years in the market. It has 241 offices in 80 countries and transports more than 100,000,000 kilograms by air and 260,000 TEU's (twenty-foot equivalent unit) by sea per year. X1 has more than 3,000 employees around the world, 100 of them in Mexico. The company has its Mexican headquarters in the City of Guadalajara, Jalisco State and two operations offices in Mexico City and Monterrey. It also has sales offices in Queretaro, Aguascalientes and Puebla.

The company's top management decided in 2000 to achieve ISO 9001 certification in all of their branches. The Mexican branch certified its operations processes (sea-freight and air-freight exports and imports) in 2002.

Due to a constant change of personnel, X1 only has one qualified internal auditor who is also quality director and top management representative. Currently, the company is training a group of internal auditors.

The company has a QMS with a maturity level of 3 according to ISO 9004:2009 and the scope of the Audit+ included the processes of sea-freight and air-freight exports and imports; insurance; and internal auditing.

Case X2

X2 clinical laboratories is a family business that was founded in 1983 in Oaxaca City, Mexico. Currently the organisation has a staff of 15 people and three offices. Clinical samples are taken at two branches and analysed at the company's headquarters.

The company was granted ISO 9001:2008 certification in October 2010 for the processes of: clinical analysis (pre-analytical phase, analytical phase and post

analytical phase); strategic; management; and special test and histopathology studies. The focus of the QMS is "conducting clinical analyses with quality from taking clinical samples until delivering the results". At present, the organisation has conducted 4 internal audits and has received 2 third party audits.

The company has a QMS with a maturity level of 3 according the ISO 9004:2008 standard and the scope of the Audit+ included all of the documented QMS processes.

Case X3

X3 is a campus of the largest higher education organisation in Iberoamerica, located in Mexico State. The university as a whole is a state organisation and has an average of 350,000 students per year in high school, undergraduate and postgraduate studies. The X3 campus was founded in 1974 and currently has an average of 13,000 undergraduate and postgraduate students. X3 has 12 degrees certified by international education registers. 65 teaching laboratories were granted the ISO 9001:2008 certification in 2009 and 15 research laboratories obtained it in 2011.

The organisation has a maturity level of 3 according ISO 9004:2009 and the scope of the Audit+ included the teaching, research and purchasing processes.

Table 8.1 summarises the background of the organisations which participated in the testing of Audit+.

Case Study	Type of organisation	Industry sector	Scope of the Audit+	Maturity level of the QMS
X1	Multinational – Family business	Logistic	Sea-freight exports and imports Air-freight exports and imports Insurance Internal auditing	3
X2	SME – Family business	Medical care	QMS	3
X3	Large – State owned	Higher education	Teaching Research Purchasing	3

Table 8.1 Background of the participant organisations in the Audit+ testing

8.2.2. Execution of the case studies

The procedure was tested in four stages in accordance with the case study protocol and the Audit+ procedure:

1. Internal auditors' training;
2. Planning the Audit+;

3. On-site Audit+; and
4. Discussion of the audit findings and creation of the Audit+ report.

Hence, the Audits+ were conducted on the following dates:

Case X1

- 17th August 2011– internal auditor training
- 18th August 2011– creation of the Audit+ plan
- 1st September 2011 – on-site audit at Mexico City international airport
- 2nd September 2011– on-site audit at Mexico City headquarters
- 3rd September 2011– discussion of the audit findings and creation of the Audit+ report

Case X2

- 5th September 2011 – internal auditor training
- 6th September 2011 – creation of the Audit+ plan
- 7th September 2011 – on-site internal audit at Oaxaca headquarters
- 8th September 2011 – on-site internal audit at Oaxaca branches
- 9th September 2011 – discussion of the audit findings and creation of the Audit+ report

Case X3

- 23rd August 2011- internal auditor training
- 13th September 2011 – creation of the Audit+ plan
- 19th September 2011 – on-site internal audit (teaching & buying processes)
- 20th September 2011 – on-site internal audit (research process)
- 22nd September 2011 – discussion of the audit findings and creation of the Audit+ report
- 29th September 2011 – presentation of audit findings to top management (this activity was requested by the top management of the organisation)

Firstly, internal auditors from each organisation were trained in the PM concepts included in the procedure as well as in each activity described in the document. This training was conducted over a full working day where each section and clause of the Audit+ procedure was explained to the audit team. During the training, the QMS processes of the company were used as practical examples. This stage allowed the identification of issues related to the clarity of some clauses of the procedure, before conducting the audit. Also, it was possible to identify the knowledge and competence of internal auditors regarding ISO 9001 clauses and audit practices.

Secondly, the planning stage of the Audit+ was conducted during a further full working day with the audit team. This constituted a main difference between the approach of the Audit+ and compliance auditing, where normally the audit team leader undertakes the planning of the audit. Internal auditors were asked to follow the procedure, as described in Chapter 7, to perform each activity in the planning

stage. The audit team performed two main activities during this stage: the categorisation of processes according the Hall and Johnson (2009) framework; and the creation of a customised checklist. The process categorisation allowed the audit team to determine the level of inspection of processes while during the creation of the checklist, auditors had to conduct an initial assessment of the performance of processes according to the PM guidelines included in the procedure. The output of this stage was the customised Audit+ checklist for conducting the on-site audit.

Thirdly, the on-site Audit+ was conducted by applying the PM assessment specified in the procedure. This assessment was performed as described in Chapter 7. The main objective of this stage was to assess QMS processes in a real environment according to the Audit+ checklist, the ISO 9001 standard and the Audit+ procedure. Hence, internal auditors corroborated their initial assessment of processes, conducted during the planning stage, working on-site as they reviewed processes and services in detail. This required them to interview personnel about the performance of processes and services and request evidence of that performance. During this assessment, internal auditors recorded audit findings in their Audit+ checklist.

Finally, in the stage of checking the Audit+, the audit team discussed and determined the audit findings and created the Audit+ report. This stage was also performed over an entire working day and represented an important change in the organisations' auditing practice, as they normally dedicate only a couple of hours to this stage. The main objective of this stage was the creation of the Audit+ report which included not only the audit findings but also an assessment of the QMS processes, KPIs and business goals according the PM criteria stated in the procedure. During this stage, auditors exchanged opinions about the performance of processes and services. They reported the failures and problems as well as possible improvement opportunities. The outcome of this stage was the Audit+ report for top management and auditees.

It is important to point out that due to time constrains, the final stage of the Audit+ procedure 'action on the Audit+' was not included in the scope of the case studies. Typically, organisations spend several months closing their audit findings and due to the fact that Audit+ requires that audit findings are closed until the stabilisation of processes, this stage was inevitably outside the scope of the case studies.

The Audit+ plan, Audit+ checklist and Audit+ report as well as the case study report provided a chain of evidence for each case study. Appendix K includes the summary of the cases, whereas Appendices I and J contain the case study protocol and the case study report of the pilot case.

8.2.3 The evaluation of the procedure

As noted above, the Platts (1993) criteria for evaluating processes according to their feasibility, usability and utility were used to assess the Audit+ procedure. The methods suggested by Platts (1993) to assess these criteria, discussed in Section 8.1, were followed in order to test the procedure. This assessment will be discussed in the following paragraphs.

8.2.3.1. Feasibility

Feasibility relates to whether the process can be followed and as Platts (1993) states, simply following the procedure as laid down can demonstrate its feasibility. The Audit+ procedure was followed in a real environment in the context of ISO 9001:2008 internal audits. Moreover, the participant organisations included the internal Audit+ in their annual audit programme and allocated the necessary resources to perform the audit according to the Audit+ procedure. The top management of each organisation appointed the audit team; reviewed and approved the audit plan; and received the audit report. Also, in two of the organisations, the CEO chaired the conclusions meeting with the staff and the audit team. All of these activities assured that the procedure was tested in real audit conditions.

All of the sections and clauses of the Audit+ procedure were followed during the three cases. Issues relating to lack of clarity of some definitions, a lack of examples and the wording of some clauses were detected during the internal audits. However, despite these minor issues, the three case studies demonstrated that the procedure can be followed without difficulty. This result was not surprising since, as discussed in Chapter 7, the procedure was structured according to the ISO/TR 10013:2001 standard for documentation. The detailed description of the problems encountered in the Audit+ procedure will be discussed in the following sections.

8.2.3.2. Usability

Usability verifies how easy the procedure is to follow and as Platts (1993) argues this can be assessed in two ways: identifying the particular problems in each section of the procedure; and the way in which each section of the procedure is structured. Appendix K provides a summary of the testing of the case studies and in the following paragraphs a summary of the problems encountered in each case study will be described.

Problems encountered in the 'planning the Audit+' stage

- *Clause 5.3 Identification of business goals.* Due to the fact that not all of the companies have stated business goals, it was difficult for auditors in X2 to separate the business goals from quality objectives (mandatory for certified organisations). Also, in cases X1 and X3, business goals were not included in the QMS and auditors found it difficult to find them (X1) and

relate them with the QMS (X3). Hence, the guidelines included in the Audit+ procedure need improvement;

- *Clause 5.3 Identification of business goals.* Auditors in the three organisations found it difficult to understand the Armistead *et al.* (1995) definition of business goals. It was not clear where "the boundaries of the organisation" started and finished. Moreover, the auditors in case X3 had problems delimiting these boundaries in outsourcing processes. This clause of the Audit+ procedure needs more clarification;
- *Clause 5.4 Process identification*. Auditors in organisations X1 and X2 faced some problems understanding what constitutes an "artistic process". More examples in the procedure are needed;
- *Clause 5.5 Analysis of processes.* It created some confusion for auditors of organisations X1 and X2 to divide processes to the task level due to the fact that some processes were not very complex. Hence, this clause needs refinement.
- *Clause 5.5 Analysis of processes*. Determining whether a task or activity was adding value to the process by only assessing it against the process objectives, as suggested by Rohleder & Silver (1997) was considered ambiguous by some auditors in the three organisations. More guidelines to assess the value of tasks and activities are needed in this clause;
- *Clause 5.7 Classification of individual metrics.* None of the audit teams were able to determine individual metrics of flexibility because the auditors found the Cox (1989) definition ambiguous;
- *Clause 5.8 Identification of ISO 9001:2008 clauses.* Some auditors from the three organisations faced problems identifying the ISO 9001:2008 clauses applicable to the activities and tasks of processes. This may have been due to the new Audit+ checklist; and
- The planning activity of assessment of processes according to their effectiveness, efficiency and adaptability was found to be missing and should be added to the stage.

Problems encountered in the 'doing the Audit+' stage

No problems were found with the procedure itself, however internal auditors in the three organisations found it difficult to change the focus of their auditing from compliance to performance. Auditors had to be reminded on a number of occasions to focus on performance in addition to compliance, but it was found that after the first couple of hours of the on-site audit, auditors could adapt to the new focus of the audit. Hence, this stage of the procedure needs to incorporate more practical guidance for auditors about what kind of evidence they should look for during the on-site audit.

Problems encountered in the 'checking the Audit+' stage

- *Clause 5.22 External assessment of the performance of processes*. The Rohleder & Silver (1997) definition of 'adaptability' was difficult to understand by auditors in the three organisations. Some practical examples need to be included in this clause;
- *Clause 5.22 External assessment of the performance of processes.* This clause did not provide enough guidance about how to assess the interaction of QMS processes and this confused some auditors. A practical example should be incorporated into this clause;
- *Clause 5.24 Identification of audit findings.* There was confusion expressed by some auditors about how to classify the audit findings. Clear definitions about what constitutes a non-conformity, observation and improvement opportunity should be incorporated into this clause;
- *Clause 5.25 Identification of performance audit findings.* Auditors in the three organisations found the classification of 'performance audit findings' confusing. Moreover, the three audit teams found no difference between the suggested definition of performance audit finding stated in the procedure and improvement opportunity. Hence, this classification should be omitted; and
- *Clause 5.*26. Construction of the Audit+ report. The Audit+ report was missing the sections for: the assessment of processes according to their efficiency, effectiveness and adaptability; evaluation of KPIs; and assessment of business goals. This created problems in the pilot case, X1. Nevertheless, the researcher and the audit team developed the complete X! Audit+ report including all of these sections. The format of this report was then used in the following X2 and X3 cases studies. However auditors pointed out that the example report included in Table 5.5 should be improved.

8.2.3.3. Utility

Utility assesses whether the procedure produces useful results for managers. As stated in Section 8.1 two possible ways of assessing the utility of the procedure were identified: by comparing the outcomes of the Audit+ with previous internal audits and identifying the number of improvement opportunities stated; and to interview the users to establish their reactions to the procedure.

Table 8.2 shows the comparison of the results of improvement opportunities detected in the two previous internal audits conducted in the participant organisations and the Audit+. As it can be seen in the table, for all of the case studies the Audit+ procedure allowed organisations to detect more improvement opportunities than with the traditional audit approach (compliance). For case X2, where the scope of the Audit+ included the whole QMS, the number of improvement opportunities detected was doubled.

Case	Penultimate internal audit	Last internal audit	Audit+
X1[38]	2	1	9
X2	4	5	10
X3[39]	18	14	21

Table 8.2 Comparison of the results of the two previous internal audits and the Audit+ regarding improvement opportunities

It is important to clarify that only improvement opportunities were considered for the comparison because this type of finding is related to performance, whilst non-conformities and observations are related to compliance. Also, it is important to note that this indicator (the number of improvement opportunities detected) may be also influenced by the maturity level of the QMS and the processes audited. Hence, this indicator should be viewed with caution.

As stated in Section 8.1, eight semi-structured interviews were conducted with users about their experience using the procedure. The interviews were conducted one or two of days after the internal audits had concluded, in order to provide auditors with some time to reflect on the Audit+. The questions included in the interview protocol were developed in accordance with the Platts (1993) criteria (see Table 8.3). The protocol was sent by e-mail prior to the interview and each interview was recorded. The eight internal auditors (out of a total of 15) who were selected for the interviews participated in each stage of the Audit+. The interviewees included the three audit team leaders. In the following paragraphs the analysis of these interviews will be discussed.

[38] The scope of the Audit+ included 4 processes whereas in the previous internal audits the whole QMS was assessed

[39] The scope of the Audit+ included 3 processes whereas in the previous internal audits the whole QMS was assessed

Criteria	Corresponding questions
Feasibility (Can the process be followed?)	Q1a: How did you feel using the audit+ procedure? Q5a: What do you think about the structure of the document?
Usability (How easily can the process be followed?)	Q5b: Do you think the procedure is easy to follow and understand? Q3: What do you think about the approach of dividing the audit measurement elements into: products/services, processes and QMS? Do you think it helps you to audit better? Q4: How do you feel using the audit performance triangle? Are you happy with all the measurement elements proposed? (product/service: quality, time, flexibility and cost; processes: effectiveness, efficiency and adaptability; QMS: audits, management reviews, measurement of customer satisfaction)
Utility (Are the results useful?)	Q2: What do you think about the audit results obtained using the procedure? Do you believe the procedure enabled you to take into account relevant factors that otherwise might have been overlooked? Q1b: Do you think it helped you to improve your competences as an auditor? Q6: Do you have any suggestions for improving the procedure?

Table 8.3 Criteria for assessing Audit+ through semi-structured interviews

Internal auditors' perspective about Audit+ (content analysis)

Criterion of feasibility (Can the Audit+ procedure be followed?)

All of the interviewees stated that they felt 'good' using the procedure. However, as auditor B2 and D6 pointed out at the beginning of the audit, the use of the new approach was not an easy task. In fact, Auditor B5 remarked "with the first interview I felt insecure, but with the subsequent interviews I realised that people [auditees] felt very comfortable with the new methodology". Auditor D6 explained his experience with the Audit+ procedure in this way: "at first I was puzzled, but as the audit was advancing, I gained more confidence and felt more relaxed and at ease, the procedure takes you step by step and you are able to detect more audit findings". Moreover, Auditors D1, D2 and D3 stated that they liked the PM focus of auditing. In fact, Auditor D3 described his experience as follows:

> "it was easy to audit with this approach. I think that I performed better. It was easier to meet the objective of the audit than with the other approach [compliance]. I was able to better understand the requirements of the standard and I realised that we were not evaluating the QMS well. I also noted that we conducted the audit more easily, the planning stage was laborious, but with practice I think it will be easier. It was easier to make the audit report because there was a natural overlap between the stages of the audit".

The auditors also agreed with the structure of the document. Auditor D3 summarised his view as “with the proposed structure it is easier to audit and is not tedious”. Nevertheless, Auditors D4 and D6 pointed out that some PM concepts were new and that auditors will need more time to fully understand them. Auditor D4 remarked “some concepts and ideas seemed a bit difficult, they were new. But I think that with more practice, they will be clearer”.

Criterion of usability (How easily can the Audit+ be followed?)

The opinion of auditors was divided between those who thought it was difficult (D5), those who had problems at first, but as the audit developed, were able to understand each stage (B2, D4, and D6) and those who thought it was easy to follow (D1, D3, D7). Also, Auditor D2 considered that he would need more practice using the procedure before being able to answer this question.

Auditor D5 was questioned about why, in her opinion, the procedure was difficult to follow. She stated that “as a practical guide for auditors, the document should have three main sections: the rationale for the procedure; general guidelines regarding its application; and a practical guide for conducting the audit. The document is missing the last part, the practical guide that auditors can check during the audit when they have doubts”. Apart from the inclusion of a practical guide, Auditor D5 also suggested adding ‘help boxes’ to the document for the PM concepts, similar to those included in ISO 9004:2000.

Nevertheless, as pointed out above, there were three other interviewees who described the document as easy to follow. In fact, Auditor D7 highlighted “Yes, I think it's easy to follow and the stages are very logical. I think that all audits should include these steps. I only found the first part of the document strange, very 'scientific'. I am not used to a procedure including all of the technical background. It is not bad, but I find it strange. But the document is fine; it is logical and well explained”.

In order to discover how easy the PM concepts described in the procedure were to follow, auditors were asked about (1) the approach of dividing the audit elements into: products/services, processes and QMS and (2) the PM elements of the performance audit triangle.

Regarding the approach of dividing the audit elements into products/services, processes and QMS; there was a consensus between the eight auditors that this approach was beneficial for both auditors and auditees. Auditor D5 explained it in this way: “the division is appropriate, assists the auditor in making an X-ray [radiography] of the QMS and determine levels [measurement scrutiny levels]. But also helps the auditee because you are able to provide him with a hierarchy of non-conformities and in this way he knows how to focus on improvements”. Auditor D1 pointed out that “the result is not only the non-conformity; it [the division] helps you to see what you have to do to change what you are doing wrong”. As far as the

benefits for auditors is concerned, Auditors B2, D1, D2, D4, D5, D6 and D7 remarked that the approach allowed them to have a better focus when auditing. In fact, Expert D2 stated “we used to audit only using the standard, we were only focused on meeting its requirements, and we were not aware of the weaknesses of the QMS processes. Dividing the QMS elements allowed us to realise what was wrong in the processes and services. So, the approach was very helpful”. Moreover, Auditor D7 highlighted the benefits of this division when an organisation has recently implemented ISO 9001:

> “During the first ISO 9001 audits in an organisation, you normally cannot assess section 8, which is about monitoring and measuring processes, products and the QMS. Organisations spend a lot of time and effort learning how to assess this section of the standard. But with this division auditors have clarity about how to do it; they are more focused and concise and are able to more clearly identify findings and improvement opportunities”

Questioned about how they felt using the performance auditing triangle and its PM metrics, all auditors stated that it was useful and allowed them to be focused during the audit. As Auditor D4 summarised “it helped us a lot. It was easy to assess processes because you knew where the non-conformities came from”. Expert D7 also explained why she considered it a good tool “the classification of metrics really helps auditors to focus and adds value to the audit. It aids the understanding of processes in their design, structure and how to evaluate their performance. This is reflected in the efficiency of the audit”. However, Auditors D5 and D7 also pointed out some issues that need to be improved in the triangle “the sub-triangles are logical, reasonable and adequate. But I had problems understanding the concepts of 'adaptability' and 'flexibility'. I think all proposed metrics are very good and have many advantages that help you to visualise aspects you normally miss during an audit, but these concepts need to be better defined in the document” (D7). Auditor D5 also stated “the triangle is very well designed because it helps to balance QMS indicators. But I do not see audits or management reviews as measurement methods, they are ‘assessment’ methods. This inconsistency in the document should be corrected”.

Criterion of utility (Are the results useful?)

Regarding the results of the Audit+, auditors agreed that the results obtained with Audit+ were better than those obtained with the compliance approach. “We obtained better results. We detected things that we would not have detected if we had audited as we previously did. The development of the customised checklist allowed us to determine more clearly the KPIs that we had to assess and it also permitted us to determine the weaknesses in the QMS more easily” (D2). Also, Auditor D3 summarised her experience as “there are issues [failures in the QMS] that we had not found in other audits and on this occasion we did, or issues we never thought were important and with this audit we realised that they are”.

Auditor D2, who is also CEO of the organisation, explained why the results were useful for top management:

> "We had focused on meeting the requirements of the standard during our internal audits, but we never pursued an approach to measure the performance of the QMS. This approach is much more rewarding for companies because it helps to establish improvements more quickly. It enables you to see your weaknesses and strengths [in the QMS], and what needs to be changed in the quality system".

As far as whether the procedure allowed auditors to improve their competences is concerned, there was a consensus between auditors that the procedure helped them to improve their knowledge about audit practice. As Auditor D2 stated "yes, I definitely improved my skills as an auditor. We learnt to audit in the traditional way [compliance with requirements], but this new approach gives additional value to the audit". Expert D7 also explained:

> "Yes, it helped me. I used to work in an organisation where we had many KPIs and were very helpful. But it has been very difficult to establish KPIs that help us to know how the QMS is performing and how to measure its processes in X3. What I value most about the procedure is the knowledge I acquired about PM metrics; it has given me a lot of clarity as an auditor to know about individual metrics of flexibility, cost and quality but also about process measurement. I did not know about these metrics before and they are very useful to visualise where the QMS and the organisation should go".

Questioned about whether Audit+ had enabled them to take into account relevant factors that otherwise may have been overlooked, auditors said that the PM audit helped them find problems and failures in the QMS that they probably would have omitted during a compliance audit. Auditor D2 remarked "we obtained better results. We detected issues that we would not been able to detect if we had audited as we normally do. The customised checklist helped us to determine more clearly the KPIs that we had to check and this allowed us to detect the system's weaknesses more easily". In fact, Auditors B2, D1, D3, D4, D5, D6 and D7 pointed out that this audit was deeper than other audits which allowed failures in the QMS to be determined more easily. Auditor D7 summarised as follows:

> "We had established indicators and knew we had to work much harder in order that these indicators would provide a correct assessment of the performance of processes. We knew something was not right with the indicators, top management especially knew it. The result of this audit helped us a lot, because it allowed us to see that we need to establish better criteria for the indicators and this was of great benefit for the organisation. Without this audit approach we would not have noticed it".

Summary of the findings of interviews

Internal auditors agreed that the Audit+ procedure can be followed, proving its feasibility. Nevertheless, their opinions were divided regarding its usability. Most of them (six out of a total of eight) also agreed that the document can be easily followed, implying that the document has good usability. The auditor who stated that the procedure was not easy to follow suggested two improvements that may be relatively easy to implement: 1) include a practical example that auditors can follow when they are conducting the audit; and 2) add help boxes in the sections which explain the new PM concepts. Auditors also stated that they liked the approach of dividing the audit elements into products/services, processes and QMS in order to better audit the QMS. In this respect, some auditors said that this approach helped them to better focus during the audit, allowing them to more easily detect failures and improvement opportunities. Similarly, auditors pointed out that they found the PM triangle useful to clarify what measures they should take into consideration when auditing. However one auditor also highlighted problems with the definitions of the 'adaptability' and 'flexibility' metrics, which were not clear enough in her opinion, while another auditor expressed discomfort with audits and management reviews being treated as 'measurement' but not 'assessment' methods. Finally, all of the auditors agreed that the procedure was useful and provided them with good guidelines to better audit. In fact, one of the auditors, who is also the CEO of his company, stated that the approach of the procedure is more rewarding for companies than the current compliance approach because it allowed them to detect failures in the system that they would otherwise have overlooked. These statements are clear indicators of the **utility** of Audit+.

8.2.4 Summary of the findings from the cases

The three case studies were conducted in real internal auditing conditions, with three trained audit teams. All of the sections and clauses of the Audit+ procedure were followed during the three cases by the auditors without difficulty. This suggests that the procedure has a good degree of feasibility. Issues relating to the lack of clarity of some definitions, a lack of examples and the wording of some clauses were detected during the internal audits. However, despite these issues, the three case studies demonstrated that the procedure can be easy followed. This indicates that the procedure has a good degree of usability, but the document needs some improvements. The procedure was also well assessed by auditors during the interviews and the results of the audits, in terms of improvement opportunities, were better than the previous internal audits that the organisations had conducted. Hence, it can be concluded that the procedure also has a good degree of utility.

8.3 Survey

8.3.1 Background of the workshops

As stated in Chapter 4, a survey targeting internal auditors and ISO 9001 internal auditors to discover their opinions about Audit+ was conducted during six workshops in Mexico. Initially, an invitation for two workshops was sent by e-mail to 430 quality managers and top management representatives of a Mexican CB and 55 certification managers from the Mexican accreditation body. Nevertheless, due to the high demand from internal auditors and the interest from companies about the procedure, another four workshops were conducted in Puebla, Mexico City and Leon. As result, 212 experts including internal and third party auditors, consultants, standardisation experts, quality managers, certification managers, top management representatives and CEOs attended the workshops. Table 8.4 shows the dates, places and number of attendees for the workshops.

Date	Place	Attendees
17th August 2011	Mexico City - Mexican Council for Culture and Arts (CONACULTA)	28
23rd August 2011	Mexico City – National Autonomous University of Mexico – Coordination of Scientific Research (UNAM)	53[40]
26th August 2011	Puebla - Yakult	28
23rd September 2011	Mexico City – Mexican Institute for Standardisation and Certification (IMNC)	26
28th September 2011	Mexico City – Mexican Institute for Standardisation and Certification (IMNC)	45
7th October 2011	Leon – Centre for Technology Development (CIATEC)	32

Table 8.4 List of the Audit+ workshops

The workshops were structured according to three main stages:

1. *Overall presentation of the research and results of the ISO 9001 audit survey*. During this stage the ISO 9001 experts were provided with the necessary background of the research;
2. *Discussion of each section of the procedure.* In this stage the researcher discussed each section of the procedure with the audience and provided them with practical exercises to understand the concepts addressed in the document; and
3. *Feedback about the procedure.* Attendees were asked at the end of the workshops to complete a feedback questionnaire.

The first phase of the workshops was dedicated to explaining the background of the research and the essential concepts of PM used in the procedure. Firstly, the audience was introduced to the context of the research by explaining its objectives and stages. Secondly, the results of the ISO 9001:2008 audit survey conducted for the theory building phase of this research (see Chapter 5), were presented so that attendees were aware of the importance of internal audits. Finally, ISO 9001 auditors were introduced to the PM field. Hence, during the presentation the following issues were explained: 1) the PM system of Neely *et al.* (1995), including the classification of individual performance metrics; 2) the processes assessment developed by Rohdler & Silver (1997); and 3) the PM methods for QMS. These concepts were used as a basis for explaining the PM triangle. During the presentation, the participation of the audience was also motivated by constantly asking if the concepts were understood and by answering questions.

For the second phase of the workshops, each section of the procedure was explained to the audience and they were asked to review its clauses. For Section 5, which relates to the conduct of the audit, practical exercises with real processes and procedures that attendees had brought specifically for the workshop were conducted. For the phase of planning the Audit+, groups of 4-5 people were formed and they were asked to develop an Audit+ checklist for any process or procedure they had brought, following the procedure. During this activity, the work of each group was monitored and their questions answered. For the stages of doing the Audit+, checking the Audit+ and acting on the Audit+, attendees were asked, while working together, to review each of the clauses of the procedure in greater detail and detect inconsistencies, problems, failures and errors.

Finally, during the last stage of the workshops, experts were asked to provide their opinions about the procedure in terms of feasibility, usability and utility using a questionnaire (see Appendix L). Hence, each question was read and the assessment scale explained so that the experts were clear about how to complete the questionnaire. Attendees were allowed 30 minutes in which to answer the questionnaire.

The questionnaire included both closed and open questions and these, like the case studies, were developed using Platts (1993) criteria for process evaluation. It was divided into two main sections: the assessment of all the sections of the Audit+ procedure and the assessment of each stage of section 5 ‘description of activities’ (planning, doing, checking and acting on the Audit+).

The assessment section of all the clauses of the procedure included a respondents’ general sub-section with items regarding the name, job title and the organisation of the respondent. It also contained a list of all of the sections of the procedure so that respondents could rate the feasibility by using a numeric scale of 1-4. Finally, this section also included a sub-section where respondents could state their proposals for improving of the document.

The assessment of section 5 was divided into four main sub-sections according to the stages of conducting the internal audit (planning the Audit+, doing the Audit+, checking the Audit+ and acting on the Audit+). Each sub-section contained two different types of questions according to the usability and utility criteria. Also each sub-section included a general open question regarding specific problems detected by the respondent in the document. The final version of the questionnaire can be found in Appendix L.

8.3.2 Survey instrument pilot testing

In order to test the validity and reliability of the questionnaire, a pilot academic/practitioner review was conducted with ten different ISO 9001 experts. The evaluation of individual items included the examination of variation; meaning; redundancy; scalability; non-response and acquiescent response set. During the review process, experts were encouraged to provide their suggested revisions of the instruments in terms of structure and content. As a result of this review, five questions were re-worded to ensure that respondents understood the intended meaning of the questions and answers; two questions were omitted to avoid redundancy and to ensure unambiguous interpretation by respondents; and one of the assessment scales was modified. The comments of the experts regarding the pilot of the questionnaire can be found in Appendix L.

8.3.3 Survey sample

As stated above, an invitation to attend the Audit+ workshops was sent by e-mail to 485 Mexican experts. As result, 212 auditors attended six workshops during the period of 17th August – 7th October 2011 (see Table 8.4). This represented 43.71% of the total number of invitations sent. However, during the workshops 174 completed questionnaires were collected which represented 82.46% of attendees or 35.88% of the total number of invitations sent. The demographic profile of respondents is shown in Figure 8.1.

8.3.4 Data analysis

The statistical software analysis package SPSS (version 18) was used for all quantitative testing. Descriptive analysis was used within this study to describe the distribution of variables (De Vaus, 2002). De Vaus' guidelines for conducting descriptive analysis were followed to present the cross-tabulation tables and graphs. The descriptive analysis is discussed in the following paragraphs.

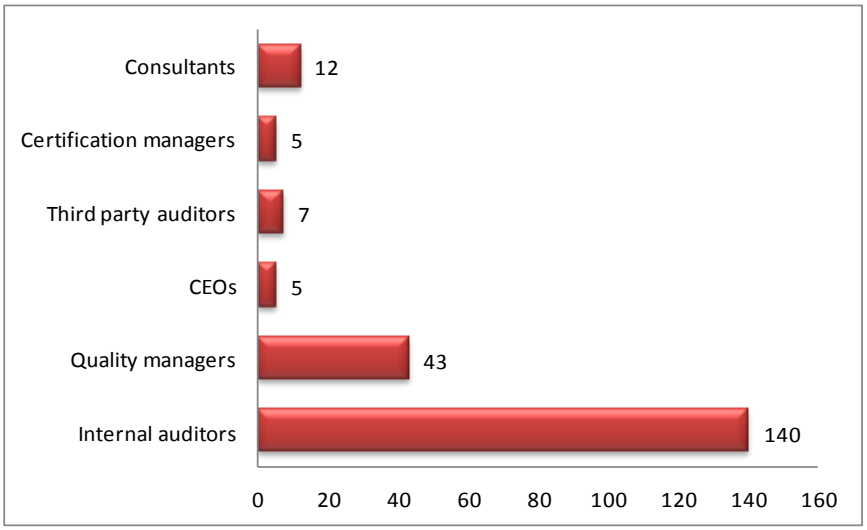


Figure 8.1 Demographic profile of survey respondents

The feasibility of the procedure

As discussed above, in order to evaluate the feasibility of the Audit+ procedure, experts were asked to assess each section of the procedure using a scale 1-4 where 1='very good', 2='good', 3='needs improvement' and 4='needs re-write'. Table 8.5 shows the results which are expressed in terms of averages for each item of the scale, while the mean is expressed on the scale 1-4[41].

All of the sections of the procedure obtained a mean score from 1.67 to 2.21 which implies they were considered as 'very good' and 'good' by ISO 9001 auditors. The best ranked sections of the procedure in terms of the mean were: 'purpose', 'scope' and 'bibliography which obtained a mean of 1.67; 1.85; and 1.79 respectively, out of a total of 4.

Interestingly, section 5 'description of activities' which is the main section of the procedure was ranked 8th by experts with a mean of 2.07. However, 44.82% of experts considered this section as 'very good' and 41.95% as 'good'; whilst only 5.74% of experts believed the section needs improvement and 1.15% that it needs re-writing.

Hence, these results support the findings from the case studies that the Audit+ procedure can be followed and is feasible.

[41] This scale is used by Platts (1993) for assessing processes

Table 8.5 Feasibility assessment of the Audit+ procedure

Item	Very good	Good	Needs improvement	Needs re-write	No answered	Mean
1) Rationale of Performance Auditing	52.3	38.5	3.44	1.15	5.6	1.86
2) Purpose of the Procedure	66.1	27.01	0.57	2.3	4.02	1.67
3) Scope of the Procedure	50.57	40.8	1.72	2.87	4.02	1.85
4) Responsibility and Authority	45.4	45.4	2.3	1.72	5.17	1.97
5) Description of Activities	44.83	41.95	5.74	1.15	6.32	2.07
6) Records	37.36	45.98	8.62	2.87	5.17	2.13
7) Appendix A- Process Categorisation	43.68	44.82	2.87	2.87	5.74	2.05
8) Appendix B – Individual Measures	41.96	47.13	2.87	2.3	5.74	2.05
9) Appendix C – The ISO 9000 PM System	41.96	46.55	2.3	2.87	6.32	2.1
10) Identification of Changes	47.13	38.5	3.45	2.3	8.62	2.21
11) Bibliography	69.54	21.26	0.57	2.3	6.32	1.8

The usability of the procedure

Experts were asked to state their opinions about how easy the different stages of section 5 of the Audit+ procedure (planning, doing, checking and acting on the Audit+) were to follow. The assessment was conducted using a Likert scale of 1-5 where 1='too easy'; 2='easy'; 3='neither easy nor difficult'; 4='difficult'; 5='too difficult'; and 6='I don´t know'. Table 8.6 shows the averages obtained for each question of the questionnaire according to the Likert scale and the mean results.

As far as the general assessment of the stages is concerned, experts rated the four stages (planning, doing, checking and acting on the Audit+) very similarly. The stages obtained means from 2.24 to 2.39 out of a total of 5 (highlighted in Table 8.6). Experts found the stage of 'planning the Audit+' the easiest with a mean of 2.24; followed by 'doing the Audit+' with 2.247, 'acting on the Audit+' with 2.37 and 'checking the Audit+' with 2.39. Interestingly, the four stages also received similar scores in the Likert scale, most of the experts assessed the stages as 'easy to understand and follow' with figures from 63.79% to 67.24%. The option of 'neither easy nor difficult' was second most marked by experts with averages from 16% to 20.11%; followed by 'very easy' with averages of 10.34% to 5.17%; 'difficult' with figures from 7.47% to 2.29%; and 'very difficult' with averages from 1.14% to 0.

Regarding the stage of 'planning the Audit+', the usability of its main activities were also rated positively by experts. The activity of 'processes identification' was evaluated as 'easy to understand and follow' by 63.79% of the respondents, whereas 18.39% found it 'neither easy nor difficult'; 8.62% considered it 'very easy'; 8.04% 'difficult'; and 0.57% 'very difficult'. Similarly, the activities of 'constructing the customised Audit+ checklist' were assessed as 'easy to understand and follow by 51.14% of the experts, whilst 25.28% believed they were 'neither easy nor difficult'; 13.79% 'difficult'; 7.47% 'very easy'; and 1.14% 'very difficult. Hence, 70% of experts chose the options 'very easy' or 'easy' which implies that these activities have good usability.

The three main activities of the stage of 'doing the Audit+' also received a positive evaluation by experts. The activity of 'assessing whether a process is adding value' was scored as 'easy to understand and follow' by 49.42% of experts; followed by 'neither easy nor difficult' with 22.98%; 'difficult' with 18.96%; 'very easy' with 6.89%; and 0.57% 'very difficult'. As far as the activity of 'assessing KPIs' is concerned, 48.27% of experts considered it 'easy to understand and follow'; followed by 28.73% who believed it was 'neither easy nor difficult'; 15.51% 'difficult'; 5.74% 'very easy'; and 0.57% 'very difficult'. Finally, the activity of 'assessing the performance of QMS processes/methods' was evaluated as 'easy to understand and follow' by 52.87% of experts; 'neither easy nor difficult' by 28.16%; 'difficult' by 10.91%; and 'very easy' by 6.89. Thus, auditors assessed these activities with a relatively good level of usability, with more than 55% choosing the 'very easy' or 'easy' options.

Item	Very easy	Easy	Neither easy nor difficult	Difficult	Very difficult	I don't know	Not answered	Mean
1.1.Was the stage of 'planning the Audit+' easy to understand and follow?	10.3448	64.943	16.666667	6.89655	1.14943	0	0	2.24*
1.2 Was the activity of 'processes identification' (Clause 5.4) easy to understand and follow?	8.62069	63.793	18.390805	8.04598	0.57471	0	0.5747126	2.316
1.3 Was the 'construction of the customised Audit+ checklist' (Clauses 5.5 – 5.10) easy to understand and follow?	7.47126	51.149	25.287356	13.7931	1.14943	0.57471	0.5747126	2.552
2.1 Was the stage of 'doing the Audit+' easy to understand and follow?	12.069	67.241	16.091954	2.29885	0	0	2.2988506	2.247*
2.2 Was the activity of 'assessing if processes are adding value' (Clause 5.18) easy to understand and follow?	6.89655	49.425	22.988506	18.9655	0.57471	0	1.1494253	2.64
2.3 Was the activity of 'assessing KPIs' (Clause 5.19) easy to understand and follow?	5.74713	48.276	28.735632	15.5172	0.57471	0	1.1494253	2.638
2.4 Was the activity of 'assessing the performance of the QMS processes/methods' (Clause 5.20) easy to understand and follow?	6.89655	52.874	28.16092	10.9195	0	0	1.1494253	2.51
3.1 Was the stage of 'checking the Audit+' easy to understand and follow?	5.17241	66.092	19.54023	7.47126	0.57471	0	1.1494253	2.391*
3.2 Was the activity of 'assessing externally'the QMS processes' (Clause 5.22) easy to understand and follow?	3.44828	51.724	24.137931	16.6667	0	0	4.0229885	2.82
3.3 Were the activities of 'creating the Audit+ report' (Clauses 5.23-5.26) easy to understand and follow?	9.1954	52.874	25.287356	10.3448	0.57471	0	1.7241379	2.51
4.1 Was the stage of 'acting on the Audit+' easy to understand and follow?	9.1954	63.793	20.114943	4.02299	0	0.57471	2.2988506	2.374*
4.2 Was the activity of 'appointing a follow-up group' (Clause 5.30) easy to understand and follow?	7.47126	57.471	21.264368	8.62069	0.57471	0.57471	4.0229885	2.632
4.3 Were the activities of 'creating the Audit+ acting plan' (Clauses 5.31-5.35) easy to understand and follow?	8.62069	57.471	17.816092	9.1954	2.29885	0.57471	4.0229885	2.65

Table 8.6 Usability assessment of the Audit+ procedure

As with the previous two stages, the activities of the 'doing the Audit+' stage received encouraging ratings by experts. The activity of 'assessing externally the QMS processes' was found 'easy to understand and follow' by 51.72%; 'neither easy nor difficult' by 24.13%; 'difficult' by 16.66%; and 'very easy' by 3.44%. Meanwhile the activities of 'creating the Audit+ report' were assessed as 'easy to understand and follow' by 52.87% of experts; 'neither easy nor difficult' by 25.28%; 'difficult' by 10.34%; 'very easy' by 9.19%; and 'very difficult' by 0.57%. Similar to the previous stage, auditors evaluated these activities with a relatively good level of usability with more than 55% choosing the 'very easy' or 'easy' options.

Finally, the activity of 'appointing a follow-up group' from the 'acting on the Audit+' stage was evaluated as 'easy to understand and follow' by 57.47% of respondents, followed by 'neither easy nor difficult' with 21.26%; 'difficult' with 8.62%; 'very easy' with 7.47%; and 'very difficult' with 0.57%. Also, the activities of 'creating the Audit+ action plan' were found 'easy to understand and follow' by 57.47% of experts; 'neither easy nor difficult' by 17.81%; 'difficult' by 9.19%; 'very easy' by 8.62%; and 'very difficult' with 2.29%. Hence, these activities were assessed by experts as having a good degree of usability with greater than 65% choosing the 'very easy' or 'easy' options.

Regarding the necessary improvements for this section of the procedure, 85 comments from experts were written in the questionnaires. Not all of them could be classified, but the most frequent comments were: the concept of 'adding value' in clause 5.5 needed clarification (14 auditors); the procedure should include a real example of the Audit+ plan and the Audit+ report (10 auditors); and the procedure should include more guidelines about the assessment of KPIs (10 auditors).

Thus it can be concluded from the results of this section of the survey, that the usability of the Audit+ procedure was good, supporting the findings of the case studies. However, experts also stated that some improvements and changes to Audit+ procedure are needed.

The utility of the procedure

In order to assess the utility of the Audit+ procedure, auditors were asked to state if the different stages of section 5 (planning, doing, checking and acting on the Audit+) had enabled them to take into account relevant factors in the audit process that otherwise could have been overlooked. Table 8.7 shows the results of this section of the survey.

The answers from experts for the four stages were very positive. The best ranked stage was 'planning the Audit+', where 94.25% of experts declared that the stage had enabled them to take into consideration relevant factors that otherwise they could have overlooked. The stage of 'doing the Audit+' was second with 93.67% of experts stating a positive answer; followed by 'checking the Audit+' with 88.5%; and

'acting on the Audit+' with 87.35%. Thus, it can be concluded that the Audit+ procedure had, in the opinion of the experts, a good utility

Item	Yes	No	I don't know	No answered	Mean
1.4 Has the planning the Audit+ stage enabled you to take into account relevant factors in the audit process that otherwise could have been overlooked with the traditional audit approach?	94.25	2.87	1.72	1.15	1.16
2.5 Has the doing the Audit+ stage enabled you to take into account relevant factors in the audit process that otherwise could have been overlooked with the traditional audit approach?	93.68	2.3	0.57	3.45	1.31
3.4 Has the checking the Audit+ stage enabled you to take into account relevant factors in the audit process that otherwise could have been overlooked with the traditional audit approach?	88.51	1.72	4.6	5.17	1.52
4.4 Has the acting on the Audit+ stage enabled you to take into account relevant factors in the audit process that otherwise could have been overlooked with the traditional audit approach?	87.36	4.02	4.6	4.6	1.49

Table 8.7 Utility assessment of the Audit+ procedure

8.3.5 Summary of the results of the survey

The results of the survey echoed the findings of the case studies. Experts rated all of the sections of the procedure as 'very good' or 'good' which indicates that the procedure can be followed, implying it has a good degree of feasibility. The results of the assessment of section 5, regarding the description of activities of the Audit+, were also encouraging. Most of the experts evaluated the main PM activities proposed in the procedure as 'easy to understand and follow'. However, as with the case studies, experts also stated that the document needs some improvements, such as clarity in some definitions and the inclusion of real examples. Hence, the results of this section of the survey showed that the procedure has a relatively good degree of usability. Finally, experts also agreed that the document was useful for their auditing practice. They indicated that all the stages of section 5 allowed them to take into consideration relevant factors that otherwise they could have overlooked. This implies that the Audit+ procedure has a good degree of utility.

8.4 Conclusions of the chapter

The objective of this chapter was to validate the Audit+ procedure by conducting internal audits in real conditions and with a survey of ISO 9001 internal auditors. The procedure was assessed using established criteria for evaluating feasibility, usability and utility (Platts, 1993).

In order to conduct this evaluation, three in-depth case studies and a survey of 174 auditors at six workshops were conducted. The case studies allowed the assessment of the Audit+ procedure in great detail, whereas the survey investigated the wider applicability of the document. Conducting the evaluation was a very substantial task for a single researcher, and for reasons of practicality and feasibility it was conducted in the author's home country of Mexico, where she was able to make maximum use of local knowledge and contacts.

The results of the evaluation were encouraging in terms of the feasibility, usability and utility of the document. However, both research methods also showed that improvements regarding the clarity of some definitions, the inclusion of real examples and the incorporation of more guidance, would be needed to enable auditors to use the procedure without problems.

Hence, these results support the view that effective PM based on current thinking in this field, can be incorporated into the internal quality audit process, to help certified organisations to better measure their QMS performance. The Audit+ procedure can provide internal auditors with a solid PM basis for enhancing their scope and improving their competence, hence allowing them to add real value to the organisation when auditing.

Chapter 9 discusses the study findings and conclusions. The limitations of the study are also analysed and further research is proposed in this chapter.

CHAPTER 9
CONCLUSIONS

This chapter provides the conclusions of the thesis. Section 9.1 revisits the research process. Section 9.2 states the outcomes of the research in terms of the original research objectives. Section 9.3 discusses the contribution of this work to the quality management body of knowledge. Section 9.4 addresses the limitations and suggests further research and finally, Section 9.5 offers some final thoughts.

9.1 The research process

As argued in Chapter 1, the ISO 9001 standard has become one of the most successful management approaches in recent decades, with more than 1,200,000 companies now certified in more than 170 countries. However, internal auditing, perhaps the most important PM method required by the standard, has been criticised by academics and practitioners, most seriously for failing to provide added-value to organisations. This failing is particularly regrettable, because it reduces the potential for ISO 9001 to enhance the performance and competitiveness of organisations; which from a global perspective represents a huge missed opportunity and waste of resource.

Seeking to make audits more effective, two main conversations have developed in the literature: firstly, changing the current compliance approach of auditing for a performance oriented one which allows for identifying not only compliance with the standard but improvement in processes and the QMS; and secondly developing different methods, guidelines, tools and techniques to improve auditing practice. In order to generate this change of focus, some research published during this decade has also advocated incorporating concepts and techniques from the PM body of knowledge into the ISO 9000 world. Although a small number of studies have been conducted in this direction, there has been no attempt to provide quality auditing with a practical basis for a performance focus.

This research aimed to fill this gap by answering the research question:

> "How can ISO 9001:2008 certified organisations better measure their QMS performance using internal audits?"

Hence, the proposed contributions of this work in terms of theoretical knowledge and practical application are:

Theoretical

1. A literature review covering the ISO 9000 core of standards, their relationship with the PM field and the creation of a new synthesis between these two bodies of knowledge;
2. An assessment of the current state of the art of the ISO 9001:2008 internal audit process;
3. A path model of the relationships between the current internal audit problems and their impacts on the performance of both the QMS and organisations; and
4. The identification of how ISO 9001:2008 QMS can be improved through a novel application of PM approaches in the ISO 9001:2008 audit context, based on empirical data.

Practical:

5. The development, refinement and testing of a procedure to conduct ISO 9001:2008 internal audits with a focus on the performance of the QMS.

In order to achieve the proposed contributions, a research process was designed. Figure 9.1 has been enhanced to show the chapters of this thesis which describe the various phases of the work. In the first phase, theory building, an assessment of the current state of the art of ISO 9001:2008 internal audit practice, including the state of PM knowledge, awareness and application within ISO 9001:2008 organisations was developed using a review of literature (Chapters 2 and 3) and a mixed methods study including a triangulation design (Chapter 5). Both the literature and this initial research indicated that ISO 9001:2008 CO were facing considerable problems when conducting internal audits. In order to understand how and to what extent these problems were affecting the performance of the QMS, a path model was developed and tested (Chapter 6). The results of the literature review, mixed methods study and path analysis indicated that a change of approach from compliance to performance auditing was needed, so that certified organisations would be able to better measure their QMS performance. Hence, a procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS was developed and sent to ISO 9000 experts for an initial assessment (Chapter 7). The experts' feedback led to refinement of the procedure. In the second phase, theory testing, the proposed procedure was evaluated by mixed methods research using three case studies. Semi-structured interviews conducted within the case companies were then supplemented by a substantial survey of practitioners to assist in generalising the research outcomes (Chapter 8).

9.2 Outcomes of the research

This section briefly summarises the outcomes of the research in terms of its research objectives.

Research objective 1. Conduct a literature review which identifies the key concepts of both the QMS and PM bodies of knowledge together with relevant operations management theories

The literature review was divided into two main areas: ISO 9001 QMS and PM, and can be found in Chapters 2 and 3 respectively.

The ISO 9001 QMS literature identified that currently, ISO 9001 auditing is a topic of considerable concern amongst both academics and practitioners. Two main conversations in the literature were recognised: changing the current compliance approach of auditing to a performance oriented approach which would allow improvement in processes and the QMS; and developing different methods, guidelines, tools and techniques to improve auditing practice. From these conversations, eight main problems regarding ISO 9001 internal auditing were identified:

- lack of internal auditor competence;

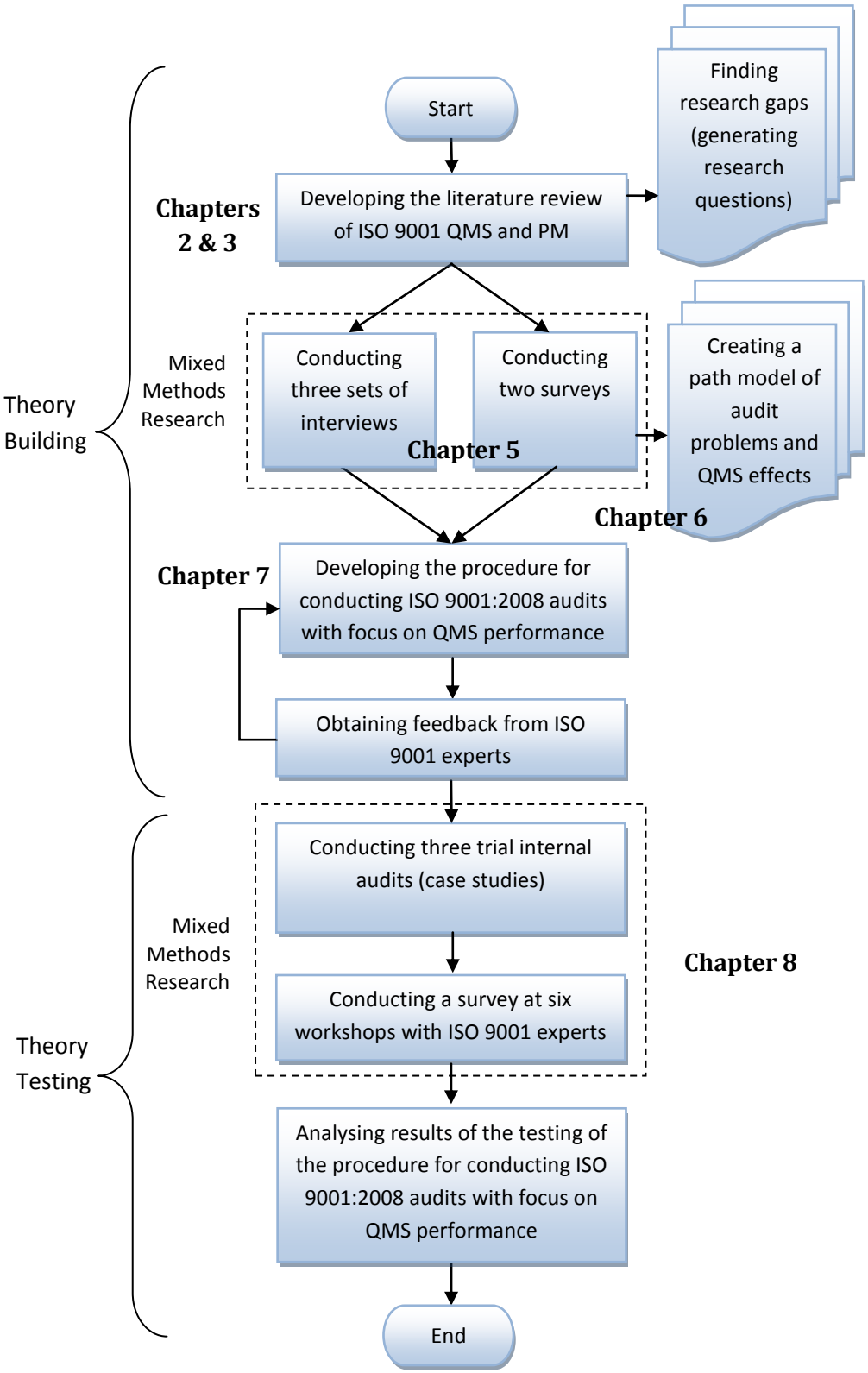


Figure 9.1 Research design by chapters

- lack of knowledge of ISO 9000 standards;
- lack of knowledge of auditing practices;
- lack of top management commitment;
- inadequate audit planning ability;
- lack of follow-up of audit findings;
- lack of ability to measure audit performance; and
- lack of ability to measure QMS performance.

Also, five main impacts on the ISO 9001 QMS due to poor auditing practice were identified:

- organisations are not detecting all non-conforming products;
- organisations are not detecting problems in their QMS processes;
- QMS is not performing correctly;
- organisations are not improving their capabilities as expected; and
- top management is dissatisfied.

The PM literature review identified that there has been a proliferation of different PM methods, tools and techniques during the last 10 years. There have been a very small number of attempts to incorporate PM concepts into the ISO world. However, no attempt has been made to integrate current PM concepts into ISO 9001 quality audits.

Research objective 2. Investigate the views of ISO 9001 experts in order to establish the current state of the art of internal audit practice, including the state of PM knowledge, awareness and application within this professional group

A mixed methods study, consisting of a triangulated design, including two surveys and three sets of interviews was conducted in order to address this research objective. To provide a framework for establishing the current state of the art of internal auditing practice, four intermediate research questions were stated (see Chapter 1). A detailed discussion of the findings of the mixed methods study can be found in Chapter 5. In the following paragraphs only their most important outcomes will be summarised.

First intermediate question: What problems do ISO 9001 certified organisations experience when conducting internal audits?

This research question was addressed by conducting a mixed methods study including two surveys and three sets of interviews with ISO 9001 experts. The results of the mixed methods study found that the eight audit deficiencies identified in the literature review still are of great concern for certified organisations. Both data sets converged in all the internal audit problems covered in the literature, with one exception: standardisation experts interviewed did not recognise the importance of the 'lack of follow-up of previous audit findings'.

The most important problems for certified organisations when conducting audits, according to the mixed methods study, were:

- 'poor' internal auditors' competence;
- the lack of ability to measure QMS performance; and
- lack of top management commitment.

Second intermediate research question: How do audit problems impact product/services, processes and QMS performance?

The mixed methods study also showed that, as with the internal audit problems, the five QMS effects identified in the literature are still impacting the performance of ISO 9001 QMS. However, some interviewees addressed other impacts which are not considered in the literature and hence were not included in the surveys. This suggests that ISO 9001 QMS are presenting more problems than the ones originally identified in the literature, which may be due to the maturity level of the QMS in some organisations.

The most important impacts on ISO 9001 QMS due to deficiencies in internal audits were:

- organisations' QMS are not performing correctly;
- organisations are not improving their capabilities as expected; and
- top management is dissatisfied with the performance of the QMS.

Third intermediate research question: how and to what extent are the internal audit problems affecting the performance of the QMS?

In order to answer this question, a path model was developed and tested using the data from the two surveys. The path model can be found in Chapter 6. Clear evidence was found of a network of interlinked audit problems, which together influence the performance of the QMS and the organisation. The impacts on the QMS and the organisation are significant, but the eight internal audit problems in the model are clearly not the only influences, as evidenced by the model decomposition and the measurement errors identified (see Figure 6.2 in Chapter 6). This is unsurprising, as the other PM methods to measure the QMS, management reviews and customer satisfaction measurement, will also impact upon the performance of the QMS.

The most significant results of the path analysis were:

- 'lack of ability to measure QMS performance' appeared as a central variable to the audit problems model, with four important impacts: 'lack of follow-up of audit findings' (40%); 'lack of top management commitment'

(51%); 'organisations are not detecting problems in their QMS processes' (22%) and 'QMS is not performing correctly' (25%). These results have important implications for CO. Firstly, managers should focus their efforts on improving the measurement of QMS performance, which will help the QMS to perform correctly. Secondly, inadequate QMS performance measurement will provoke problems in the follow-up of audit findings, generating spurious or inaccurate findings with little value for auditees. Finally, organisations should focus on PM, because if senior management do not find the system metrics useful or reliable, this will adversely impact their commitment to the auditing process and the QMS;

- 'Poor internal auditors' competence' was mainly explained within the model by 'lack of knowledge of auditing practices', accounting for 56% of the effect. Also, the variable has linkages only with the variable of 'lack of ability to measure audit performance' (20%); and
- 'Organisations' QMS is not performing correctly' was significantly influenced by 'lack of ability to measure the QMS performance' (25%); 'organisations are not detecting all non-conforming products' (22%) and 'organisations are not detecting problems in their QMS processes' (32%) – in total 79% of the effect. This result highlights the importance to managers of establishing a comprehensive PM system including all three levels of scrutiny required by the ISO 9001 standard: products, processes and the QMS.

Fourth intermediate research question: What are the PM techniques currently most used by ISO 9001:2008 certified organisations?

This question was also addressed in the mixed methods study. Only eight interviewees mentioned one of the PM techniques listed in the surveys. The 'BSC' was mentioned by seven experts whereas the 'dashboard' was mentioned by only one. These results correspond with the CB survey where these PM techniques were ranked first and second. However, they were ranked fourth and third respectively by organisations in the CO survey. Moreover, only three interviewees from CO declared that their companies use the BSC, whereas the other interviewees mentioned that they only use the requirements of ISO 9001 and KPIs. Hence, it may be concluded that CO do not use PM techniques as much as CB and standardisation experts believe.

Research objective 3: Develop a procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS

Chapter 7 described the design of Audit+, a procedure for conducting ISO 9001:2008 audits with a focus on the performance of the QMS. It was developed to address the core research question of this thesis regarding how ISO 9001:2008 certified organisations can measure their QMS performance using internal audits.

The procedure incorporated both the PM concepts discussed in Chapter 3 and the recommendations of ISO 9001 experts presented in Chapter 5, into the context of ISO 9001 internal audits. Thus, the document aimed to provide internal auditors with a PM framework for assessing QMS performance.

The procedure was developed in accordance with the ISO/TR 10013 standard for developing QMS documentation and the ISO 19011:2002 standard for conducting quality audits. Also, it followed the Neely *et al.* (1995) PM systems design and included the following key PM concepts:

- individual measures of performance: quality, time, cost and flexibility (Neely *et al.*, 1995);
- evaluation of processes: effectiveness, efficiency and adaptability (Rohleder & Silver, 1997);
- assessment of the design, implementation and use (Franco-Santos & Bourne, 2005) of the ISO 9001 PM system methods: management reviews, customer satisfaction measurement and audits;
- identification of business processes using the Armistead *et al.* (1995) approach; and
- the categorisation of processes by Hall & Johnson (2009).

The procedure was initially reviewed by 15 experienced ISO 9000 experts.

Research objective 4: Validate the procedure by means of trial internal audits using the proposed document in actual company audits and by a survey of ISO 9001 experts

The procedure was tested and validated using a mixed methods study consisting of three in-depth case studies conducted in real auditing conditions and by a survey of 174 ISO 9001 experts. The procedure was assessed using the Platts (1993) criteria of evaluating its feasibility, usability and utility. The case studies allowed the assessment of the Audit+ procedure in great detail, whereas the survey investigated of the wider applicability of the document.

The results of both research methods showed that the Audit+ procedure has good feasibility, usability and utility. However, both research methods also showed that some improvements regarding the clarity of some definitions, the inclusion of real examples and the incorporation of more guidance, are needed in order that auditors will be able to use the procedure without problems.

These validation results support the view that the PM body of knowledge can be incorporated into the QMS world, in order to help organisations to better measure their QMS performance. The Audit+ procedure provides internal auditors with a solid PM basis to enhance their scope and improve their competence, helping them to add real value to the organisation through internal auditing.

The Audit+ procedure was not based on specific national context. Indeed, it is intended to have global applicability wherever ISO 9000 series standards are used.

9.3 Contribution to the body of knowledge

This research has contributed to the existing body of knowledge by:

- providing a current assessment of the state of the art of the ISO 9001:2008 internal audit process;
- developing an original path model of the relationships between the current internal audit problems and their impacts on the performance of both the QMS and the organisation; and
- identifying how ISO 9001 QMS can be improved through a novel application of PM approaches within the ISO 9001:2008 audit context.

The most important problems that ISO 9001:2008 certified organisations face when conducting internal audits were identified. In addition, the most important impacts on the performance of the ISO 9001 QMS and the organisation, due to deficient internal auditing were determined from the mixed methods study. The identification of internal audit problems and QMS and organisational impacts, led to the development of a unique path model which traced the relationships between internal auditing problems and their impacts on the performance of the QMS and on the organisation. This model provided statistical estimations for those relationships, determining to what extent each internal audit problem impacts on the performance of products/services, processes, QMS or the organisation.

Both the mixed methods analysis and the path model formed the basis for the development of a novel procedure for conducting ISO 9001:2008 internal audits with a focus on the performance of the QMS. The Audit+ procedure incorporated key PM concepts into quality auditing, to help auditors to determine the performance of ISO 9001:2008 QMS in addition to their compliance with the standard. The Audit+ procedure was also validated by further mixed methods research including case studies and semi-structured interviews as the primary methods, while its general applicability was evaluated by using a survey of ISO 9001 auditors.

Thus, this research has contributed to filling the identified gaps in the body of knowledge by incorporating current PM approaches into quality auditing, to help ISO 9001:2008 certified organisations to measure and improve their QMS performance.

The results of this research should be of interest to both academics and practitioners. Results concerning the current state of the art for internal audits, including the path model, should be of interest to quality and operations management scholars. The Audit+ procedure is designed for being used by practitioners and will be of interest to internal auditors, quality managers, management representatives, top management, consultants and ISO 9000 experts. Third party auditors and certification managers may also be interested in using the

procedure to conduct an impartial assessment of the QMS when required by certified organisations.

9.4 Limitations of the study and further research

Limitations

During the research process of this work some limitations were identified. For the initial phase of the study, two surveys and three sets of interview protocols for the different groups of experts were designed (see Figure 4.5 in Chapter 4). This design and the resulting data led to certain limitations:

- The organisations' survey was answered by respondents in twenty countries, whereas ISO 9001 has been implemented in more than 175 countries. Hence, there may be different factors and variables affecting the ISO 9001 audit process in other countries. This was mainly due to the questionnaire only being available in English, Spanish and Portuguese, despite the fact that ISO TC/176, ISO CASCO and IQNet distributed the questionnaires to their members worldwide. More translations of the questionnaires, perhaps in the other official languages of ISO, may have increased the number of participants in the surveys. In the QMS field, however, where global standardisation is a primary principle, there are no specific reasons to suppose that the results obtained are unrepresentative of other nations that were not surveyed;
- Similarly, the organisation's interviews were mainly conducted with Mexican quality managers and internal auditors. Again, the problems that certified organisations face when conducting and receiving ISO 9001 audits may be different in other countries. This limitation was caused by the difficulty of collaborating with other companies in different countries;
- Also for the interviews, a more limited number of standardisation experts were interviewed (5) with respect to internal (12) and external (8) auditor groups. This occurred mainly due to the limited time that standardisation experts have to participate in these types of studies, most of the them are extremely busy, for example dealing with clients and constantly travelling to participate in other management system committees and subcommittees, and this makes it very difficult to target them;
- The transformation of qualitative data into quantitative data may have caused some of the richness of the qualitative data to be lost. Nevertheless, as Creswell & Plano Clark (2007) argue, due to the fact that the transformation was made by 'topic' and not by 'codes' the probability of this is relatively low; and
- The use of variables instead of constructs in the path analysis due to the limited number of studies exploring the effects of poor quality audit in the performance of the QMS was also a limitation of this stage of the research.

Nevertheless, this first approach of using variables could be the basis for a more rigorous statistical analysis of this relationship in a future study.

Finally, the validation of the procedure for conducting ISO 9001:2008 audits with a focus on the performance of the QMS, presented the following limitations:

- Due to the time and resource constraints of this research, only three in-depth case studies were conducted for testing the procedure and as pointed out above, more than one million companies worldwide are ISO 9001:2008 certified. The robustness of the Audit+ procedure might have been further improved if more test cases had been applied. However, the document was also reviewed by 15 international ISO 9000 experts who provided valuable comments which were incorporated into the tested version of the procedure;
- Similarly, the case studies were only conducted in Mexico. Hence, different factors and variables in other countries may affect the results of the case studies; and
- The case studies were only conducted in service organisations. Hence, the testing of the audit procedure may have had different results in other industrial environments.

Further research

An interesting area which needs more research is the relationship between audit problems and their effects on the performance of the QMS. Other studies including other variables and constructs would provide greater understanding of quality audits.

Future research could test the internal auditing procedure in other industries and countries, in order to increase the generalisation of the audit procedure with a focus on the performance of the QMS.

Also, as the ISO has recently launched the “high level structure for management system standards” where audits are the primary PM method for assessing all of the ISO management systems standards, a similar PM auditing approach is needed for other ISO management standards such as environment, social responsibility and risk management.

A similar PM auditing approach could be also developed for third party audits. The challenge of this approach would be incorporating PM into certification and surveillance auditing without interfering with CB regulations (i.e. ISO 17021).

Finally, PM should also be incorporated into the context of the other ISO 9001 PM methods: management reviews and customer satisfaction measurement. A suitable overall framework, based on current PM approaches for the whole ISO 9001 PM system would be desirable.

9.4 Conclusions

The ISO 9000 family of standards may be the largest standardisation effort that the world has ever seen. Its global reach, the vast number of certified companies and its broad scope of application mean that it presents immense opportunities. The improvement approaches to quality, such as TQM and Six Sigma, point the way to excellence but have not been successfully adopted worldwide, to the same extent as ISO 9001. Small advances in the way ISO 9001 is applied or assessed could have great implications for the effectiveness of global business, reducing waste, delay and frustration while engaging staff in the search for excellence, rather than simply compliance.

This research has addressed a central issue of the ISO 9001 QMS field, and has achieved its key objectives in setting out a novel approach to PM, suitable for the ISO 9001 internal auditing process. Audit+ is firmly based on the relevant QM and PM literature and on a considerable body of data collected from standardisation experts and practitioners. It is presented as an audit procedure, in a practical format familiar to practitioners. It has been validated by practical testing and through exposure to a substantial number of practitioners and experts. The author believes that the Audit+ approach has a real future, in the enhancement of internal auditing for ISO management systems standards.

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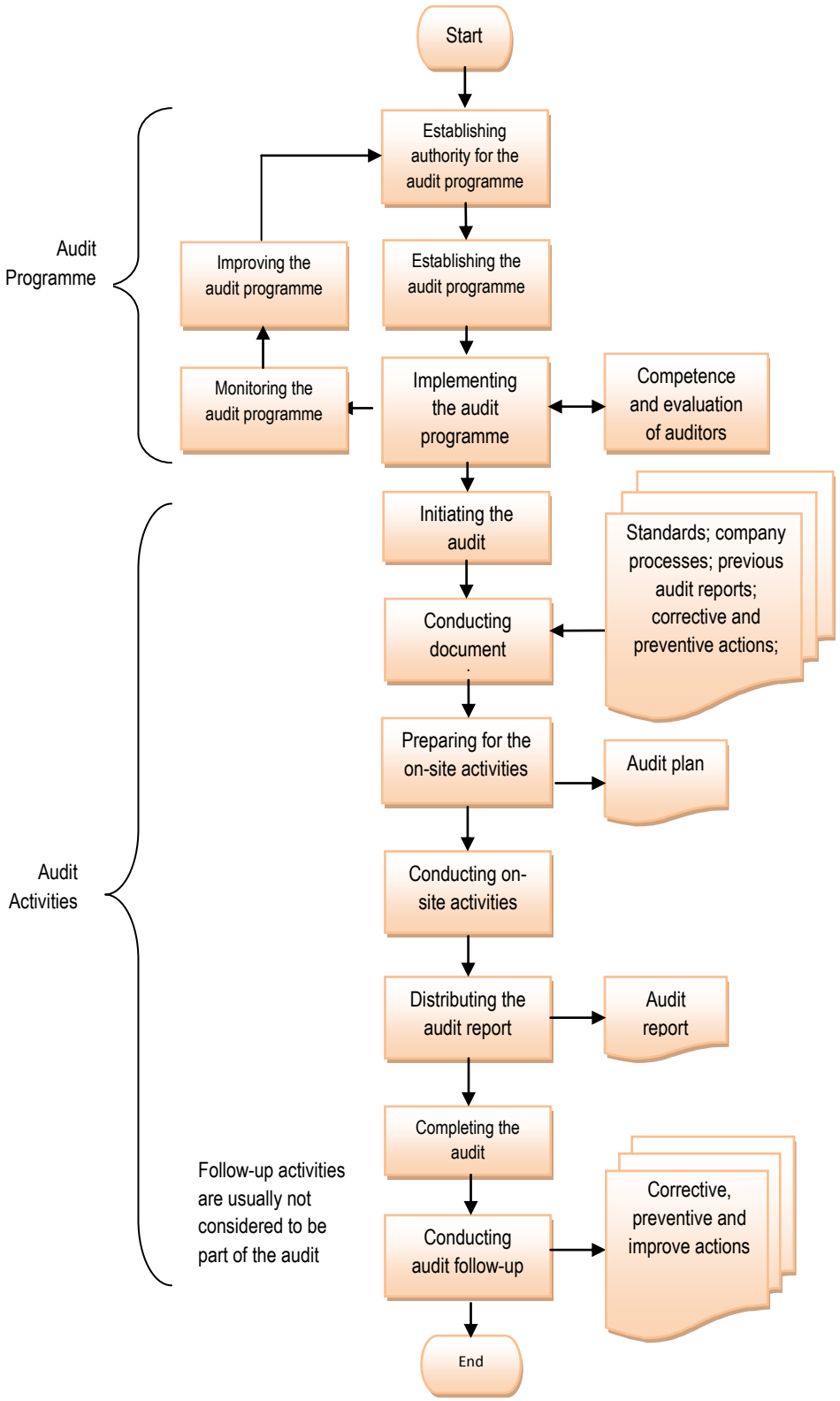
APPENDICES

APPENDIX A

THE INTERNAL AND THIRD PARTY AUDITING PROCESSES

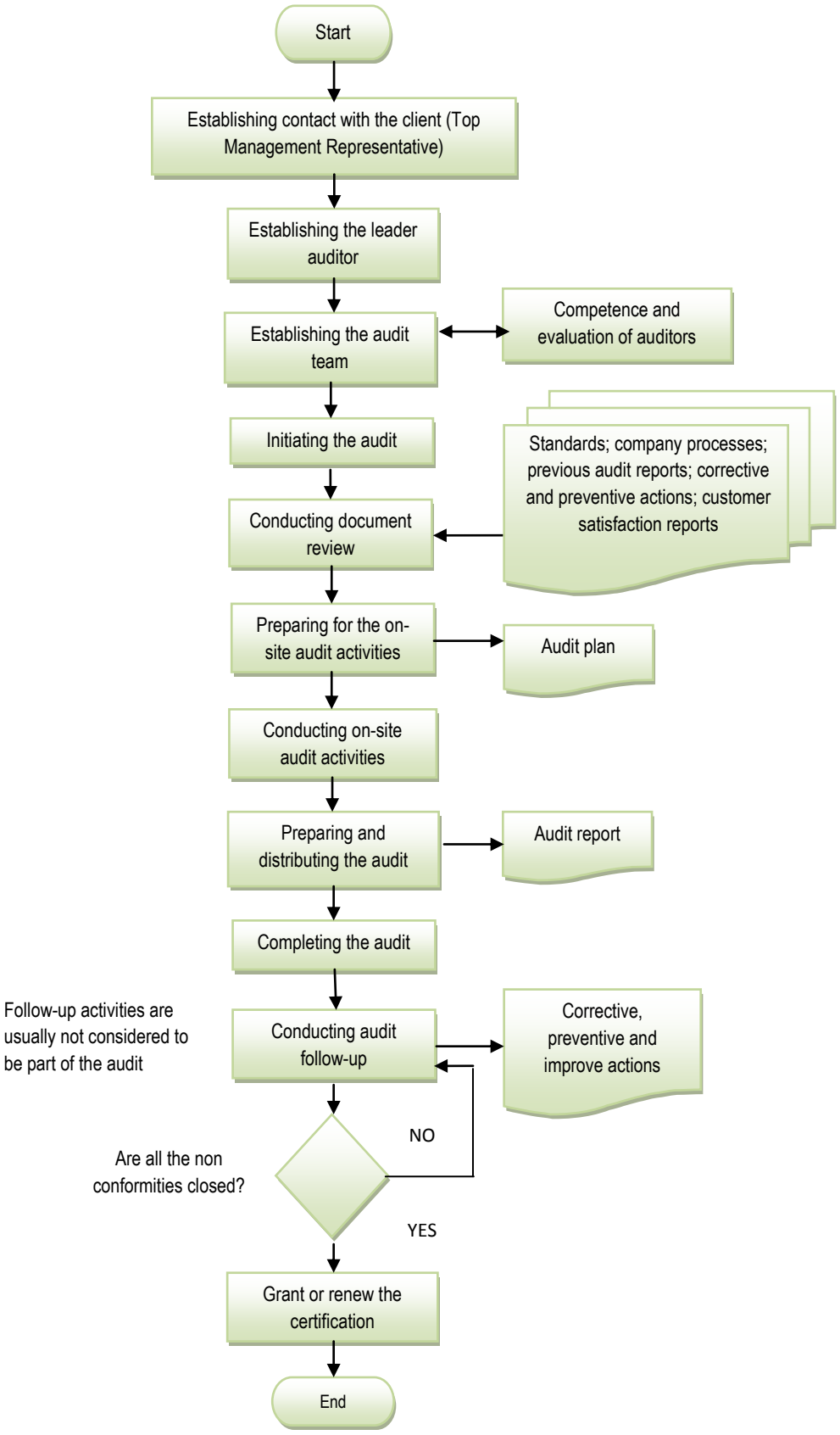


Adapted from: ISO 19011:2002

Figure A.1 The internal audit process flow chart

Stage/Activity	Top mgmt	Top mgmt represent.	Leader auditor	Audit team	Consultant
Establishing authority for the audit programme	■				
Establishing the audit programme		■			■
Implementing the audit programme Scheduling audits		■			■
Evaluating auditors		■			■
Selecting audit teams	■	■	■		■
Directing audit activities		■	■	■	■
Maintaining records		■			
Competence and evaluation of auditors	■	■	■	■	■
Monitoring and reviewing the audit programme	■	■			■
Improving the audit programme		■			■
Initiating the audit Appointing the leader auditor	■	■			■
Defining audit objectives, scope and criteria		■			■
Determining the feasibility of the audit		■			■
Selecting the audit team		■	■		■
Establishing initial contact with the auditee			■		
Conducting document review Reviewing relevant MS documents, records,			■		■
Preparing for the on-site audit activities Preparing the audit plan			■		
Assigning work to the audit team			■		
Preparing work documents			■		
Conducting on-site activities Conducting opening meeting	■	■	■		
Communicating during the audit			■		
Determining roles and responsibilities of guides and observers			■		
Collecting and verifying information			■	■	
Generating audit findings			■	■	
Preparing audit conclusions Conducting closing meeting			■	■	
Preparing, approving and distributing audit report Preparing the audit report			■		
Approving and distributing the audit report			■	■	
Completing the audit Checking that all the activities of the audit programme has been completed		■			■
Conducting follow-up			■	■	

Table A.1 The relationship of stages and main actors involved in the internal audit process



Adapted from: ISO 19011:2002

Figure A.2. The third party audit process flow chart

Stage/Activity	Top Mgmt	Top Mgmt. Represent.	CB Represent.	External Leader Auditor	External Auditor Team
Establishing contact with the client Determination of the objective, scope and day(s) of the audit					
Establishing the Leader Auditor					
Establishing the Audit Team					
Competence and evaluation of auditors					
Initiating the audit Analysing audit objectives, scope and criteria of the organization					
Determining the feasibility of the audit					
Establishing initial contact with the auditee					
Conducting document review Reviewing relevant MS documents, records, etc.					
Preparing for the on-site audit activities Preparing the audit plan					
Assigning work to the audit team					
Preparing work documents					
Conducting on-site activities Conducting opening meeting					
Communicating during the audit					
Determining roles and responsibilities of guides and observers					
Collecting and verifying information					
Generating audit findings					
Preparing audit conclusions					
Conducting closing meeting					
Preparing, approving and distributing audit report Preparing the audit report					
Approving and distributing the audit report					
Completing the audit Checking that all the activities of the audit has been completed					
Conducting follow-up					
Grant or renovate the certification					

Table A.2. The relationship of stages and main actors involved in the third party audit process

APPENDIX B

LIST OF INTERVIEWEES

Interviewee	Position	Organisation	Country
A1	Member of the Board of a Swiss Certification Body - Third Party Auditor - Former Director of IQNet - Delegate of the ISO TC/176 and ISO Committees - 23 years of experience in QMS	Swiss Certification Body	Switzerland
A2	Technical Manager - Lead Assessor of QMS - Third Party Auditor - Delegate of the ISO TC/207 Committee - 18 years of experience in QMS	Global Certification Body	Germany
A3	Standardisation Manager - Third Party Auditor - Delegate of the ISO TC/176 and ISO TC/207 Committees - 10 years of experience in QMS	Latin American Certification Body	Bolivia
A4	Third Party Auditor - 16 years of experience with ISO 9001	Mexican Certification Body	Mexico
A5	Certification Manager - Third Party Auditor - 17 years of experience in ISO 9001	Mexican Certification Body	Mexico
A6	Technical Manager - Third Party Auditor - Delegate of the ISO/JTC1 Committee (IT MS) - 14 years of experience in QMS	Mexican Certification Body specialised in IT	Mexico
A7	Foreign Affairs Director - Third Party Auditor - ISO TC/207 Delegate - 20 years of experience in QMS	Global Certification Body	Portugal
A8	Training Manager - Third Party Auditor -Consultant - 13 years working with the ISO 9000 standards	Mexican Certification Body	Mexico

Table B.1 List of third party interviewees and corresponding countries

Interviewee[43]	Position	Organisation
B1	Dr in Management - Internal Auditor - Human Resource Manager - ISO 9000 consultant - Expert in the Iberoamerican Business Excellence Model - Member of the National Committee of Quality Management - 17 years of experience in ISO 9000 QMS	Japanese food multinational
B2	Internal Auditor - Quality Manager - 12 years of experience in ISO 9000 QMS	Italian logistic multinational
B4	Internal Auditor - Quality Director - 12 years of experience in ISO 9000 QMS	Body member of ISO
B5	Internal Auditor - Manager of the Measurement and Standards Department - Expert in Environmental Management System - Chief of the Audit Office - Member of the National Committee of Quality Management - Member of the National Committee of Environment Systems - 16 years of experience in ISO 9000 QMS	Electricity large enterprise
B6	Internal Auditor - Quality Assurance and Process Manager - 16 years of experience in ISO 9000 QMS	Telecommunications multinational
B7	Internal Auditor - Quality Director - Responsible of the Integrated MS (ISO 9001, ISO 14000, OHSAS) of 430 certified centers - 12 years of experience in ISO 9001 QMS	Electricity large enterprise
B8	Internal Auditor - Quality Manager - 12 years of experience in ISO 9001 QMS	Electricity large enterprise
B9	Internal Auditor - Quality Manager of a thermoelectric plant - Auditor of the National Business Excellence Model - Consultant for the Council of Queretaro for environment and quality - Third party auditor for Canacintra[44] - 22 years of experience in quality and ISO 9001 QMS	Electricity large enterprise
B10	Internal Auditor - Quality Manager - Third party auditor for accreditation bodies in ISO 17025 - Consultant in implementation of ISO 9001 and ISO 17025 MS - Trainer of auditors - 16 years of experience in ISO 9001 and ISO 17025 MS	Higher education institution (large enterprise)
B17	Internal Auditor - Quality Manager of a metrology laboratory - Auditor of the National Business Excellence Model - Consultant of the Mexican Government in management systems - 26 years of experience in quality and 15 in ISO 9000 QMS	Electricity large enterprise
B18	Dr in Management - ISO 9000 consultant - Second Party Auditor of ISO 9000 - Third Party Auditor - Internal Auditor - Trainer for companies - 16 years of experience in Quality and ISO 9000 QMS	Consultancy firm
B19	Internal Auditor - Quality Manager - 15 years of experience in ISO 9000 QMS and integrated systems	Petroleum multinational
B20	Internal Auditor - Quality Manager - Auditor of the National Excellence Model - 9 years of experience in ISO 9000 QMS	TV broadcaster (large enterprise)

Table B.2 List of internal auditors' interviewees and corresponding countries

[43] All the interviewees are based in Mexico, with the exception of B!8 who is from Canada

[44] Canacintra is the Mexican Chamber of Manufacture Industry

Interviewee	Position	Organisation	Country
C1	Delegate for ISO TC/176 – Mexican Delegate of ISO CASCO - Chairman of the Spanish translation committee – Director of the Mexican Standardisation Body – 32 years of experience in international standardisation	Standardisation Body	Mexico
C2	Secretariat of the ISO TC/176 Subcommittee, responsible for the development of ISO 9001 and ISO 9004 – 20 years of experience in international standardisation	Standardisation Body	UK
C4	Delegate for ISO TC/176 - Delegate ISO TC/207 - Member of the committee in charge to review the High Level Structure for Management Systems - Chairman of different work tasks groups of the ISO /TC 176 and ISO/TC 207 – 15 years of experience in international standardisation	Standardisation Body	Spain
C7	Delegate for ISO TC/176 – Delegate for ISO CASCO - Member of the working group in charge of the development of ISO 9004:2009 – Chairman of different work task groups of the ISO /TC 176 – Consultant of the Australian and US governments for standardisation – Professor at different Australian, UK, US and French Universities – Member of the Australian Parliament – 30 years of experience in international standardisation	Body Member of ISO	Australia
C8	Delegate for ISO TC/176 - Chairman of the working task group in charge of the development of ISO 9004:2009 – Consultant – 20 years of experience in international standardisation	Body Member of ISO	Nederland

Table B.3 ISO TC/176 interviewees and corresponding countries

APPENDIX C
SURVEY QUESTIONNAIRES AND RESULTS OF THEIR PILOT

Standard cover letter of the questionnaire

Dear Quality Manager/Internal Auditor,

The Nottingham University Business School is conducting a research project based within the Quality Management Standardisation field. The main objective of the research is to build an audit framework that compliments the ISO 9001:2008 and ISO 19011:2002 standards, to promote more effective performance measurement in organisations.

The research methodology is planned to consist of three main stages:

- survey based research and selected interviews with the main actors involved in the audit process;
- developing a framework and guidelines; and
- testing and confirmation of the framework within the context of selected organisations.

At present the research is at the stage of primary data collection from those currently engaged in the audit process, with ISO 9001 Certified Organisations representing the most important group. For this reason, we would like to request your help, by filling out the following questionnaire. The aim of this survey is to identify the problems that Certified Organisations face, when conducting Internal Audits as well as when they receive Third Part Audits. We believe that the opinion of Top Management, Internal Auditors, Quality Managers and Top Management Representatives will be particularly important because of their extensive experience in the use of International Standards, as well as Audit Best Practices. All responses will be treated as confidential and will only be used for the purposes of this study.

When the research is complete, we will be delighted to share our findings with all the participant organisations.

We feel confident that, with your support, the results of this study can contribute to the improvement of internal and third party audits as well as potentially being an input for future International Standards and Audit Best Practices.

Thank you for your time and support.

Monica Gutierrez

On behalf of the research team

Questionnaire

Part I – The Internal Audit Process

1. What are the reasons that your organisation decided to implement an ISO 9001 Quality Management system? (*Please tick (✓) all of the options that apply*)

   a. _____ We export our products to international markets
   b. _____ Clients required us to achieve ISO 9001 Certification
   c. _____ Top Management desire to improve our organisation's capabilities
   d. _____ Our competitors had obtained the certification
   e. _____ I do not know
   f. _____ Others (please specify) _____

2. What are the standards, methods, guidelines and tools that your organisation uses to conduct ISO 9001 internal audits? (*Please tick (✓) all of the options that apply*)

   a. _____ The ISO 19011 standard
   b. _____ The ISO 9004 standard
   c. _____ Other ISO 9000 family standards
   d. _____ ISO 9001 auditing practice group documents
   e. _____ Others (please specify) _____

3. Which **stages**/tasks of the ISO 9001 Internal Audit Process are presenting your organisation with the most problems? (*For each **stage**/task please tick (✓) the level of problems, where '1' indicates that the stage does not present any problem and '5' indicates many problems)*

Audit Process Stages	*No problems at all* 1	2	3	4	*A lot of problems* 5
Developing the audit program					
a. Establishing, implementing, monitoring and improving the audit program	1	2	3	4	5
Initiating the audit					
b. Appointing the audit team leader	1	2	3	4	5
c. Defining objectives, scope and criteria	1	2	3	4	5
d. Determining the feasibility of the audit	1	2	3	4	5
e. Selecting the audit team	1	2	3	4	5
f. Establishing the contact with the auditee	1	2	3	4	5
Conducting document review					
g. Reviewing relevant documents	1	2	3	4	5
Preparing on-site audit activities	1	2	3	4	5
h. Preparing the audit plan					
i. Assigning work to the audit team	1	2	3	4	5
j. Preparing work documents	1	2	3	4	5
Conducting on-site audit activities					
k. Conducting opening meetings	1	2	3	4	5
l. Establishing communication	1	2	3	4	5
m. Establishing roles and responsibilities of observers	1	2	3	4	5
n. Collecting and verifying information	1	2	3	4	5
o. Generating audit findings	1	2	3	4	5
p. Preparing audit conclusions	1	2	3	4	5

q. Conducting closing meetings	1	2	3	4	5
r. Preparing and distributing the audit report	1	2	3	4	5
s. Completing the audit	1	2	3	4	5
Conducting the audit follow-up					
t. Defining the responsibilities of the audit follow up	1	2	3	4	5
u. Analysis of the root cause	1	2	3	4	5
v. Establishing the action plan	1	2	3	4	5
w. Follow up the action plan	1	2	3	4	5
x. Measuring the efficacy of the action plan	1	2	3	4	5
Other (please specify)_____	1	2	3	4	5

4. Why, in your experience, is your organisation facing problems when conducting ISO 9001 Internal Audits? *(Please indicate by ticking (✓) the appropriate column whether the following factors are causing problems)*

Factors	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. Internal auditors' competence						
b. Lack of top management commitment						
c. Lack of understanding of ISO 9000 standards						
d. Lack of knowledge of auditing practices						
e. Lack of follow-up of previous audit findings						
f. Bad audit planning						
g. Inadequate audit management program						
h. Lack of ability to measure audit performance						
i. Lack of ability to measure quality management system performance						
j. Inadequate use of sampling methods when collecting evidence						
k. Inconsistencies in audit findings between Internal and External Audits (External auditors use a different criteria)						
l. Other (please specify)_____						
m. Other (please specify)_____						

5. Are any of these problems impacting on the performance of your quality management system? *(Please tick (✓) whether you agree or disagree with each statement)*

Statement	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. We are not detecting all non-conforming products or services						
b. Our quality management system is not performing correctly						
c. We are not detecting problems in our quality management system's processes						
d. We are not improving our capabilities as expected						
e. Our Top Management is dissatisfied with the performance of the quality management system of the organisation						
f. Other (please specify)____						
g. Other (please specify)____						

6. In your opinion, what would be necessary to improve ISO 9001 Internal Audits? *(Please tick (✓) whether you agree or disagree with each factor)*

Factors	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. Develop more specific ISO 9001 Audit guidelines, such as the self assessment guide included in ISO 9004						
b. Create ISO 9001 Audit Best Practices focused on Industry Sectors						
c. Develop methods, guidelines, tools, or metrics to assure the quality of ISO 9001 audits						
d. Develop more ISO 9000 family standards such as one for conducting management reviews						
e. Certification Bodies should be benchmarked by National Accreditation Bodies and the results should be published						

f. Improve the number of hours/auditors in order to deeply review the Quality Management System						
g. Internal Auditors should be more focused in performance than compliance						
h. The organisations personnel should be more involved in the follow up of the audit findings						
i. Other (please specify)_____						
j. Other (please specify)_____						

Part II – The External Audit Process

7. How long has your organisation been working with an ISO 9000 series Quality Management System? *(Please indicate by ticking (✓) the appropriate option)*

    a. _____ 1 – 5 years
    b. _____ 6 – 10 years
    c. _____ 11 – 15 years
    d. _____ more than 15 years

8. Has your organisation implemented any other Quality Management System or improvement approach apart from ISO 9001? *(Please indicate by ticking (✓) all of the options that apply)*

    a. _____ No
    b. _____ The ISO 14000
    c. _____ The ISO/TS 16949
    d. _____ Six Sigma
    e. _____ TQM
    f. _____ CMMI
    g. _____ National Excellence Model
    h. _____ Other ISO Standards (please specify) _____
    i. _____ Other (please specify) _____

9. What kind of problems does your organisation experience when it receives ISO 9001 Third Party Audits? *(Please tick (✓) whether you agree or disagree with each statement)*

Statement	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. Third Party Auditors do not know/understand our organisation, processes and/or products						
b. Third Party Audits results do not help us to improve our capabilities or performance						
c. Errors remain undetected by the audits						
d. The audit findings are difficult to understand or they do not add value to our organisation						
e. The Quality Management System is ineffective and Certification Body has accepted it						
f. Audits are declared closed/finished when they are not						
g. Inconsistencies in audit findings between internal and external Audits						
h. Third Party Auditors' lack of ability to assess our Quality Management System performance						
i. Our organizations' lack of ability to measure Third Party Audit performance (we don't know if the audit was correctly performed by the certification body)						
j. Deficient or missing verification of evidence						
k. Subjective or biased audit report						
l. Lack of follow-up of our Audit findings						
m. Other (please specify)___						

10. In your opinion, what would be necessary to improve both Internal and Third Party ISO 9001 Audits? *(Please tick (✓) whether you agree or disagree with each factor)*

Factors	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. Develop more specific ISO 9001 Audit guidelines, such as the self assessment guide included in ISO 9004						
b. Create ISO 9001 Audit Best Practices focused in Industry Sectors						
c. Develop methods, guidelines, tools, or metrics to assure the quality of ISO 9001 audits						
d. Develop more ISO 9000 family standards such as one for conducting management reviews						
e. Certification Bodies should be benchmarked by National Accreditation Bodies and the results should be published						
f. Improve the number of hours/auditors in order to deeply review the Quality Management System						
g. Third Party Auditors should be more focused on performance than compliance						
h. Certification Bodies should be more involve in the follow up of the audit findings						
i. Other (please specify)___						

11. In your opinion, how could value be added to the ISO 9001 Audit Process for both Internal and External Audits?

_____
_____
_____

Part III – Performance Measurement

12. How much are the following performance measurement techniques used in your organisation? (For each item p*lease tick (✓) the level of use, where '1' indicates that the technique is not used at all and '5' indicates used a great deal)*

	No used at all				*Used a great deal*
Performance Measurement Technique	1	2	3	4	5
a. Balanced Scorecard	1	2	3	4	5
b. Dashboard / *Tableau de Bord*	1	2	3	4	5
c. The Performance Measurement Matrix	1	2	3	4	5
d. The Performance Measurement Questionnaire	1	2	3	4	5
e. CAM-I (Computer Aided Manufacturing International)	1	2	3	4	5
f. Nine-step process	1	2	3	4	5
g. Guidelines for Performance Measurement System Design	1	2	3	4	5
h. Seven Principles of Performance Measurement System Design	1	2	3	4	5
i. Other (please specify)_____	1	2	3	4	5
a. We do not use performance measurement techniques _____					

13. Does your organisation and its audit staff currently have the competence to assess your organisation's performance in addition to compliance?

    a. ____ Yes, Which performance measurement technique do you use?
    _____

    b. ____ No

14. Would your organisation be prepared to receive a Third Party Audit which includes performance measures on ISO 9001 processes? *(Please tick (✓) whether you agree or disagree with each measure)*

Individual Performance Measures	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Don't know
a. Measures of Time (such as manufacture lead time and of delivery)						
b. Measures of Cost (such as manufacturing cost and service cost)						
c. Measures of Flexibility (ability to respond to client demand)						
d. Measures of Quality (such as conformance and serviceability)						
e. Measures of Finance (such as inventory turnover and sales growth rate)						
f. Other (please specify)_____						

15. Do you think that your organisation would be prepared to pay for an "Audit+" service for ISO 9001 which includes targeted performance measures?

    a. ____ Yes
    b. ____ No

16. In your opinion, how could Certification Bodies better interpret their client's performance when conducting Third Party Audits?

    _____
    _____
    _____

Part IV - About You

17. How long have you been working in the quality field? *(Please indicate by ticking (✓) the appropriate option)*

    a. _____ 1 – 5 years
    b. _____ 6 - 10 years
    c. _____ 11 – 15 years
    d. _____ 16 – 20 years
    e. _____ more than 21 years

18. What is your current job title?

    a. _____ General Director
    b. _____ Quality Director/Manager
    c. _____ Divisional Director/Manager, please specify your title_____
    d. _____ Top Management Representative
    e. _____ Internal Auditor
    f. _____ Other (please specify) _____

19. In which city and country is your organisation's headquarters located?

    _____

20. In which countries does your organisation have a presence?

    _____

Can we contact you if we need to clarify an answer? If so, please provide us with your name and e-mail address.

Name:

_____

E-mail:

_____

The pilot questionnaires

For both surveys, two versions of the questionnaire, one in English and another in Spanish were developed due to the main audience of the surveys being Mexican auditors. The first version of the questionnaire was produced in English and reviewed by Dr James Tannock from the University of Nottingham. Then, a Spanish version was created from the English document and reviewed by Dr Nydia Lara Zavala from the National University of Mexico.

The certified organisations questionnaire

The Spanish version of the CO questionnaire was sent to a group of twenty two experts including quality managers, internal auditors, senior executives of CB and ISO 9000 consultants. The experts were specifically asked to review the document according to the following criteria:

1. Are all of the questions and the introduction letter understandable?
2. Are the instructions about how to fill out the questions clear enough?
3. Do the multiple choice questions include all of the relevant options? Is it too long for the audience, considering that it is expected to be filled out by internal auditors, top management representatives, quality managers and CEO?
4. Is there anything else the questionnaire should include?; and
5. Should the questionnaire include some topics as open questions instead of closed ones?

The pilot of the CO questionnaire was conducted during the period of 24th May to 21st June 2010. The following comments were received by e-mail and telephone:

C6 (telephone) – Foreign affairs director of a Mexican CB

The CB is a Mexican think tank specialising in certification and standardisation issues. It is the main standards developer body in Mexico and has published and translated standards for 17 years. The CB is also the biggest ISO 9001 certification body in the country.

- Change the words 'ISO 9000' for 'ISO 9001' in question 1;
- For question 3, change the word '*monitorear*' for a better Spanish translation such as '*dar seguimiento';*
- The option 'the external auditors have documented non-conformities related to the certification conditions of IAF requirements' should be added to question 8;
- Question 9 is very important and should be included in section I instead of section II. Also, options 'e' and 'h' should be changed to:

    - The Certification Bodies should assess internal auditors comepetence (*Los Organismos de Certificación deberían evaluar la competencia de los auditores internos*); and
    - The organisation's personnel should be more involved in the audit follow-up (*El personal de la organización debería involucrarse más en el seguimiento de los hallazgos de la auditoría*).
- In question 9, the word '*Que*' needs to be stressed (*Qué*); and
- The questionnaire is easy to understand and is the right size.

B13 (e-mail) – Technical and environmental audit manager of multinational energy enterprise

The company operates in 23 countries and has more than 20 million customers around the world.

- The questionnaire is understandable and easy to fill out;
- Section III about performance measurement "was a little bit frustrating for me because we do not know the techniques mentioned"; and
- In my experience, a lot of the problems in the certification audit process are caused by the lack of homogeneity in the criteria between internal and external auditors. Unfortunately, it is usual that during the on-site audit different criteria arise and this causes non-conformities that most of the time do not add value to the audit.

B3 (e-mail) – Quality system manager of a Mexican civil engineering company

The company is 15 years old and has more than 300 employees.

- The opening letter should explain how the objectives of the questionnaire are going to complement the aims of the study, what are the expected research results and what are the advantages of having these results;
- All of the questions are easy to understand with the exception of option 'j' in question 4, where it is unclear when the statistical methods are inadequate;
- The instructions about how to fill out the questionnaire are clear;
- There is no need for more questions and options;
- The questionnaire has the correct size and is not too long. However, it will be difficult for CEOs to answer it because it is very technically oriented, they will send it to quality managers; and
- In question 9, the word '*Que*' needs to be stressed (*Qué*).

B2 (e-mail) – Quality director of a multinational logistics company

This company is a privately owned international logistics provider. The company is 32 years old and has a presence in around 65 countries.

- The questionnaire is too big. However, the information is very valuable;

- The option 'No' should be included in question 7; and
- The option 'Do not apply to my organisation' should be included in some questions.

B14 (e-mail) – Quality and social responsibility consultant

The expert has more than 25 years of experience as a consultant in quality management, productivity and social responsibility

- The questionnaire is understandable and easy to answer; and
- The following open questions in sections I and II should be included: 'how, in your opinion, can value be added to ISO 9001 audits?' and 'What are the desirable audit results?'

A11 (e-mail) – Manager of the management and assurance department of a CB

The CB is a Mexican think tank specialising in certification and standardisation issues. It is the main standards developer body in Mexico and has published and translated standards for 17 years. It is also the biggest ISO 9001 certification body in the country.

- Option 'g', in question 3, could be clearer if the phrase "study/reviewing of the relevant documents for the audit" is added, instead of "reviewing of the relevant documents";
- Considering that one of the main problems for organisations is the follow-up of audit findings, Option 't', in question 3, could be divided into:
    a. Defining the responsibilities of the audit follow up;
    b. Analysis of the root cause;
    c. Establish the action plan;
    d. Follow-up of the action plan; and
    e. Measuring the efficacy of the action plan.
- In question 4, the option "the audit findings are not understandable" should be included, because it is usual that auditors write the audit findings in a very technically-complex way which is difficult to understand for the company's personnel;
- The Spanish word "*ata*" needs to be corrected to "*alta*";
- The option "the audit findings are not understandable or they do not add value to the QMS" should be added to question 8; and
- Option 'e', in question 9, regarding Certification Bodies being benchmarked by National Accreditation Bodies should be omitted.

B12 (e-mail) – Quality and innovation manager of a science and technology council

The council runs the national programs for quality certification for SMEs.

- The questionnaire is a good tool and is well structured; and

- Questions 4 & 14 should not start asking “Why you believe…?” This is an incorrect way of asking because the verb “believe” implies an “act of faith”. Another verb should be used.

B15 (e-mail) – Quality and IT consultant

The expert has more than 15 years of experience working as a quality and IT consultant for the banking industry.

- The word “ata” should be changed to “alta” in Option ‘e’ of question 5;
- For question 14 ‘Do you think that your organisation would be prepared to pay for an Audit+ Service for ISO 9001 which includes targeted performance measures?’ It is not clear if the question is about having the financial resources to pay for the service or if the organisation is mature enough to receive the service. Also, it is not clear what “Audit+” means;
- Question 17 has a two “d” options;
- A stress is needed in question 19 for the word “*que*”; and
- Change the phrase “If so, please provide us with your name and e-mail address. If no please leave the options blank” for “just in case your answer is affirmative, please include your name and e-mail address” in the last question.

B6 (e-mail) – Process and quality assurance manager of a telecommunications multinational

The company is the leader in its sector in Latin America and also has a large market presence in the US and Europe. The company employs around 160 000 people in the Americas.

- The questionnaire is good and captures all of the audit topics;
- The use of the IMNC logo and the mention of the institution as a partner of the research may cause respondents to be afraid to mention problems they are facing when they receive certification audits. There is a conflict of interest because the quality managers or internal auditors have to assess their external auditors and certification bodies. Thus, the respondent’s confidentiality of the information should be guaranteed in order to have accurate results for the survey; and
- There is a problem in certification audits when third party auditors assess top management responsibilities. Generally, auditors are soft with top management and they do not ask for evidence, taking all of the responses of management for granted. This causes top management to not be interested in the quality system; this also depreciates the value of certification. The survey should capture this issue.

B1 (e-mail) – Quality manager of a Japanese multinational food company

The expert has 17 years of experience in ISO 9000 QMS

- The questions are well worded and do not create confusion;
- The number of questions is okay;
- The time necessary to answer the questionnaire is reasonable;
- It should be interesting to ask in question 4 about the understanding of the concept 'quality management' and the Deming cycle because the ISO 9001:2008 standard is focused on these two concepts; and
- The process interaction should be highlighted in the audit report section for question 5. Quality audits should be conducted to improve processes and QMS otherwise the audit report is a list of failures.

B16 (e-mail) – Internal auditor a large higher education institution

The institution is the biggest in Mexico and is also one of the biggest in the world with around 360 000 students. Currently, the organisation has more than 100 ISO 9001 certified laboratories and its internal audit team is one of the biggest in the country.

- The use of the verb 'to be', in question 1, indicates that the company has been working with a QMS for some time. What happens if the company is implementing the QMS?;
- The phrase *"¿Por qué cree usted..?"* (Why you believe), in question 4, is incorrect. "Believe" is a subjective verb, the phase should be changed to something like *"¿Cualés son los problemas que las organizacion indentifica al realizar las auditorías internas ISO 9001?"* (What are the problems that the organisation has identified when developing ISO 9001 internal audits?);
- It is not clear what "inconsistencies in the audit plan" means, in option 'f', question 4;
- Question 5 should be worded as *"¿Cuál es el impacto de estos problemas en el desempeño de su sistema de gestión de la calidad?"* (What is the impact of these problems in the performance of the quality management system?);
- The Spanish word *"por"* should be omitted in question 6;
- The word "*clase*" can be omitted in question 8;
- The phrase *"¿Qué tanto son usadas …?*" (How often) in question 11 can be changed to *"¿Con qué frecuencia son usadas..?* "(How frequently…?); and
- It is not clear what 'Audit+' means.

Certification bodies questionnaire

The CB questionnaire was sent to ten experts including quality managers, third party auditors, senior CB executives and ISO 9001 consultants. The experts were specifically asked to review the document according to the following criteria:

1. Are all the questions and the introduction letter understandable?
2. Are the instructions about how to fill out the questions clear enough?

3. Do the multiple choice questions include all of the relevant options? Is there something else the questionnaire should include?
4. Is any important question missing?; and
5. Are the questions correctly worded?

The pilot was conducted during the period of 15th to 30th March 2010. The following are the experts' comments received by e-mail and telephone:

C6 (telephone) – Foreign affairs director of a Mexican CB

The expert has been working in the quality management field for more than 25 years. During the last 5 years he was the certification manager of the CB. Currently, he is in charge of the foreign affairs department of the same Institution. He is also a third party auditor of the CB and of the Mexican accreditation body (EMA). Moreover, he is also a third party auditor of the International Certification Network (IQNet) and has conducted third party audits of CB in Italy, Russia and Switzerland. He is also a delegate for the ISO/TC 176, ISO/CASCO and IAF.

- Include in questions 2 and 3 the stages related to the appointment of the audit team leader and the audit team;
- The option 'lack of knowledge of auditing practices' should be added in question 4. Also, the other options of section 7 of ISO 19011 should be incorporated as items in this question;
- Change the phrase 'how much do the external auditors of your organisation…' for 'how much do the certification body's auditors of your organisation' in question 7; and
- The questionnaire is easy to understand.

A11 (telephone) – Manager of the management and assurance department of a CB

The expert is in charge of the accreditation area of the CB and his responsibilities include the preparation of internal audits of the CB and receiving the accreditation audits conducted by EMA and IQNet.

- Include the option "best auditing practices of IAF" in questions 6 and 7; and
- The CB's auditors are not prepared in the PM area, they are not going to answer much in section III.

A12 (telephone) – Third party auditor of a CB

The expert is lead auditor for ISO 9001 of the CB. He has more than 20 years of professional experience as a QMS Auditor.

- Give more space to the 'others' options in order that respondents can answer;
- Add the option 'lack of follow up of previous audit findings' to question 4;

- Add the option 'third party auditors receive pressure from the organisation because it is expected to achieve the certification' to question 8;
- Include a statement to thank you at the end of the questionnaire; and
- The questionnaire is easy to answer.

C1 (telephone) – CEO of a CB

The expert has more than 30 years of professional experience in quality management. She was in charge of the standards office of a government treasury department and later founded a CB. She has been an ISO/TC176, ISO/CASCO and ISO/207 delegate and has also been in charge of the development of international standards. The expert was part of the original group that developed the ISO 9000 family since its first version. Currently, she is member of the climate change panel of the UN and works actively on the development of QMS and Environment audit standards.

- Change the phrase 'errors in products' in the question 5 for 'non conforming products';
- Question 11 needs to clarify who is intended to use the measures. Are these measures for CB or CO or both?;
- More emphasis on internal auditor's competence is needed in the questionnaire; and
- Otherwise the questionnaire is good.

B11 (telephone) – QMS consultant

The expert has more than 30 years of experience in quality management mainly in the construction industry.

- Include in the cover letter of the questionnaire what the objective of the survey is and why it is important for respondents to complete it;
- Add open questions where the respondent can state his/her own point of view about how the audit process can be improved;
- Add an open question about how the CB can better interpret the organisation´s performance ; and
- The questionnaire is a good way to better understand quality audits.

B10 (e-mail) – Quality manager of a higher education institution

The expert has more than 20 years of experience in quality management in industry and academia. From 2002 to 2009 she was in charge of the certification program of technical laboratories of the biggest higher education institution in Mexico and under her supervision and coaching, more than 100 laboratories were granted ISO 9001:2000 certification. She trained more than 150 internal auditors of the

institution. She is also a QMS consultant for the liquor industry and acts as a third party auditor for the Mexican Accreditation Body (EMA).

- The order of questions in the questionnaire is good;
- Try to avoid open questions and include more options in the tables; and
- Change the order of the audit process stages for question 2 and 3 to c, g, a, b, d, e, f, h.

B12 (e-mail) – Quality and innovation manager of a science and technology council

The expert is in charge of the quality and innovation area for SMEs in the council. His responsibilities include helping SMEs to achieve ISO 9001 certification in order to export their products and improve their services and processes. He is also a QMS and innovation consultant. He has 10 years of professional experience.

- Put 'the other' questions included in the tables, in a separate section in order that respondents do not to classify them;
- Give more explanation about the survey in the cover letter because it is not clear what the survey is about;
- Questions which ask for an opinion to be provided should be omitted because opinions are subjective;
- Change the phrase 'in your opinion' for 'in your experience' in questions 2, 6, 9 and 14;
- question 5 should be re-worded to include services; and
- In the stage of analysing data, questions 16 and 17 should be analysed together so that opinions from people who do not have much professional experience but who are working in the QMS field are not dismissed.

APPENDIX D
INTERVIEW PROTOCOLS

Interview protocol for CB experts

1. In your opinion, what are the most frequent problems that ISO 9001 Certified Organisations are facing when they conduct internal audits?
2. What do you think are the reasons for these problems? Why do you think they are facing these problems?
3. How are the problems in the internal audit process affecting the performance of ISO 9001 quality management systems in organisations?
4. In your experience, as a member of a certification body, what are the most frequent problems that you face when conducting third party audits?
5. How do the deficiencies in internal audits relate to the deficiencies you have found when you conduct external audits?
6. From your point of view, how can be the internal and external audits improved?
7. In your experience, how much are performance measurement techniques used in the quality audit process by organisations and your certification body?
8. How might an academic proposal addressing quality audit process introduced into ISO/TC 176? (for standardisation experts only)

Interview protocol for CO experts

1. In your opinion, what are the most frequent problems that your organisation is facing when conducting internal audits?
1. What do you think are the reasons for these problems?
2. How are the problems in the internal audit process affecting the performance of your ISO 9001 quality management system?
3. In your experience, what are the most frequent problems that your organisation faces when receiving third party audits?
4. What do you think are the reasons for these problems?
5. From your point of view, how can be the internal and external audits improved?
6. Does your organisation use performance measurement techniques? If so, how much are performance measurement techniques used in the quality internal audit process of your organisation?
7. In your experience, how could Certification Bodies better interpret their client's performance when conducting Third Party Audits?

Interview protocol for standardisation experts

1. What do ISO TC/176 experts understand by the word 'performance' in the context of the ISO 9000 standards?
2. Clause 8.2.1 of ISO 9001:2008 states that 'customer satisfaction' is one of the measurements of the performance of quality management system. What are the other measures of the performance of QMS?
3. The ISO 9004:2009 standard has a strong emphasis on performance; however the ISO 9001 standard is more focused on 'effectiveness'. What is the reason for the different approaches between these two standards?
4. In your opinion, what are the most frequent problems that ISO 9001 Certified Organisations are facing when they conduct or receive audits?
5. What do you think are the reasons for these problems?
6. How are these problems in the audit process affecting the performance of ISO 9001 quality management systems in organisations?
7. From your point of view, how can internal and third party audits be improved?
8. In your experience, how much are performance measurement techniques used in the quality audit process by certified organisations and certification bodies?
9. How could an academic proposal addressing performance measurement for QMS using audits be introduced into ISO/TC 176?
10. In your opinion, as a Secretariat of an ISO/TC 176 committee, what are main challenges that the ISO 9000 family is facing?

Interview protocol for case studies

1. How did you feel using the audit+ procedure? Do you think it helped you to improve your competences as auditor?
2. What do you think about the audit results obtained using the procedure? Do you believe the procedure enabled you to take into account relevant factors that otherwise could have been overlooked?
3. What do you think about the approach of dividing the audit measurement elements into: products/services, processes and QMS? Do you think it helps you to better auditing?
4. How do you feel using the audit performance triangle? Are you happy with all the measurement elements proposed? (product/service: quality, time, flexibility and cost; processes: effectiveness, efficiency and adaptability; QMS: audits, management reviews, measurement of customer satisfaction)
5. What do you think about the structure of the document? Do you think it is easy to follow and understand?
6. Do you have any suggestions to improve the procedure?

APPENDIX E
INTERVIEWS CONTENT ANALYSIS

Findings from the interviews with third party auditors and members of certification bodies

The interviewees identified two different types of organisations. Those that develop their own QMS and organisations that tend to rely on external consultants to tailor their systems and propose measures and techniques. According to the experts, companies that internally develop their systems and have a competent internal audit team tend to work to prevent problems rather than to correct them. “These organisations seem to conduct better internal audits, they plan the activities more efficiently and have a more in-depth knowledge of their own products and processes and how to improve them”, remarked executive A6. Similarly, the internal auditors tend to be senior members of staff. According to a number of interviewees, the experience of auditors is a critical issue in organisations. The set of skills that an internal auditor should embody were highlighted during the interviews. The more experience that internal auditors gain during audits, the more they know about the business. This knowledge directly affects the quality of the audit process and, in consequence, the PM of the QMS and implementation of improvement actions. Nonetheless, the experts interviewed in the study acknowledged the existence of difficulties for the organisations to develop auditor competence. The main difficulty relates to the lack of guidelines and focus on PM present in the ISO 9000 standards. “The internal auditor may move to another company and, consequently, this knowledge goes with the professional” (executive A3). For the interviewees, clearer guidelines and a proper framework for the PM of ISO 9001 QMS could represent the way forward. Thus, if another professional replaces the internal auditor, by following a set of guidelines provided with the standards, the audit can be conducted with no further difficulties. Similarly, the new auditor will be trained according to the requirements of the guidelines. The competency of the internal auditor greatly depends on training as remarked by auditors A2 and A6. The existence of a clear framework for QMS performance assessment may address this issue in their point of view.

For CB, the main issue also relates to the current emphasis of the ISO 9000 standards. In the opinion of executive A6, “the mere verification between conformities and non-conformities does not fully express the depth and importance of the audits for improvements in the processes of a company”. The current ‘checklist’ view, according to the interviewees, allows the evaluation of compliance of the standards, but it is far from representing an efficient measure of performance of the QMS. Furthermore, this view does not facilitate improvement actions. The results from audits tend not to represent a consistent feedback for top management, for instance. “No one teaches them [the top management] on how to use this information”, auditor A5 pondered. A framework and guidelines for the PM

of ISO 9001 QMS should be included in the standards to tackle this issue. Most of the interviewees concluded that a clear set of audit criteria on how to measure the performance of QMS is necessary if improvements are to be expected.

These difficulties and issues affect the performance of ISO 9001 QMS. Auditor A1 remarked that any auditing should be faced as a learning opportunity together with a management tool. Even though third party audits are a crucial requirement for CO, they should be seen as a 'learning tool' most of all. The auditor pondered that "if they [audits] are professionally done, they can motivate people, they can give them more energy to improve and to understand what needs to be done". The current emphasis of ISO 9000 standards prevents many companies from using the information from audits efficiently and improving the performance of their QMS. The lack of a focused framework for the PM of QMS and corresponding audit criteria, affects the commitment of top management to process improvements as well, according to executive A3. "When the high administration does not perceive any benefits coming from the audits, organisations tend to conduct less cause analyses, spending excessive time in corrective actions instead of working on improvement initiatives", the auditor elaborated. In consequence, the performance of the organisation's QMS is not properly assessed and the information does not represent a consistent feedback for top management.

In terms of the problems faced by certification bodies in third party audits, three main points were emphasised by the interviewees. First, the lack of planning for audits which echoed the findings of the study of Karapetrovic and Willborn (2000). According to expert A3, many companies request audits, but are not ready to receive them on the appointed date. "We have to seek the information … and many times we have to trust information given by the auditee due to time limitations; we also work with a representative set of their processes". A more in-depth analysis of processes and sensitive areas are not always carried out due to this lack of planning as remarked by interviewee A3. Auditor A5 pointed out that the lack of planning is a recurrent problem, "auditing dates are changed very often, because either the professionals in charge of a set processes are busy or absent from the company". Although a lack of planning represents a difficulty for certification bodies, the way organisations face the ISO 9001 standard and the performance measurement of QMS was indicated as one of the main concerns in the executives' opinion. Auditors A1, A3, A5, and A7 emphasized this concern. The audits and existing criteria for performance measurement are faced as a mere obligation to keep or obtain certification as pondered by interviewee A1. Expert A2 indicated that this issue is often experienced in audits: "the audit process is viewed as 'police action' instead of a supporting, management tool".

Auditor A4 indicated that a third problem found in third party audits is the lack of clarity on the focus and criteria defined in the standards and related to PM of QMS. "One needs an objective set of criteria to assess the performance, translating the principles of the standards and applying those principles in the audit process". Expert A2 also elaborated on that issue saying that the standards are not very clear

on what to assess and how to go about assessing QMS performance. The auditor exemplified that issue, “usually quality experts take part in the audit process, but they do not speak the language of finance, for instance; members of that area may refuse to supply information or get overprotective of their area as a result”. The interviewee remarked that this occurs because there is no framework for assessing performance with clear criteria for measuring it and proposing improvements. Auditor A3 emphasised that the members of an organisation do not necessarily understand the ‘language of quality’ or speak it. As a consequence, organisations do not learn how to prepare for audits and how to use the information provided by the process after its completion.

All interviewees agreed that the problems found in internal audits directly correspond to the problems found in the external audits. The fact that there are no clear criteria for assessing the performance of QMS, for instance, generates the lack of planning of organisations for external audits, pondered auditor A8. Expert A6 highlighted that “the ISO 9001 standard and external auditors assume that a more in-depth audit has been undertaken by internal auditors to prevent problems, avoid non-conformities and improve processes”. Nonetheless, the interviewees understood that the process is troublesome precisely because a more in-depth audit is prevented by the lack of clearer principles and criteria. Interviewee A3 remarked that this issue directly affects the commitment of top management. Top management has to foresee benefits emerging from audits in order to commit to the audit process, provide necessary resources and implement improvements to the processes. “If the audit is poorly performed due to the lack of specific performance measurement guidelines and no problems are found, but organisation members know they exist, there is no feedback in the process and the audit is not effective in any way” (Auditor A1).

After identifying the issues and deficiencies found in internal and external auditing, the interviewees were asked to provide some suggestions on how they could be improved. In the opinion of auditor A8, the emphasis of the 9001 standards is much more related to efficiency than actual performance measurement and improvement. Although the focus has changed as mentioned in the literature review, the interviewees believe that the way forward to measure performance effectively is to create a clearer set of criteria and guidelines for the audit processes. Expert A6 reinforced the importance of those guidelines for internal and external auditors. In the case of internal auditors, they could more easily understand ‘the spirit of the standards’. According to executive A7, robust performance measurement guidelines would constitute a more in-depth analysis of an organisation’s processes, procedures, and practices through internal audits. Similarly, this could enhance the competency of internal auditors that would be trained according to that view. For external auditors, organisations would be more prepared to receive audits, improving the planning of activities. Through a framework for the assessment of QMS performance based on the 9000 standards, organisations and certification bodies would have a common set of criteria to appraise and monitor performance as

suggested by interviewee A3. Interviewee A2 remarked that, “the indicators of performance should speak the language of management”. This point is directly related to the commitment of top management as remarked some of the experts. A clear set of criteria for performance measurement that feeds the strategic orientation of the company would highlight the importance of audits in terms of improvement opportunities. A continuous improvement approach to QMS PM is required, according to the interviewees. A framework for PM of QMS based on the ISO 9000 standards was suggested as means to address this need.

Finally, the interviewees were asked to indicate the frequency of the use of PM techniques by organisations and their own certification bodies. The majority of executives identified the balanced scorecard as the tool most commonly mentioned by companies. Executive A1 mentioned other tools usually developed in-company. Interviewee A2 remarked that managers tend to adopt performance measurement techniques that are advertised in magazines: “you usually have single tools that are popping up; managers are only adopting them because they read about them”. Companies tend to use novel approaches and combine those tools with the ISO 9001 standard in audits. Six sigma and its continuous improvement focus were also mentioned by executive A2. Nevertheless, the interviewees remarked that the PM of QMS is carried out using the minimum requirements of ISO 9001. Given the importance of this assessment, the current criteria associated with the ISO 9000 standards are considered insufficient to correctly evaluate the performance of ISO 9001 QMS.

Findings from the interviews with internal auditors and quality managers

The interviewees recognised that ‘internal audits’ are fundamental for the development of an ISO 9001 QMS. In fact, expert B7 stated that “internal audits are immensely more difficult than external audits because the people who audit us, the people we face when conducting the audit, are the people who know the system [the management system] perfectly because they have developed it with us. Hence, they know the weaknesses of the system”. Hence, improving audit practice is fundamental for improving the QMS. This perception is also shared by experts B6, B10 and B18.

There are several problems affecting internal audits in organisations according to interviewees. Notably, the most common problem addressed during the interviews was the ‘lack of competence of internal auditors’. This lack of competence can have two main aspects: lack of auditing qualities and lack of management skills. The lack of auditing qualities refers to the desirable attributes that auditors should have according the ISO 19011:2011 standard, such as being ethical, open-minded, diplomatic, observant, perceptive, versatile, tenacious, decisive, self-reliant, acting with fortitude, open to improvement, culturally sensitive and collaborative (pp. 25 & 26). Nevertheless, as executive B6 regrets, some auditors “are not tolerant, analytic, good observers and diplomatic”. The lack of these qualities sometimes causes, as

expert B20 explains, an undesirable empowerment of internal auditors who do not understand their role as auditors, “they do not understand that the standard [9001] should be used as a quality tool, not as a dogma or a law”. Also, the lack of management skills, such as communication and listening, was considered by interviewees as an important problem because, as consultant B18 pointed out, auditors are unable to clearly explain to auditees what the problems in the QMS are.

Questioned about the reasons for the lack of competence of internal auditors, executive B6 pointed out that "often auditing teams are formed by people with a low profile because they do not have much responsibility. Frequently they do not have the qualities you need to have in an auditor". This perception is also echoed by experts B2, B5, B8 y B20. In fact, auditor B8 indentified the root cause of the problem when affirming “there is no awareness of the importance of quality and audit activities [in organisations]. Many people are assigned to quality areas because they 'do not have enough work' and these people see it as a punishment”. Nevertheless, in the opinion of experts B9 and B20, this perception is changing and being an auditor is not perceived as something bad in some companies anymore. In fact, expert B9 explained that being an auditor provides some positive recognition from colleagues.

But a lack of experience in auditing is closely related to a lack of auditors’ competence according to experts. Executive B19, explained it in this way: “auditors often have a lack of experience in implementing QMS, so they do not understand what is behind each system concept”. And gaining this experience takes years, as expert B10 pointed out. Hence, organisations find it very difficult to form a good audit team with the right competences and experience (Executives B5, B9, B10 and B19).

Nevertheless, when auditors fill out the necessary criteria to become auditors and they are interested in conducting audits, another problem arises according to interviewees B5 and B9: it is expensive for organisations to provide good training for its auditors. Bad auditors’ training was also viewed as a reason for the lack of internal auditors’ competence by experts. In the opinion of executive B5, there is too much emphasis on compliance auditing in auditors’ courses and this is why "80% of the findings [audit findings] are related to control of records and control of documents which gives no value to the organisation”. According to consultant B1, the emphasis on compliance auditing is the product of an old standardisation problem, when in the year 2000 the approach of the ISO 9000 standards was changed from quality assurance to quality management with a focus on processes, the ISO/TC 176 committee did not update the auditing standard. Hence, there was a gap of two years between the publication of the ISO 9000 standards and the new ISO 19011:2000 standard for auditing. In fact, as executive B1 explained, "the hole was disastrous, because with the new ISO 9001 standard, organisations had to implement a new management approach and it was not clear how this would be audited. As there were no guidelines to be followed, audits were performed with the previous approach [quality assurance rather management system]". But more

surprising was that when the ISO 19011:2002 standard was published, it contained the same quality assurance approach of the previous version and this approach has been maintained until the present time. Hence, the divorce of approaches within the ISO 9000 family is causing a wrong audit focus which is not giving much value to organisations.

And this is precisely the most important problem that CO are facing with internal audits according to the interviewees: audits are not providing organisations with added value. Executive B1 explains it in this way:

> "Auditors conduct internal audits with an established checklist which does not permit them to detect management findings, but failures. For example, an audit report stating that a lamp does not work; that no assessment was made to a specific supplier; and so on, does not provide value to the directors. From the point of view of management, that audit report does not add value".

The lack of added value of internal audits means that organisations personnel and top management do not take this practice seriously, according to experts B4, B5, B7, B8, B17 and B19. As auditor B4 points out:

> "there are areas where audits are perceived as 'useless', people think there is too much emphasis on records and that there are also differences between the documented activities [in the quality manual and procedures] and the real operations. Therefore, they do not cooperate by giving information [necessary for the audit]".

Interviewee B5 describes the normal reaction of top management in these circumstances "No consideration is given to the results of the audit in improving organisational performance, so no resources are allocated to the audit. People think, 'I will not allow this person doing testing [at a laboratory] to stop what he is currently doing to address an audit that does not add value'".

Questioning the experts about the reasons why internal audits do not provide added value to organisations, interviewees shared the view of third party auditors and certification managers that the "checklist" view of standards is causing most of the problems. Expert B7 explained it in this way "the audits do not focus on the operation of the organisation but on the requirements of the standard, which does not add value". And audits focus only on the requirements of the ISO 9001 standard is an incorrect approach because the standard itself has a lack of clarity as well. As Executive B10 remarks: "the standards are not clear and explicit, have errors. ISO 9001 is not clear in many concepts and its guidelines are brief. Standards bodies are not concerned about clarifying the [ISO 9001] requirements".

But there is also another reason why audits are not providing added value according to the interviews, the lack of focus on performance of the ISO 9001 standard. Expert B1 explains:

> "There are no guidelines on how to do an audit with a focus on processes, there are no unified criteria about how to do it. Auditing standards have a huge hole there. There is a lack of indicators needed to measure the performance of audits, but also indicators to measure the QMS are needed. All processes of the QMS should have indicators of customer satisfaction and continuous improvement to determine whether the QMS is operating properly and these indicators have to be related to the quality policy, which establishes a system of measurement. If you do not have a consistent measurement system, you cannot have a good audit"

Regarding how the problems in internal audits are impacting the performance of QMS, interviewees agreed that the biggest impact is that organisations' QMS are not improving as expected. Indeed, expert B19 pointed out:

> "The systems [QMS] are not utilised for the purpose which they were designed. They are not a strategic tool, as they should be. Most systems have lost their focus, they were 'over-documented' or not integrated properly and the audit did not detect it…The organisations know that the system is poorly implemented, that is not giving the expected results, but they do not know how to change it".

And a QMS that is not improving as expected creates dissatisfaction in all the personnel working with it as well as top management, according to experts. This echoed Power & Terziovsky (2006) findings about top management dissatisfaction with the current audit practice.

As far as third party audits are concerned, the most common problem addressed by interviewees is also the lack of added value of the audits. As expert B1 explains "the Directors do not see the audit process as an activity that gives them value. Hence, what to pay for something that only reports failures?" Indeed, auditor B4 pointed out that generally, auditees see external audits as an 'easier' exercise that internal audits.

According to interviewees, there are a couple of reasons that explains why third party audits do not add value to certified organisations. Firstly, in the opinion of interviewee B2 "external auditors do not completely understand the business [companies' business] and that makes them 'block', which causes them to mark non-conformities that do not give value to the organisation". This perception was shared by experts B5, B6, B7, B9, B10, B17 and B20.

A further reason is that third party auditors also have to deal with an inherent 'conflict of interest' when they conduct audits. Auditors have to audit QMS with the pressure to satisfy clients' expectations which give them little room to conduct a deep assessment because it can cause that the client complains and changes the certification body. Executive B19 remarked "auditors conduct audits with the objective to 'please' the customer and not with the aim to deeply assess the system.

It is not a matter of competence, but of attitude. They think 'If the customer asks me, I will give a plus, but if not, I will only review the requirements'".

Interviewees also believed that third party auditors face the same problem that internal auditors regarding the lack of clear audit criteria to assess QMS performance. As expert B1 explained "there is a lack of supportive standards and guidelines for certifications bodies to audit with a focus on processes instead on assurance, there is not a competence problem, clear audit criteria are missing".

Finally, problems in third party auditing are also a consequence of the lax accreditation system established by the ISO, as B10 executive pointed out "certification bodies are not concerned about assessing you, but about profits. There is no ethic in many certification bodies because there is a lack of international monitoring about how certification bodies are assessing clients". Hence, more regulations and a clear accreditation system for certification and accreditation bodies are needed, according experts B1, B6, B10 and B19.

Regarding the necessary improvements for the audit process, interviewees agreed that audits should be focused on the business performance of the organisation in addition on compliance with ISO 9001 requirements. In the words of expert B1, audits can be improved by "using the audit as a strategic business tool, where the audit traces all quality management processes with a focus on systems' improvement and not only on a compliance approach to requirements". This view was shared by auditors B5, B6, B7, B9, B17, B18, B19 and B20.

In order to provide audits with a focus on organisations' performance experts suggested two main actions: involve top management in the audit objectives and create a clearer set of criteria for the performance measurement of the QMS. As far as the first action is concerned, experts believed that if the audits are also focused on top management needs, their results will be more appreciated because they will be aligned with the strategy of organisations. As executive B7 explained "auditors should ask managers: how they see their business? What concerns do they have? And then ask them: What do you want from the audit? What do you want it to be focused on?" The second action refers to the creation of performance measurement guideless for QMS that provide clear audit criteria to auditors about how to assess the performance of QMS. Interviewee B5 put it in this way "we need tools to help measure the performance of audits that result in a good measure of organisational performance [QMS performance]. If the managers see the benefits, then they will assign resources". This view was shared by experts B1, B6, B17 and B19.

Interviewees also suggested creating clear measurement guidelines for services in order to improve audit practice, because the ISO 9000 standards are mainly aimed at manufacturing companies and not at service organisations. As expert B6 pointed out "there must be clarity in the standard [9001] between 'product' and 'service'. Guidelines for measuring service should be clear". Hence, individual performance measures for processes need to be incorporated into ISO 9000 standards.

Regarding the PM techniques used by certified organisations; all the interviewees recognised that they have not implemented any technique to measure the performance of the internal audit process or of the QMS. Nevertheless, they have implemented KPIs to processes and most of the organisations have designed a dashboard containing all the KPIs required by the ISO 9001 standard. The balanced scorecard is the most known PM technique between experts, but it is not used jointly with the QMS.

Finally, experts were asked about how CB could better interpret their client's performance when conducting third party audits. As with internal audits, experts believed that third party auditors should conduct audits with a focus on the business of the organisations. Consultant B1 explains the normal reaction of top management regarding this issue "Did I pay to be told that I have to paint security stripes? No, better tell me how I can improve the business". Nevertheless, interviewees also agreed that in order to change the focus of audits from compliance to business, more audit criteria regarding how to measure the performance of the QMS is needed. In this way "auditors would see audits as an improvement tool, because if they are conducted only to meet the requirements of the standard and do not detect improvements, businesses can stay out of market" (Executive B2).

It is also necessary that auditors conduct a better preparation prior to undertaking the on-site audit. As consultant B18 remarked "they need to know the business, their goals and strategies prior to conduct the audit". This is important because, in the opinion of interviews, only if they know the business, auditors will be able to provide added value.

Findings from the interviews with standardisation experts

All the interviewees agreed that the concept of 'performance' is not defined within the ISO 9000 family, even if some of the standards use the term. This omission, as expert C1 clarifies, has an historical reason:

> "The term 'performance' was not defined because it was not considered a key concept at that time [when the ISO 9000 standards were created]. What the ISO/TC 176 committee was looking for was that companies met the requirements of the standard, which had to be included in the QMS. So, we never talked about performance but compliance with the requirements. The 2008 version speaks of 'performance' only in the customer satisfaction clause, but the standard is still really focused on the effectiveness (the result obtained versus the planned objectives). Even now ISO 9001 is not focused on efficiency, not to mention 'performance'".

Executive C2 also remembered that the focus on compliance of the ISO 9001 standard has its origins in the military background of the standards. In fact, he explained:

> "The 9000 standards came from the military purchasing standards. When the military industry buys something, they just care about the product; they do not care about the performance of the business. So, the focus of their standards [military] was really on the quality assurance of the product. The 1997 version of 9001 adopted that approach. It was just recently; in the 2000 and 2008 versions, that some requirements of the standard changed to provide a benefit for the organisation itself, not only the customer that purchased the product."

Hence, performance is a relatively new concept within the ISO 9000 family and this is the reason why even if it is used in some clauses of ISO 9001 and ISO 9004, it is not defined in ISO 9000.

Nevertheless, the interviewees agreed that performance has two main connotations within the ISO 9000 family. For ISO 9001 it is meeting customer requirements and achieving customer satisfaction, whereas for ISO 9004 the meaning is wider and implies satisfying all relevant third parties not only customers. However, as executive C7 pointed out, the problem of the concept not being defined is that "if you ask 150 people at the committee [about the meaning of 'performance'] you will probably get 150 different answers".

Furthermore, the meaning of performance in the ISO 9000 family is also closely related with the two different approaches of its main standards. ISO 9001 is focused on effectiveness whereas ISO 9004 on sustained success. Expert C7 explained that the reason for two approaches is that "ISO 9004 is focused on improving the organisation as a whole, not the quality, not the environment, but the organisation as a whole. Whereas ISO 9001 is just talking about the effectiveness of QMS, it is talking about one part of the organisation, a subsystem".

There is also another subjacent reason for the two approaches and executive C2 clarified it as follows:

> "You cannot judge a company by its efficiency; you cannot give someone a certificate based on efficiency. You can only judge their effectiveness. If the company manufactures products and you audit their products and they have good quality, then you can give a certificate to the organisation because they meet customer requirements. But you cannot say 'I looked at company A and it was 10 times more efficient that company B, then I will give the certificate to Company A'. It is a problem about audit criteria"

Thus, ISO 9000 standards have not adopted the highly accepted meaning of performance of Neely *et al.* (1995), discussed in Chapter 3, because the ISO/TC 176 committee has not found the way to audit effectiveness within organisations in order to grant certification. Expert C2 also explained how the ISO/TC has analysed this issue:

> "There are many measures about performance assessments; the problem is how you report it. Some Business Excellence Models do it in terms of points. So, we discussed [at the ISO/TC 176] if the audit process should be changed for a points based system. But people are comfortable with the current audit criteria, if we move it to a points based system, audits will be more subjective because they will be based more on auditors' opinions and people are not comfortable with that, they want repeatable audits based on objective criteria"

Hence, audit limitations are stopping the development of the ISO 9000 family from compliance to performance and, as executive C4 pointed out, to measure the effectiveness of the QMS is not enough for certified companies anymore. Experts from the ISO/TC 176 know it and that is why ISO 9004 was launched. But the problem is that ISO 9004 is not certifiable and its PM concepts should be included in ISO 9001 in order for companies to adopt them (Expert C4).

Asked about what are the other PM methods within the ISO 9001 standard to measure the performance of the QMS, most of the interviewees agreed that customer satisfaction, management reviews and audits are the methods to measure the performance of the QMS (Experts C1, C2 and C8). Nevertheless, there was a no consensus between experts on this issue. In fact, as executive C4 stated the problem is that "the clause of customer satisfaction is the only one which explicitly talks about performance, but the problem is that ISO 9001 does not tell you how to perform this measurement, it is left wide open". Moreover, as expert C4 also explained, the lack of PM criteria is causing other performance problems "the auditors have no parameters to see if what organisations are doing to measure customer satisfaction is correct".

But, there are more problems in the audit process, apart from PM criteria. Regarding internal audits, there was a consensus between interviewees that the main problem is that organisations are not getting sufficient value from their audits. In the opinion of interviewee C2, this is closely related to how organisations see quality and certification. In fact, he pointed out "If they [companies] see quality and ISO 9001 negatively, they are going to do the minimum to comply with the standard. But if they treat it seriously, they will see it as strategic for the business and they do the best to maximise the benefits of their QMS". This perception is also shared by expert C4 who also added "for companies it used to be very important to have ISO 9001, ISO 14001 and OHSAS. Now it is not that important, companies see it as a cost. The problem is that if companies do not take the QMS seriously, then to have ISO 9001 becomes a routine. This impacts audits because they can become a routine exercise that do not add value".

Interviewees also agreed that auditors' competence and experience is a problem when conducting internal audits (Experts C2, C7 and C8). The competence of auditors who conduct internal audits is simply "not sufficiently high and also it has declined during the last decade" (Expert C7). Moreover, according to interviewee C8,

internal auditors cannot provide their organisations with good audits because they do not have knowledge of risk management and process management which is need to have a good assessment of QMS.

Finally, experts also addressed the lack of Top Management commitment as a problem in internal auditing (Experts C1 and C4). Executive C4 explained that "companies do not see internal audits as an important exercise, they have other priorities and this explains why audits are constantly re-planned".

Regarding third party audits, experts considered that the false expectations that organisations have about certification is one of the main problems (Experts C2, C4 and C7). As executive C7 explained, "many organisations think that the result of certification is excellent products and this is not what ISO 9001 certification delivers, it delivers the capacity to do that". Expert C2 pointed out that the misunderstanding about the objective of the third party audit about only assessing compliance is one of the reasons for this. He explained it clearly by stating "external auditors are only allowed to assess compliance". Hence, organisations cannot expect more from third party audits than a compliance focus and this is one of the reasons they create false expectations about the certification. Nevertheless, as interviewee C4 recalled, when certification bodies have tried to provide organisations with an added value audit, this new approach has not been welcomed by many organisations. He stated it in this way "the problem of certification bodies' auditors is that if they try to add value, they raise many non-conformities and companies do not like it". There is also another reason why third party audits do not provide an added value to organisations "companies do not pay for better auditors. They want cheap services. It has reached a point where 9001 [certification] is seen as a cost, companies want the lowest price and the least disturbing auditing" (Expert C4). Executive C2 explained the root cause of this:

> "For the 1994 version of 9001 you needed the checklist approach [compliance] but with the 2000 you need auditors to act as business consultants in assessing the company system. But companies [CB & certified organisations] already have 13 years working with the checklist approach, so they cannot afford to move into the new auditing approach that is needed. So, what you have is that auditing has become a commodity system which is determined by the lowest price just in order to get the certificate. Hence, certification bodies are conducting third party audits with not much value and certified organisations do not see any benefit from that. They [certified organisations] will have a better benefit if auditors can act as business consultants, but they need to pay for that. So, there is a conflict where certification bodies are not paid enough for conducting the type of audits that are needed for the 2000 and 2008 versions and organisations are not willing to pay for a better audit"

But third party audits are not providing added value to organisations because there is a lack of PM criteria within the ISO 9000 core of standards (Experts C1, C4, C7 and

C8). In fact, the interviewee C4 conclusively remarked "there is a lack of metrics to measure the performance of the QMS". Also, Expert C1 addressed the issue that there are no metrics to assess the performance of audits either. In the view of interviewee C8 this is a direct consequence of a lack of attention of the ISO/TC 176 committee about the problems that industry is facing with the audit process. Furthermore, expert C7 argued “more audit criteria [PM criteria] is necessary but there is no pressure from industry to do that. It is not an obvious problem, but it is a problem”.

Interviewees also agreed that third party auditors’ competence and training is an important problem in external auditing. As expert C2 explained “certification bodies train their auditors a lot and they are not good enough, this is a big problem”. Moreover, interviewee C8 provided a reason for this problem, “there is not enough attention to human factors in the standards [ISO 9001 and ISO 19011]. Auditors speak the language of ISO clauses and managers speak in terms of cost and risk. So, auditors should also speak the language of business and not just the standards one”. This view was also shared by expert C1 who also added “auditors are very technical and have a hard time understanding management concepts, such as costs. It may appear that these concepts are easy for them, but they are not. It is a learning issue for auditors, but also for the organisation [CB]”. In fact executive C2 emphasised “many companies [CB] are trying to recruit auditors in very sophisticated ways, but there are a lot of problems with auditors individually”. Also interviewees C2 and C7 addressed the problem of subcontracted auditors in the third party audit process. Interviewee C2 emphasised “they [CB] have also problems with subcontracted auditors, they are not as good as internal auditors [internal auditors of a CB]”.

Questioned about how the problems in the audit process are affecting the performance of the QMS, executive C2 stated:

> “This depends on how much the company values its 9001 certification and how they see audits. Unfortunately, we know that more than 50% of 9001 certified companies see the certification as a bureaucratic cost that they have to face in order to do business in certain sectors, these companies are not bothered about auditors. They want people [third party auditors] who come and check the system, go away and give them the certificate, they do not really care. On the other hand, we have progressive companies who really value good audits and if they receive just a compliance audit, they will complain”

Nevertheless, for experts C1, C4, C7 and C8 the main effect on ISO 9001 QMS is that organisations are not taking advantage of their systems. As interviewee C4 explained “in many organisations there are many records that do not add value, the system is not providing good feedback that will serve to improve processes”. As executive C1 remarked “a mishandled QMS is a burden to the organisation if it is not used properly”. Also a QMS which is not performing correctly causes dissatisfaction and frustration of the top management who have to maintain it (Experts C1, C4 and C8).

Interviewees also suggested that changing the current approach of audits will improve the audit process (Experts C1, C7 and C8). Executive C1 explained it in this way “the current audit focus of compliance with the requirements should be changed to an improvement focus. So auditors would have to seek improvements and opportunities within the organisation”. Interviewees C1 and C8 also believed that the improvement focus should be complemented with a focus on the business as well. In fact, executive C1 argued “the 9001 standard should include a section regarding how to align the organisation’s strategies with the QMS. The ISO 19011 and ISO 17011 [for CB] auditing standards should have guidelines on how to audit these strategies, so auditors will be able to audit them”. However, as expert C7 remembered “the body in charge of developing more auditing guidelines is IAF [the International Accreditation Forum], but unfortunately they are not developing more audit criteria and guidelines”. In fact, as executive C1 explained “the new 19011 is focusing on the competence of the auditor, but the original problem is in the audit criteria in 9001. Although auditors are very good and detect problems, if these problems are not included in the audit criteria of ISO 9001, auditors cannot state non-conformities”. Expert C4 was also sympathetic with the idea of developing more audit criteria to help auditors to assess the QMS and these audit criteria should be created according to industry sectors, such as ISO/TS 16949 for the automotive industry.

There was also the view between experts that in order to improve the audit process, it is necessary to provide better training to auditors (Executives C1, C7 and C8). As interviewee C7 explained “better auditing training is needed to increasing auditor's competence. Many auditors do only one training course and then they get the certification to perform audits. So, more and better audit training is needed”. Interviewee C1 also added “audits should help the organisation to learn, to create an atmosphere of 'knowledge management'. Hence, better guidance should be provided to auditors to obtain better information from the audit”.

Regarding how much PM techniques are used in the audit process by organisations and CB, experts agreed that there is more penetration of PM techniques in CO than in CB. Nevertheless, their use at CO is not standardised. As expert C2 recalled:

> “the standards do not require using performance measurement techniques. So, some companies are using self-assessment models or tools such as the European Business Excellence Model, others are using statistical process control techniques and statistical software. But apart from that, there are no other performance measurement techniques used. In fact, one of the discussions we already had between the committee [ISO/TC 176] is whether the standard will include a more rigorous statistical approach for measurement”.

According to experts C1 and C8, the balanced scorecard is the PM technique most used by CO but they do not use it together with their QMS.

Questioned about how an academic proposal to improve audit practice may be included in the ISO/TC 176 agenda, interviewees agreed that the best way to raise a topic at the committee is by becoming a national delegate. If fact, expert C7 stated "academics need to belong to the ISO/TC 176, there is no possibility to influence the committee if you are not a member". He also remarked "there are not many academics on the TC/176 committee. One of the reasons is that scholars do not see the ISO/TC 176 as relevant, so they are not involved which is a pity because the committee will be better with more academics".

Finally, experts addressed the challenges of the ISO 9000 family. Experts C1, C4 and C7 agreed that the ISO 9001 standard needs to evolve into a performance oriented tool which helps organisations to improve. Executive C7 stated it in this way "the great challenge is that the ISO 9000 family needs to be re-written in terms of ISO 9004, including whole organisation issues such as knowledge, management, risk and innovation". For experts C1 and C4 a focus on performance was needed "excellence models incorporate performance measurement, but the 9001 is intended only for effectiveness. The 9004 looks at the issue of performance a bit, with the KPI clause. However, there are other standards that are more focused on performance such as UNE 66174" (Executive C4). Nevertheless, in order to change the approach of the ISO 9001 standard, the experts in the ISO/TC 176 committee need more competence (Experts C4, C7 and C8). In fact, interviewee C7 stated "there is no competence in the committee to include these issues [management]. There is a lot of competence regarding quality but not in other management issues and this is the biggest concern". Interviewee C2 explained the problem within the ISO/TC 176 committee:

> "9001 is a very successful product and there is a negative perception [from customers] about changing the standard. How can any organisation survive with a product that is based on technology which is 20 years old? We need to evolve the product but we have an internal conflict between some people wanting the standard to remain as it is today and those who want the standard to progress and go to new areas".

Another important challenge for the ISO 9000 family is regarding the integration of the management systems standards. As expert C4 pointed out "companies are implementing models of sustainability, social responsibility and environment and the ISO TC/176 is not incorporating these concepts. The 9001 could disappear if does not adapt to these changes".

Interviewees C4 and C8 also addressed the issue that the ISO TC/176 committee has to prove the relevance of ISO 9001 and ISO 9004 to managers, in terms they understand and not in subjective ways. There are organisations which have been certified for more than 15 years and the certification does not represent a competitive advantage for them anymore (Expert C4).

There are also problems with the standardisation process which affects the ISO 9000 family. Executive C4 explained that the whole standardisation process is very slow

and this means that when standards are published they are not at the cutting edge of management systems.

APPENDIX F
THE AUDIT+ PROCEDURE

Procedure for conducting ISO 9001:2008 audits with focus on performance (Audit+)

This methodology is part of a research project conducted by the University of Nottingham Business School and funded by the Mexican Council for Science and Technology (CONACYT), under Grant Number *211638*.

Developed by Flor Monica Gutierrez-Alcantara and reviewed by James D. Tannock

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1. Rationale of Performance Auditing (Audit+)

The ISO 9001:2008 standard requires that certified organisations implement controls to assure that they are appropriately assessing products/services, processes and their quality management system (QMS). Moreover, organisations must implement and maintain three QMS Performance Measurement methods: *Management Reviews, Customer Satisfaction* and *Audits*. In the ISO 9000 context, the implementation of these methods ensures that the organisation's QMS is performing correctly and providing Top Management with the information needed to improve the QMS (ISO 9001[45], 2008) and the capabilities of the organisation. Nevertheless, organisations, especially SMEs, experience considerable problems with the measurement of their QMS (Briscoe *et al.,* 2005). The authors of this procedure believe this may be due to the lack of standards and guidelines regarding the performance of the QMS.

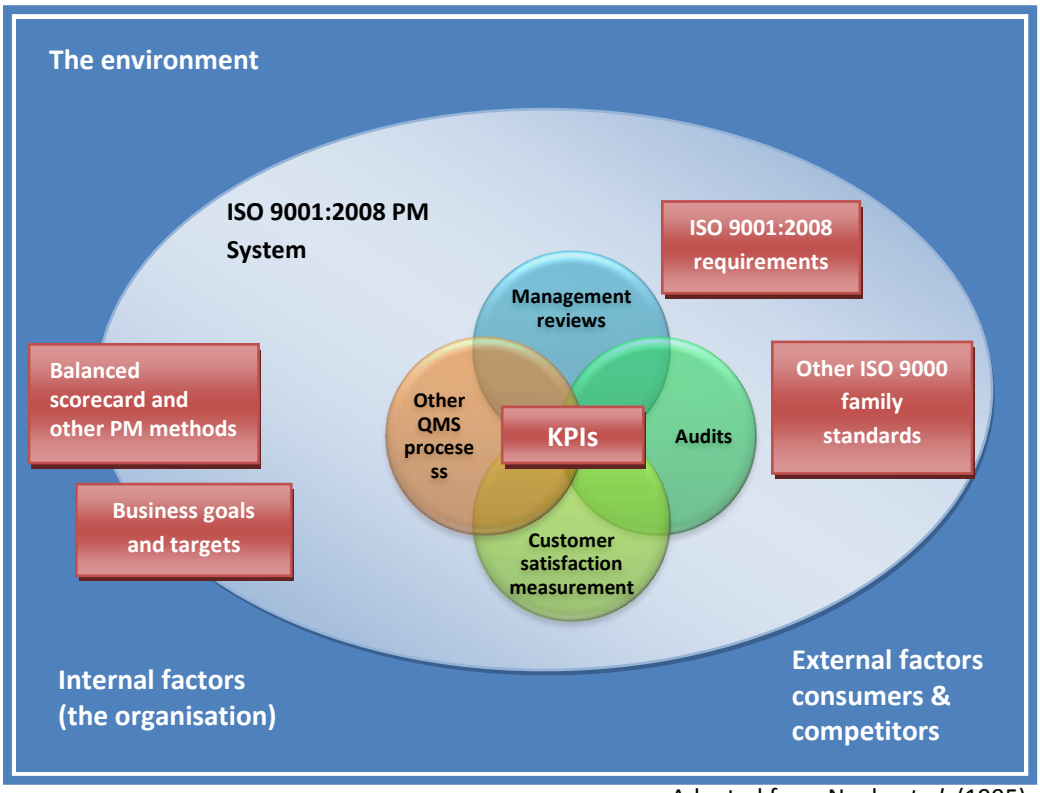
In order that organisations are able to improve their capabilities, it is necessary that they monitor, measure and control their environments (Taticchi *et al.,* 2010). The implementation of Performance Measurement (PM) techniques helps to improve the capabilities of organisations (Honque & James, 2000; Ittner & Larcker 2003; Rey-Marston & Neely, 2010).

PM is defined as *"*the process of quantifying the efficiency and effectiveness of action" (Neely *et al.,* 1995, pp. 80). Bourne *et al.* (2003) argue that although this definition is still valid, the concept of PM has changed and currently refers to a multi-dimensional set of performance measures for the planning and development of a business. This set includes financial and non-financial measures regarding its internal factors (measures related to the organisation) and external (measures related to market in which the organisation competes) which are contrasted in current and future scenarios, to evaluate and predict the organisation's performance. Examples of internal factors affecting the performance of organisations are: structure, culture, management style and resources; whereas external factors can be: competitiveness of the industry and the economic and political situation (Franco-Santos & Bourne, 2004). One of the internal PM factors that encourage the improvement of organisations are quality initiatives (Neely *et al*. 1995).

Moreover, Bourne *et al.* (2003) also conclude that PM cannot be done in isolation because PM is only relevant when a correct reference model exists and the measures can be compared. The authors of this procedure argue that the ISO 9000 family of standards provides a good reference model where performance measures can be compared (see Figure 1.1). In fact, it is important to note that the ISO 9000

[45] The ISO standards published by British Standard Institution (BSI) have been consulted to develop this document. The BSI is a National Member Body of the International Organization for Standardisation (ISO) and is authorised to publish official ISO standards in English on behalf of the ISO.

family has a strong focus on quantifying efficiency and effectiveness which is in accordance with the PM definition.



Adapted from Neely *et al.* (1995)

Figure F.1 The framework for performance measurement of ISO 9001:2008 QMS

The ISO 9000 QMS performance measurement methods (*Management Reviews, Customer Satisfaction* and *Audits*) are granted the same importance within the ISO 9001 standard. Nevertheless, in practice, Audits are the most important method for evaluating the performance of QMS because "[a]udit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement" (ISO 9000, 2005, pp. 5). Also, audits are used by certification bodies to grant ISO 9001 certification, as well as being used as a self-assessment tool for certified companies. This dual usage of audits makes them the primary PM method in the ISO 9000 context. Moreover, the use of audits as a PM method for QMS is reinforced in the management process of the ISO 9001 standard, where the results of both internal and external audits are used as an input for conducting Management Reviews (see ISO 9001:2008, Clause 5.6.2).

In order to conduct quality audits with a focus on performance, it is necessary to plan and develop them with regard to the three levels of scrutiny of the ISO 9000 standards: products/services, processes and the QMS (see Figure 1.2 in ISO 9001:2008). Also, when planning and conducting the audit, it is necessary to identify and evaluate the effective development of business measures and targets. The division of measures within the QMS into products/services, processes, QMS will

permit audits to have a better focus and provide the basis for a clearer assessment of the performance of the QMS.

For assessing the 'products/services' level of scrutiny, it is important to focus on individual performance measures. Neely *et al*. (1995) categorise them into four types: **quality**, **time**, **flexibility** and **cost**. Regarding the 'processes' level, auditors have to pay attention in assessing their **effectiveness**, **efficiency** and **adaptability** (Rohleder & Silver, 1997). As stated above, **Management Review**, **Customer Satisfaction** and **Audits** are special performance methods of the ISO 9001:2008 standard and when they are implemented as processes should be audited taking into consideration their correct **design**, **implementation** and **use** (Franco-Santos & Bourne, 2005). Finally, when planning and conducting the audit, auditors have to establish how the measures of the three levels of scrutiny are impacting the overall business measures and targets (Franco-Santos & Bourne, 2005). The interaction of these measures is shown in Figure 1.2. It is important to highlight that PM is more effective when the measures are appropriately designed (Neely e*t al.,* 1997), include multiple dimensions (Lingle & Schiemann, 1996) and are structured in a way that helps managers understand the interrelationship and reflects strategy (Lipe & Salterio, 2000; 2002).

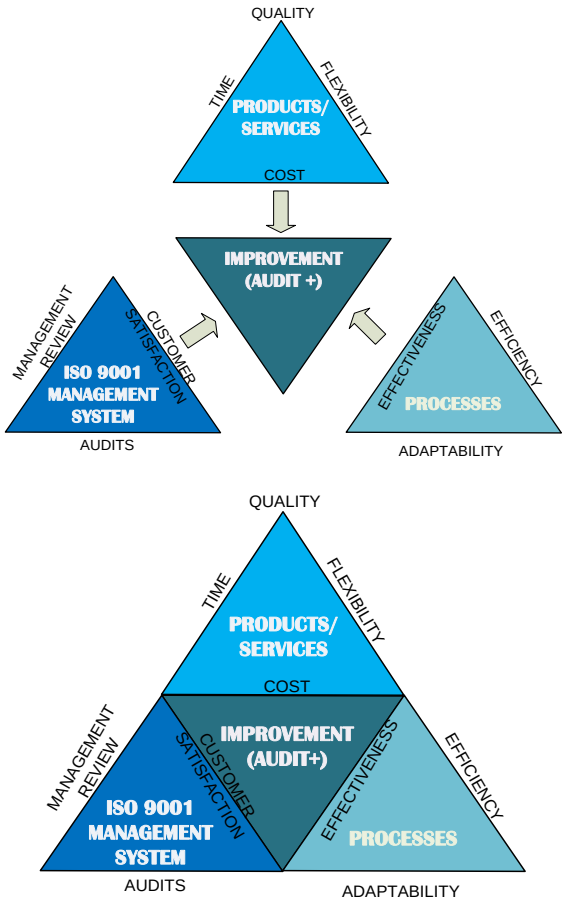


Figure F.2 Performance Auditing Triangle (Audit+ Triangle)

In order to help organisations to measure the performance of their QMS through conducting audits, this procedure includes concepts of Performance Measurement, Business Process Improvement, Business Process Re-engineering and Resource-Based View. A bibliography is included at the end of this document.

2. Purpose of the Procedure

The purpose of this procedure is to provide Audit guidelines to ISO 9001 certified organisations to conduct internal quality Audits based on performance. These guidelines are generic and organisations need to take into consideration their size, QMS maturity and industrial sector when planning, developing and conducting the follow-up of the Audits in order to correctly apply this procedure.

Other third parties such as Certification Bodies can use this procedure to conduct a third party assessment in order to provide an impartial examination to the Top Management of the organisation.

3. Scope of the Procedure

This procedure can be used by ISO 9001:2008 certified organisations for conducting internal Audits as well as for third party assessment.

Organisations can conduct their ISO 9001:2008 audits with a focus on performance (Audit+) following the proposed sequence of this document. However this procedure can be adapted to the particular needs of each organisation.

The use of this procedure is recommended when certified organisations have a maturity level of 1 to 4 according to Annex 'A' of ISO 9004:2009. The Spanish standard UNE 66174 (2010) "Guide for the assessment of management system standard for the sustained success of an organisation according to UNE-EN ISO 9004:2009" provides a complementary numeric framework for assessing the maturity level of ISO 9001 QMS and should be used before applying this procedure.

This procedure is complementary to the ISO 19011:2002 standard "Guidelines for quality and/or environmental management systems auditing" and ISO 9001:2008 "Quality management systems – Requirements". This procedure must be applied in conjunction with these international standards.

4. Responsibility and Authority

Audit Team Leader: appoint the Audit Team in conjunction with Top Management or its representative (internal Audits); create the Audit+ plan and the Audit+ checklist in conjunction with the Audit Team; agree the Audit+ plan with the auditee as well as the dates and times for conducting the on-site Audit+; conduct the opening and closing meetings of the Audit+; assess the performance of

products/services, processes and the QMS according to the Audit+ plan and Audit+ checklist; draw the conclusions of the Audit+ with the Audit Team; present the Audit+ report to Top Management on behalf of the Audit Team; review the proposed Audit+ action plan for resolving the audit findings; declare the Audit+ closed.

Auditor Team: create the Audit+ plan and Audit+ checklist for the on-site Audit+ in conjunction with the Audit Team Leader; attend the opening and closing meetings of the Audit+; assess the performance of products/services, processes and the QMS according to the Audit+ plan and Audit+ checklist; draw the conclusions of the Audit+ in conjunction with the Audit Team Leader.

Top Management: appoint the Audit Team Leader and the Audit Team; provide the Audit Team with the necessary resources to conduct the Audit+; communicate to the organisation's personnel the importance of participating in the Audit+; attend the opening and closing meetings of the Audit+; review the Audit+ report and appoint a "follow-up group of experts" who will be in charge of developing an Audit+ action plan to act to resolve the findings; review on a periodic basis and during Management Reviews the status of the audit findings.

Top Management Representative: conduct all the Audit+ activities assigned by Top Management.

Follow-up Group of Experts*:* determine the root-cause of the audit findings; develop the Audit+ action plan to resolve the audit findings; review the suitability of the Audit+ action plan with the Audit Team Leader to resolve the audit findings; conduct the follow-up of the Audit+ action plan; report the results of the action plan to Top Management on a periodic basis and Management Reviews.

Auditee: agree the Audit+ plan with the Audit Team Leader as well as the date and times for conducting the on-site Audit+; provide the Audit Team with all necessary information in order for them to conduct a comprehensive assessment of products/services, processes and the QMS; attend the opening and closing meetings of the Audit+ when required; support the 'follow-up group of experts' to resolve the audit findings.

5. Description of Activities

Inputs

- Audit programme
- Quality manual
- Procedures, work instructions and records of the QMS
- Business goals and targets

- Maturity level diagnosis (obtained by conducting the self-assessment evaluation provided in Annex A of ISO 9004:2009 and the Spanish standard UNE 66174 (2010))
- Balanced Scorecard, Dashboard, List of Key Performance Indicators (KPIs) (if applicable)

Planning the Audit+

5.1 The audits with a focus on performance (Audit+) are conducted with a process-based approach, thus the Audit Team Leader and the Top Management (in the case of an internal audit) or its representative will appoint an Audit Team with a strong knowledge of the QMS and business processes of the organisation. In order to appoint the auditors, the proposed objectives, scope and criteria needed to develop the Audit+ as well as the business goals and targets of the organisation should be taken into consideration. The appointed auditors should have a clear knowledge, not just about the processes they will review but also about the business strategies and goals of the organisation.

When planning the Audit+, it is important to maintain the 'independence principle of auditing', thus owners of processes must not audit their own processes.

5.2 Audit+ provides Top Management with information to improve the QMS according to the business targets and goals of the organisation, therefore when the Audit Team have developed the Audit+ plan, Top Management or its representative will review it to ensure that the Audit+ plan takes into consideration all of the organisation's goals and targets that are important for the Top Management, in addition to the requirements of the ISO 9001:2008 standard.

Depending on the size of the organisation, the scope of the Audit+ may be limited to specific processes or the QMS.

***NOTE**: If Top Management has developed a balanced scorecard or a similar performance measurement tool identifying the goals and targets of the organisation, the Audit Team should be provided with a copy*

5.3 The Audit Team will identify all of the processes in the quality manual that will be audited and all other relevant documents which are a part of the QMS (for example work instructions and procedures). Also, the Audit Team will identify all the business processes that interact with these processes (for example processes relating to strategy and finances).

NOTE: *Business processes are those that transform resources that originated from outside the boundaries of the organisation and the outputs (goods and services) leave the boundaries of the organisation (Armistead et al., 1995)*

5.4 From the process identification of clause 5.3, the Audit Team will determine if 'artistic processes' will be assessed.

NOTE: *Artistic processes are not fully standardised and should be assessed taking into account that the inputs are variable (for example, no two pieces of wood used in piano soundboards are alike) and customers value variations in process outputs (each pianist appreciates the distinctive sound and feel of his piano). Examples of artistic processes may include*:

- **Leadership training**: developing decision making capabilities and self-awareness in individuals takes time and one-to-one coaching
- **Auditing:** applying the broad principles of new international reporting standards requires understanding the implications for each firm and using judgement to determine the right response
- **Customer service:** satisfying individual customers might require frontline employees to go 'off script' and do what they feel is best
- **Software development:** writing code for new applications often involves interacting with customers to learn how to refine the program to address their needs, as well as decisions on which corners can be cut

Source*:* Hall & Johnson, 2009.

Appendix A provides guidelines about how to categorise processes according the value of output variation for customers and the process environment.

5.5 The Audit Team will analyse the processes in terms of process elements, activities and tasks including their inputs and outputs. Hence, the Audit Team will identify the elements, activities or tasks which may not be adding value to the process (see Table F.1). This is a first review, the Audit Team will also be able to review if these elements are contributing to the process at the on-site audit stage.

One way to determine if an activity or task is not adding value to the process is reviewing if the process is filling out its objectives (Rohleder & Silver, 1997).

NOTE:

- **Process elements:** They are the major elements into which a process can be best organised. For example, a customer service business

process may have three elements: sales, order management and transportation

- **Activities:** Process elements can be broken down for ease of management into recognisable activities. For example, a sales process element can be broken down into management of customer accounts and claims processing
- **Tasks:** Activities can be broken down into tasks which are written up as standard operating procedures for individual owners to carry out

Source: Armistead *et al.,* 1995

Process	Element	Activities	Task	Inputs	Outputs	Value added
Customer service	Sales	Management of customer accounts	Assign order number	Client call	Purchase order number	No
			Process order	Client requirements	Purchase order	Yes
		Claims processing	Verify the validity of the guarantee	Purchase order	Claim order	Yes
				Product specifications		
			Process refund	Claim order	Bank deposit or check	Yes
	Order Management					
	Transportation					

Table F.1 Example of the construction of an Audit+ checklist based on processes

5.6 After analysing the processes in terms of elements, activities and tasks, the Audit Team will include the key performance indicators (KPIs) of each process in the Audit+ checklist (see Table F.2). If the organisation has developed a dashboard or similar tool with KPIs, the Audit Team will add these KPIs to the list. The auditors should then check the final list to ensure that no important KPIs relating to activities or tasks are missing. One way of detecting missing KPIs is to ask about measures of **quality**, **cost**, **time** or **flexibility** that help to control the activity or task (see Figure 1.2).

NOTE: *It is important that the Audit Team conducts its own revision of KPIs in order to identify possible omissions.*

Process	Element	Activities	Task	Inputs	Outputs	Value added	KPIs
Customer service	Sales	Management of customer accounts	Assign order number	Client call	Purchase order number	No	--
			Process order	Client requirements	Purchase order	Yes	Number of attended calls per person
		Claims processing	Verify the validity of the guarantee	Purchase order	Claim order	Yes	Number of attended calls per person
				Product specifications			Time to process the complain
			Process refund	Claim order	Bank deposit or check	Yes	Refunds granted

Table F.2 Example of the construction of an Audit+ checklist based on processes and KPIs

5.7 When all of the KPIs have been identified, the Audit Team will classify them as measures of **quality**, **time**, **cost**, and **flexibility** according to the guidelines provided in Appendix B of this procedure (see Table F.3). It is important to highlight that these four types of measures are strictly the minimum set of measures for an Audit+ based on ISO 9001:2008. Organisations which want to exceeded the scope of ISO 9001:2008 should consider that good measurement schemes include customer, internal operations, finances and improvement/learning needs (Kaplan & Norton, 1992)

NOTE: *If the organisation has implemented other management system standards such as ISO 14001, the individual KPIs of the management system, in this case environmental KPIs, may also be classified. Nevertheless, it is highly recommended that other management systems are included in the Audit+ plan after the first Audit+ has been declared 'closed'.*

Process	Element	Activities	Task	Inputs	Outputs	Value added	KPIs	Type of measure
Customer service	Sales	Management of customer accounts	Assign order number	Client call	Purchase order number	No	--	--
			Process order	Client requirements	Purchase order	Yes	Number of attended calls per person	Quality
		Claims processing	Verify the validity of the guarantee	Purchase order	Claim order	Yes	Number of attended calls per person	Quality
				Product specifications			Time to process the complaint	Time
			Process refund	Claim order	Bank deposit or check	Yes	Refunds granted	Cost

Table F.3 Example of the construction of an Audit+ checklist based on processes, KPIs and type of measure

5.8 The Audit Team will also identify the ISO 9001:2008 clauses that apply to each element, task or activity of the processes to be audited (see Table F.4). If the organisation has to comply with other regulations, the Audit Team should include these requirements in another column.

Process	Element	Activities	Task	Inputs	Outputs	Value added	KPIs	Type of measure	ISO 9001
Customer service	Sales	Management of customer accounts	Assign order number	Client call	Purchase order number	No	--	--	7.2.1 7.2.2 7.5.3
			Process order	Client requirements	Purchase order	Yes	Number of attended calls per person	Quality	
		Claims processing	Verify the validity of the guarantee	Purchase order	Claim order	Yes	Number of attended calls per person	Quality	7.2.3 7.5.1 7.5.3 8.2.1
				Product specifications			Time to process the complaint	Time	
			Process refund	Claim order	Bank deposit or check	Yes	Refunds granted	Cost	7.5.3 8.2.1

Table F.4 Example of the construction of an Audit+ checklist based on processes, KPIs, type of measure and ISO 9001:2008 clauses

5.9 When conducting an Audit+ which includes in its scope the assessment of the QMS, the Audit Team will pay particular attention to the evaluation of the processes or methods of Management Reviews, Customer Satisfaction and Audits due to them being performance measures of the QMS (ISO 9001, 2008). The Audit Team will develop an Audit+ checklist for these processes as described in clauses 5.4 – 5.8. The Audit Team will also include in the Audit+ plan the revision of the **design**, **implementation** and **use** of these processes (see Clause 5.20)

NOTE: *Appendix C provides generic examples of the processes of Management Reviews, Customer Satisfaction and Audits.*

5.10 Finally, the audit team will highlight the process elements, activities, tasks, inputs, outputs, KPIs and ISO 9001:2008 requirements which are related with the business goals and targets of the organisation.

5.11 The Audit Team Leader will prepare the final version of the Audit+ plan and assign the work to the Audit Team according to the Audit+ checklist developed in 5.5 - 5.9.

5.12 The Audit Team Leader will review the final version of the Audit+ plan and Audit+ checklist with the Top Management or its representative in order to assure all of the organisations goals and targets have been considered for the Audit+.

5.13 The Audit Team Leader will contact the auditees to agree a date and time for the Audit+.

5.14 The Audit Team Leader will agree with each team member his/her responsibilities for auditing specific processes, processes elements, activities, tasks, inputs, outputs, KPIs, products, services, sites, areas or functions.

Doing the Audit+

5.15 The Audit Team Leader will conduct the opening meeting of the Audit+ according to the ISO 19011:2002 guidelines.

5.16 Based on the Audit+ plan and the Audit+ checklist, auditors will collect and verify information to generate the Audit+ findings. In order to assess the effective implementation and performance of processes, auditors should assess QMS processes internally (process elements, activities, tasks, KPIs) and externally (their interaction with other processes of the QMS and with business goals and targets).

NOTE: Clauses 5.17-5.20 address how to assess QMS processes internally, whereas clause 5.22 describes how to assess them externally.

5.17 To assess QMS processes internally, auditors will use the Audit+ checklist prepared in the Audit+ planning stage, as well as the ISO 9001:2008 standard and the applicable regulations. Auditors will review that the activities and tasks of each process are functioning correctly and are delivering the correct outputs.

5.18 In order to assess if a process element, activity or task is not adding value to the process, auditors can use the 5W2H method: asking w*hat, why, where, when, who, how, and how much* about each one that is perceived as not contributing to the process. Auditors should be careful that an element, activity or task will not be required in the future before discarding it.

Note: The following is a list of possible sources of waste that auditors should consider when conducting the on-site Audit+:

- To assess if a process element, activity or task is complicated or unclear, auditors should check if simplification is possible (e.g. use simple language, use visual control tools, etc.)
- To detect possible non conformance output (causing inspection, rework, scrap, customer dissatisfaction, etc), auditors should conduct the Re's exercise (Robson, 1991) which asks the following questions:
    - Do you have places where products are sent because they have defects?
    - Do certain people do nothing but fix errors?
    - Is there a budget to cover corrective action for internal defects or errors?
    - Is there always time for re-doing things a second or third time?
    - Are there things that people do in a normal work day that begin with the prefix "re" (rework, re-examine, etc)?

  A positive answer to any of these questions may indicate a source of waste
- To evaluate if there is unnecessary transportation/movement of products, workers or consumers, auditors may review the layouts and look for simplification (relative locations of the different tasks in the process, as well as the layout of tools, files, supplies, etc.). In addition, combining, eliminating or changing the sequence of certain activities may obviate the need for some of the transport/movements.
- To assess unnecessary inspection, auditors should ask why defective products are produced in the first place. Some monitoring will be required, but it is important to determine if all of the inspection activities are needed.
- If workers or customers are waiting, this is a sign of waste unless the individuals involved are using the time for other productive purposes.
- Another important source of waste is duplication of effort – the same thing being done two or more times in the overall process.
- Auditors should also check if there is an unnecessary retention of records, quite often organisations continue creating and processing records even when they have become obsolete.
- Processing goods/information in large batches may be bad if for example it increases inventories or introduces extra delays. It tends to be caused by actual or perceived high setup or

changeover cost/times in moving from working on one type of service or good to another.

Based on: Rohleder & Silver (1997)

5.19 For evaluating the performance of KPIs, auditors will have to assess them against their established targets or goals.

5.20 When assessing QMS performance measurement processes (Management Reviews, Customer Satisfaction and Audits), it is important to review their **design**, **implementation** and **use**. The auditor should considering the following facts during the on-site Audit+:

- ***Design:*** The Audit Team should assess the specific metrics and KPIs of those processes related to business strategy; this approach requires going beyond the traditional approach of assessing them only against quality objectives. The audit team will have to answer the following questions: how well are these processes connected with the business goals, strategic targets and improvement initiatives of the organisation?; and are they designed to provide the Top Management with measurements that lead to the improvement of the QMS?

- ***Implementation:*** Here, it is important to assess how much are Management Reviews, Customer Satisfaction and Audits being used by Top Management to take decisions. Also, it is important to evaluate how much people in the organisation are involved in the development of these processes, e.g. audit activities (*empower*)[46]; how much education and training is needed by the organisation's personnel to conduct activities regarding these processes, such as data collection (*enable*); and how much are employees motivated to use the information generated from these processes, e.g. management reviews results (*encourage*). Finally, it is important that auditors assess the level of communication about the results of Audits, Management Reviews and Customer Satisfaction to employees.

- ***Use:*** To assess the use of the ISO 9001:2008 QMS performance measures, auditors should evaluate the continuous improvement of the measures themselves and their results and impacts on business goals and strategy with a clear focus on improvement and learning. For example, how much are audit and management review results leading improvement initiatives to the QMS.

[46] This management tool is known as "The 3E's: empower, enable, encourage"

Based on: Franco-Santos & Bourne, 2005

5.21 The Audit+ should be perceived as a learning activity by auditees. Hence when stating an audit finding, auditors have to be sure that auditees have perfectly understood the reasons for the findings and what may be necessary to resolve them (see section 'Acting on the Audit+').

Checking the Audit+

5.22 When preparing the audit conclusions, the Audit Team will state in the Audit+ report the current performance of QMS processes internally (process elements, activities, tasks, KPIs) and externally (their interaction with other processes of the QMS and with business goals and targets).

In order to look at the processes externally, auditors have to evaluate the overall performance of the processes according to the audit findings of each auditor. This can be done by assessing their effective implementation in three dimensions:

- **Effectiveness.** How well the current process achieves its objectives, including business goals and targets.
- **Efficiency.** The amount of effort and resources required to achieve the objectives
- **Adaptability.** How quickly and easily a process can be changed to meet different objectives or a reprioritization of the current objectives can be done.

***Based on*:** Rohleder & Silver (1997)

Also, auditors should evaluate how well is the process interacting with other processes of the QMS (e.g. customer satisfaction, sales, etc.) in order to have a complete assessment.

Note: In clauses 5.17 to 5.20 the assessment of QMS processes from an internal point of view was conducted. Hence, the audit team will discuss each individual finding and decide which will be stated as *'non conform' [non-compliant]*.

5.23 The Audit+ report will be developed following the classification of process elements, activities, tasks, inputs, outputs, KPIs, and ISO 9001:2008 requirements used in the Audit+ checklist (see Table F.5).

5.24 The Audit Team will clearly identify in the Audit+ report the conformance with ISO 9001:2008 requirements. Nonconformities with the ISO 9001:2008 standard should be graded according to the audit criteria of the Certification Body which granted the certification. Also, they should

be summarized according to ISO 19011:2002 guidelines (e.g. indicating locations, functions, processes assessed, etc.).

5.25 Performance findings will be stated in the Audit+ report only as '*performance audit findings*' without any extra categorisation. It is important that the report includes a clear description of the performance audit findings by process element, activity, task and outputs. The performance findings in products/services should also be included in this list of findings categorised by process in order that they can be easily traced. An example is provided in Table F.5.

Audit+ elements	Finding 1	Finding 2
Process	Customer service	Customer service
Process element	Sales	Sales
Activity	Management of customer accounts	Management of customer accounts
Task	Assign order number	Process order
Input	Client call	Client requirement
Output	Purchase order number	Purchase order number
ISO 9001:2008 requirement	7.2.1, 7.2.2, 7.5.3	7.2.1, 7.2.2, 7.5.3
KPIs	Not applicable	Number of attended calls per person The performance of the KPIs was satisfactory
Type of measure	Not applicable	Quality
Audit finding	The task is not adding value to the process. Revision by the owner of the process is recommended	This activity is not correctly interacting with the shipping process which is causing delays in supplying goods to clients. It is not affecting KPI performance or ISO 9001 requirements but it is affecting customer satisfaction
Type of audit finding (Performance and/or ISO 9001:2008 and/or other applicable regulation)	Performance audit finding	Performance audit finding

Table F.5 Example of an Audit+ report - Internal process assessment

5.26 The Audit+ report will also include a special section regarding the findings of KPIs. It is important that the audit team disclose them by type of measure (quality, time, flexibility and cost) in order that Top Management will easily understand them.

5.27 As stated above, the Audit+ has to be a learning exercise for the organisation. Hence, the Audit Team will develop an easy-to-follow Audit+ report which can be used as the basis of an action plan. It is important that the findings are written in an easy-to-understand language and not only in the technical terms of the ISO 9001:2008 standard.

5.28 The Audit Team Leader will conduct the closing meeting in accordance with ISO 19011:2002 guidelines.

5.29 The preparation, approval and distribution of the Audit+ report will also be conducted according to the audit guidelines provided in the ISO 19011:2002 standard.

Acting on the Audit+

5.30 After finishing on-site Audit+ activities, Top Management or its representative will appoint a "follow-up group of experts" who will review the audit findings and determine which actions are needed in order to resolve any issues raised. These experts should not be the auditors that conducted the Audit+ (in the case of an internal audit) and must have a deep knowledge of the audited processes.

5.31 The audit findings and conclusions should lead to corrections, corrective and preventive actions, improvement initiatives and/or re-engineering. Hence, the group of experts may use the problem-solving methodology or other quality approaches to determine the root-cause of the audit findings. It is important that the expert group classify the audit findings into product/service, processes and QMS in order to easily determine the root causes.

NOTE: *Dale et al. (2007) provide a complete review of quality and management techniques that may be used to determine the root-cause of audit findings.*

5.32 When the root-causes have been defined, the group of experts should propose an Audit+ action plan to Top Management in order to resolve the audit findings.

5.33 The Audit+ action plan also has to be reviewed by the Audit Team Leader in order to check that the proposed actions cover all of the audit findings.

5.34 Top Management will appoint a leader from the group of experts who will be in charge of conducting the follow-up of the Audit+ plan until all audit findings have been declared closed.

5.35 Each action in the action plan will be monitored until they stabilise and the results of the monitoring will be reported to Top Management on a periodic basis and also in Management Reviews. Moreover, it is important that a revision of the action taken to resolve the audit findings is included in the next internal Audit+ of the organisation.

5.36 The Audit+ will be declared closed by the Audit Team Leader when all the actions of the Audit+ plan have been closed.

6. Records

Audit+ plan
Audit+ Checklist
Audit+ report
Audit+ action plan (follow-up on audit findings)

7. Appendices

Appendix F.A- Process Categorisation

Hall and Johnson (2009) developed the following matrix to categorise processes according to the value of output variation for customers and the process environment

Process environment

Value of output variation to customers	Low variability	High variability
Positive	Mass Customisation	Artistic processes
Negative	Mass Processes	Nascent or broken processes

- ***Mass processes*** are standardised processes that are geared to eliminate variation in output. They are appropriate when the goal is completely consistent output for a narrow range of processes and services. In such cases all the artistic discretion should be eliminated. Steel, cars and consumer financial services are examples of industries where mass processes are widely applied
- ***Mass customisation*** uses a scientific process to produce controlled variation in outputs. Assemble-to-order products such as computers, cars and yachts are examples of outputs of this type of process. The possible number of combinations might be enormous but the outputs variability is limited to combinations of pre-defined components
- ***Nascent or broken processes*** cannot produce the consistent outputs that customers demand. Out-of-control processes are common when a product or processes uses radically new materials, technology and design. It should be considered whether controlling output variation is feasible or desirable. If variation cannot be controlled but customers can be persuaded to value it, an artistic process is the solution. If customers will not tolerate variation, the focus should be on understanding its causes and creating a standard process
- ***Artistic processes*** leverage variability in the environment to create variations of products or services that customers value. They rely on the judgment and direct experience of crafts people. Building pianos, serving passengers on flights, and developing radically new software applications are but a few of the processes that meet these criteria. Before choosing art, it is critical to make sure that customers really value output variation. It is important to consider that the vast majority of customers really want a standard product

Source: Hall & Johnson (2009)

Appendix F.B – Individual Measures

Neely *et al*. (1995) categorise individual measures into four types: quality, cost, flexibility and time. The following table provides some examples of this categorization:

Quality	Time	Cost	Flexibility
Performance	Manufacture lead time	Manufacturing cost	Material quality
Features	Rate of production introduction	Value added	Output quality
Reliability	Delivery lead time	Selling price	New product
Conformance	Due-date performance	Running cost	Modify product
Technical durability	Frequency of delivery	Service cost	Deliverability
Serviceability			Volume
Aesthetics			Resource mix
Perceived quality			
Humanity			
Value			

Source: Neely *et al.* (1995)

Table B.1. Examples of individual performance measures

Appendix F.C – The ISO 9000 Performance Measurement System

Since its 2000 version, the ISO 9001 standard considers four methods of measuring QMS performance in organisations: Management Reviews (clause 5.6), Customer Satisfaction (clause 8.2.1), Internal Audits (clause 8.2.2) and External Audits (Third Party Assessment). It is important to point out that ISO 9004:2009 suggests other two additional performance methods, Self-assessment (clause 8.3.4) and Benchmarking (clause 8.3.5) (see Figure C.1).

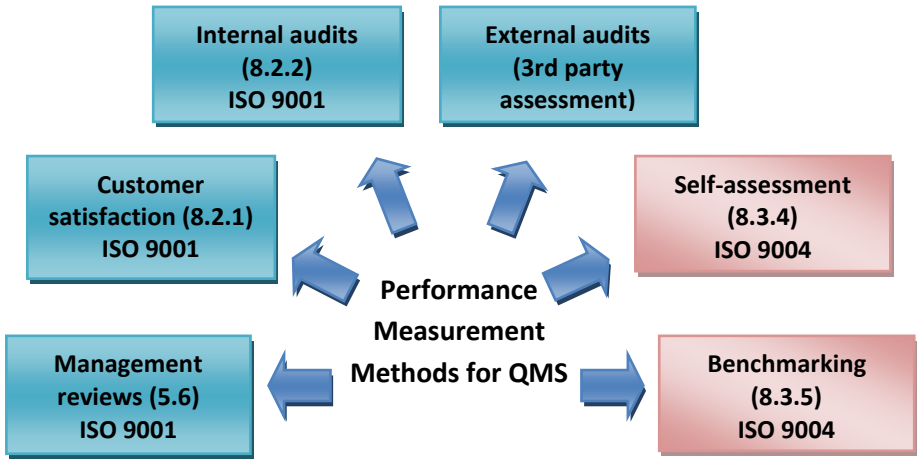


Figure C.1. The ISO 9000 performance measurement methods for QMS

Management Reviews

Conducting Management Reviews is a mandatory requirement of the standard and is part of the section of Management Responsibility. This section requires that the Top Management of the organisation is committed to the development, implementation and improvement of the QMS of the organisation for gaining and

maintaining the certification (Clause 5.1). In order to demonstrate its commitment, the Top Management has to conduct different mandatory activities (ISO 9001, 2008):

- Communicating to all the personnel of the organisation the importance of meeting customer, regulatory and statutory requirements;
- Establishing the quality policy;
- Ensuring that quality objectives are established;
- Ensuring the availability of resources; and
- Conducting management reviews.

Regarding the last point, the standard points out that the Top Management is also responsible for conducting periodic Management Reviews. In fact Clause 5.6.1 states (ISO 9001, 2008, pp. 5):

> "Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives."

Nevertheless the standard does not address how Top Management should conduct a Management Review, this has to be established by each organisation according to its size, industry, processes and strategy. The ISO 9001:2008 standard only provides guidance about the possible inputs (Clause 5.6.2) and outputs (Clause 5.6.3), that Top Management should consider when conducting its review.

Regarding the inputs, the ISO 9001:2008 standard states that Management Reviews should include: results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement. It is important to highlight that audit results and customer satisfaction feedback, which are also the other QMS Performance Measurement methods, are inputs of the Management Review. Hence, there is natural overlap in the ISO 9000 QMS Performance Measurement methods to complement each other (Figure C.2).

Figure C.2. ISO 9001 Performance Measurement System overlap

After conducting the Management Review activities, it is expected that the Top Management of the organisation will take actions related to (ISO 9001, 2008):

- Improvement of the effectiveness of the QMS and its processes;
- Improvement of the products and services related to customer requirements; and
- Resource needs.

There is no official ISO 9000 standard for conducting Management Reviews. However, the process shown in Figure C.3, based on the professional experience of the authors, describes how a typical Management Review may be conducted.

As far as ISO 9004:2009 is concerned, the concept of 'Management Reviews' has slightly changed in the 2009 version. Management Reviews are now included in the new Clause 8.5 entitled 'Review of information from monitoring, measurement and analysis'. Clause 8.5 specifically requires that Top Management use a systematic approach to reviewing available information regarding (ISO 9004, 2009):

- Monitoring of the organisation's environment;
- Measurements of the organisation's performance, including key performance indicators;
- Assessments of the integrity and validity of the measurement processes;
- Results of internal audit, self-assessment and benchmarking activities;
- Risk assessment; and
- Feedback from customers and other interested parties.

Thus, the focus of ISO 9004:2009 goes beyond the traditional approach of the ISO 9001:2008 standard. With the inclusion of input elements such as KPIs, measurements of the organisation's performance and risk assessment, the Top Management of the organisation is provided with more objective performance information not only regarding the management system but also the organisation.

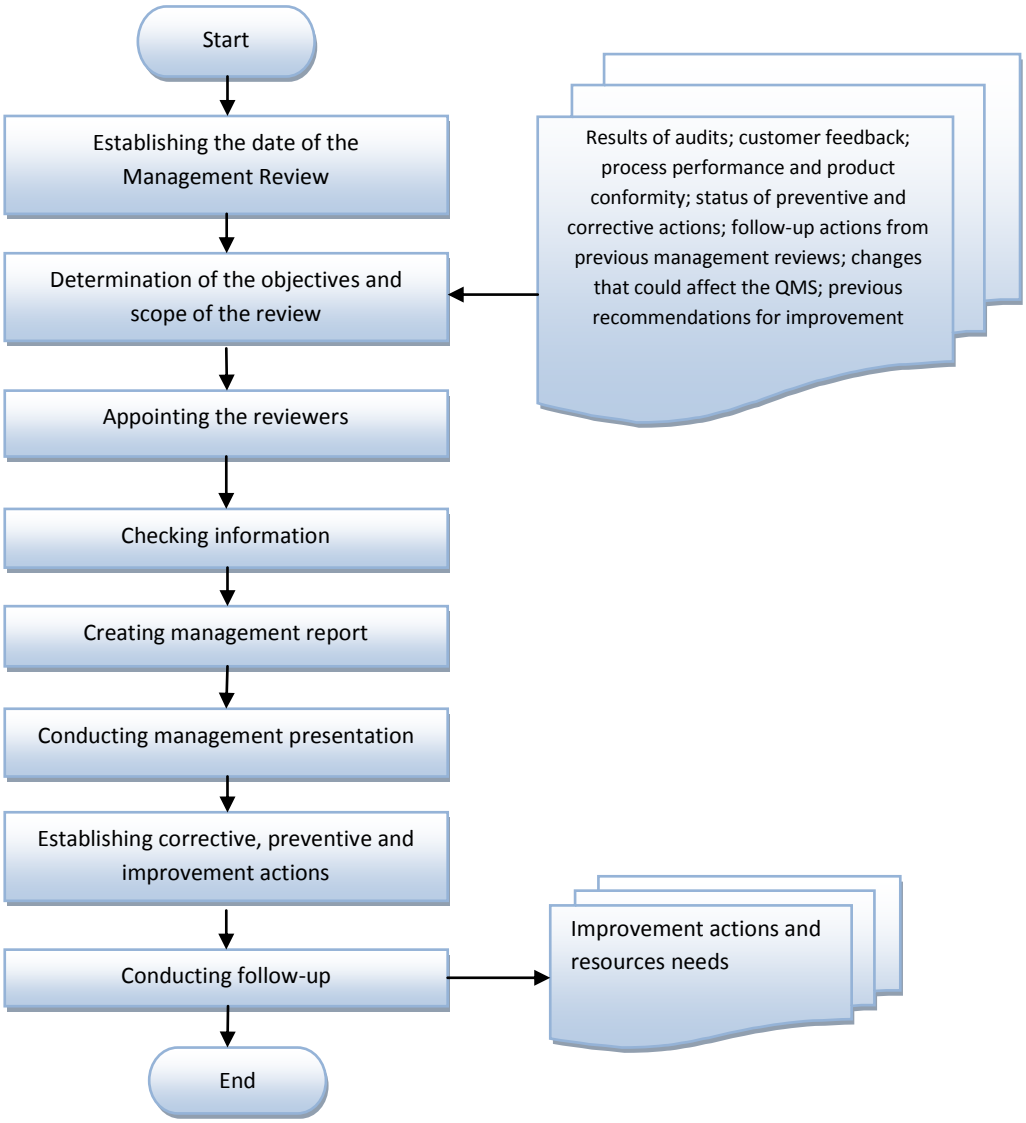


Figure C.3. Example of a Management Review process

Customer Satisfaction Measurement

Customer Satisfaction is one of the most important concepts of ISO 9000 QMS. In fact, the principle of 'Customer Focus' is the first quality management principle of the ISO 9000 core of standards (ISO 9000, 2005). The ISO 9000 standard provides a description of this principle (ISO 9000, 2005, pp. v):

> "Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations"

Also, the Customer Focus Principle is used as the basis for the 'Fundamentals of QMS' of the ISO 9000 core. Moreover, the 'Rationale for QMS' section' points out

that QMS “can assist organizations in enhancing customer satisfaction” (ISO 9000, 2005, pp. 1).

Customers require products which satisfy their needs and expectations. These needs and expectations are expressed in product specifications and are commonly known as ‘customer requirements’. Organizations have to continuously monitor and measure customer satisfaction in order to improve their product and processes because customer requirements change constantly (ISO 9000, 2005). The ISO 9000 standard argues that a QMS can provide the framework for the continuous improvement of the product and processes of the organisation to increase the probability of enhancing customer satisfaction (ISO 9000, 2005). Hence, these intentions are expressed in requirement 8.2.1 'Customer Satisfaction' of ISO 9001, which sets out (ISO 9001, 2008, pp.12):

> “as one of the measurements of the performance of quality management systems, the organization shall monitor information related to customer perception as to whether the organization has met customer requirements”

As with the Management Review, the Customer Satisfaction clause of ISO 9001:2008 is general and does not provide particular guidelines on how to measure Customer Satisfaction. Clause 8.2.1 only includes one note clarifying that monitoring customer perception can be done through different methods such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports. However, the ISO Technical Committee for Quality Management and Quality Assurance (ISO/TC 176) has developed specific standards to address different issues regarding Customer Satisfaction:

- ISO 10001:2007 Quality management —Customer satisfaction — Guidelines for codes of conduct for organisations
- ISO 10002:2004 Quality management —Customer satisfaction — Guidelines for complaints handling in organisations
- ISO 10003:2007 Quality management —Customer satisfaction — Guidelines for dispute resolution external to organisations
- ISO TS 10004: 2010 Quality management —Customer satisfaction — Guidelines for monitoring and measuring

It is highly recommended that ISO 9001:2008 certified organisations use these standards to monitor and measure customer satisfaction, in particular the technical specification ISO TS 10004:2010.

Whereas the ISO 9004 standard is concerned, its previous version had a special section dedicated to provide guidance about methods to measure Customer Satisfaction. However in the 2009 version, this section has disappeared and the Customer Satisfaction concept has been included as a method for collecting information regarding KPIs of the organisation (Clause 8.3.1).

Audits

The last method for measuring the performance of QMS in the ISO 9001 context is Audits. The ISO 9000:2005 defines the word 'Audit' as (ISO 9000, 2005, pp. 16):

> "[a] systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled"

There are two different types of Audits, internal and external. Internal Audits are those conducted by, or on behalf of, the organisation itself for Management Review and other internal purposes (ISO 9000, 2005). External Audits are further classified into second and third party Audits, second party audits are conducted by parties having an interest in the organisation, such as customers, whereas third party audits are conducted by external organisations, such as certification bodies.

An ISO 9001 certified organisation has to conduct internal audits on a periodic basis (ISO 9001, 2008) and has to receive periodic third party audits to maintain its certification. It is important to consider that, despite third party audits not being a requirement of the standard, most organisations use them to give their clients' confidence that the organisation is capable of delivering products or services that will meet their clients' requirements (ISO 9000 Essentials, 2011). Moreover, quality Audits are of great importance to managers who can call an internal or external Audit to conduct an impartial examination of the compliance of the QMS with the standard, as well as an evaluation of the QMS's suitability to achieve quality objectives (Karapetrovic and Willborn, 2000). That is why nowadays, to conduct quality Audits is one of the most important activities for ISO 9001 organisations.

Conducting internal Audits has been a mandatory requirement of ISO 9001 since 1984. The new 2008 version includes Clause 8.2.2 entitled 'Internal Audits' which states (ISO 9001, 2008, pp. 12):

> "The organization shall conduct internal audits at planned intervals to determine whether the quality management system
>
> c) conforms to the planned arrangements (see 7.1) [those related to developing all the processes needed for realising the products and services], to the requirements of this international standard and to the quality management system requirements established by the organization, and
> d) is effectively implemented and maintained.
>
> An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditor and conduct of audits shall ensure

objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define responsibilities and requirements for planning and conducting audits, establishing records and reporting results."

The logic behind the standard requiring organisations themselves to audit their QMS is to verify that the organisations are managing their processes effectively or, as the ISO has stated, to check that they are fully in control of their activities (ISO 9000 Essentials, 2011). It is important to note that ISO 9001:2008 contains several clauses to control and assure the quality of products, services and processes on a daily basis. When carrying out audits, it is necessary to verify that these clauses are correctly carried out, this will ensure that the QMS is operating properly. Thus, quality audits are oriented towards measuring QMS performance, capability of processes and product quality.

Moreover, the ISO 9001:2008 standard demands that organisations implement both a programme and procedure in order to conduct internal audits. The standard also suggests that organisations use the ISO 19011 standard for developing these tasks. Figures C.4 and C.5 are examples of internal and third party audit processes based on ISO 19011.

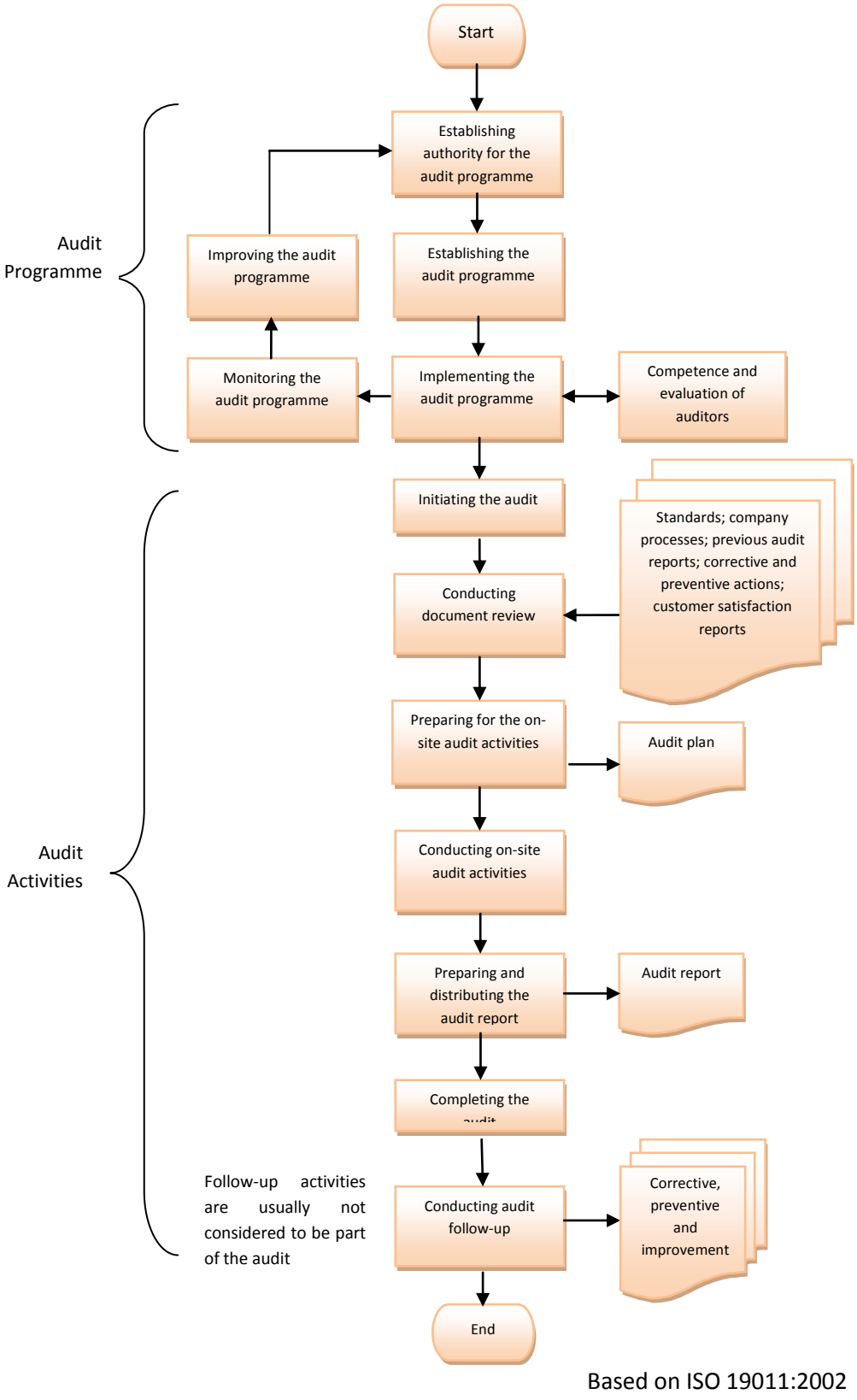
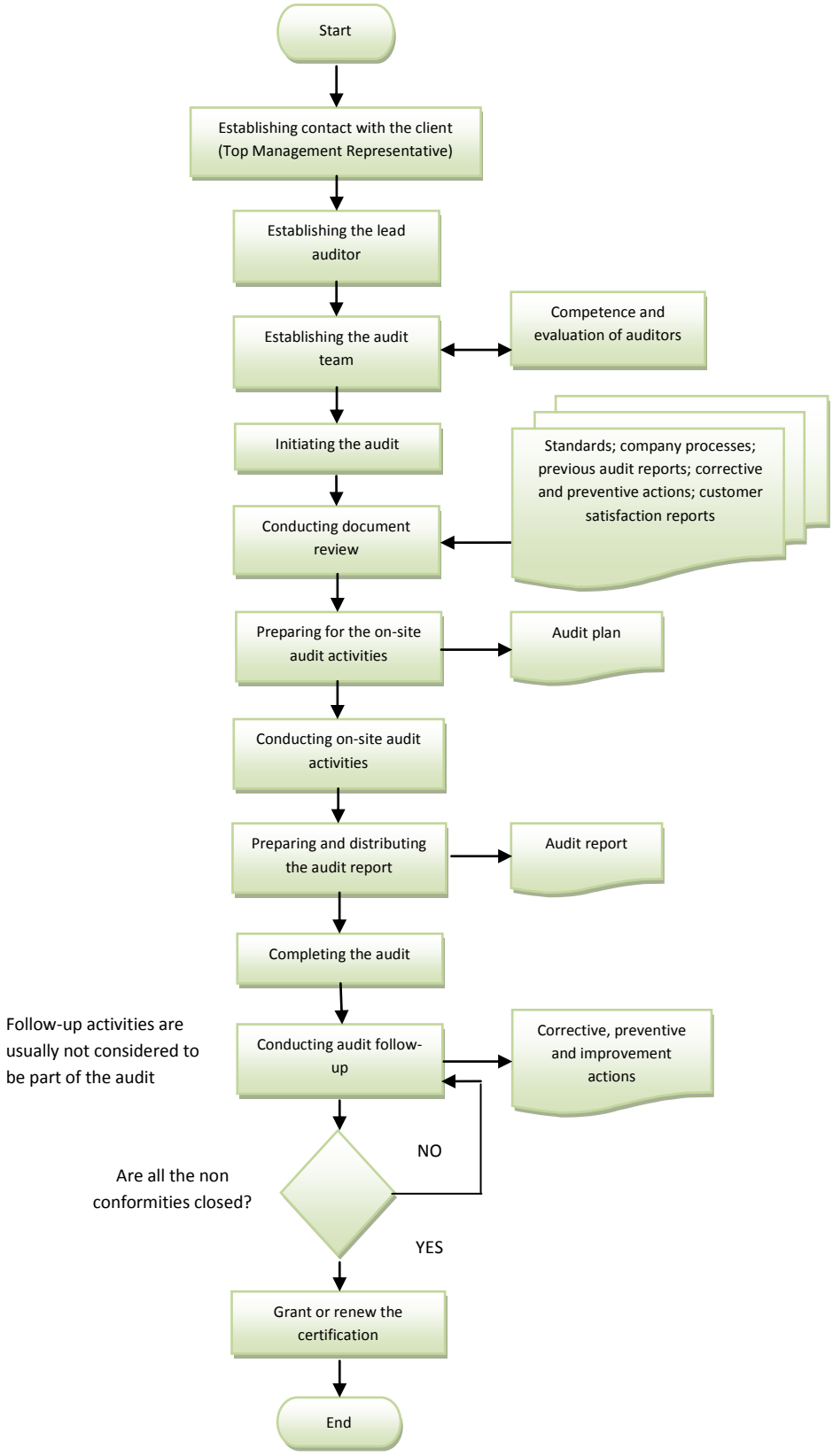


Figure C.4. Example of an internal audit process



Based on ISO 19011:2002

Figure C.5. Example of a third party audit process

8. *Identification of Changes*

Version	Description	Release Date	Author
V 1.0	Initial revision	15th June 2011	Gutierrez-Alcantara, F.M & Tannock, J.D.

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APPENDIX G

FEEDBACK FORM FOR REVIEWING THE PROCEDURE

Nottingham University Business School

Procedure for conducting ISO 9001:2008 audits with a focus on performance (Audit+) – ISO 9000 experts feedback form

Reviewer information

Name:

Organisation:

Country:

Contact e-mail:

Proposed Changes

Page #	Procedure Section/Clause	Comment (justification for change)	Proposed Change

General Comments

© Nottingham University Business School
Jubilee Campus, B26 South Building, Wollaton Road, NG8 1BB, Nottingham, UK
E: lixfmg@nottingham.ac.uk; fmga@unam.mx; T: +44 (0) 115 846 1151

APPENDIX H

FEEDBACK FROM EXPERTS ABOUT THE PROCEDURE

Expert	Feedback	Actions taken
C2	**General comment.** "I have no comments on the document 'NUBS procedure for conducting ISO 90012008 audits with a focus on performance (Audit+)'. It is a good piece of work."	---
C8	**Section 1.** Include the text as given in Clause 1.1 of ISO 9001:2008: "ISO 9001:2008 standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements"	Because Section 1 attempts to clarify the PM system of the ISO 9000 core of standards, it was considered not appropriate to include clause 1.1 of ISO 9001, as it relates to the objectives of the standard
C8	**Section 1.** Audits and monitoring of customer satisfaction are QMS Performance Measurement methods, but two other elements are not mentioned: - Monitoring and measurement of processes, - Monitoring and measurement of product.	When all clauses of the ISO 9000 core of standards were reviewed to identify which were related to PM, it was considered that the clauses relating to monitoring and measurement of processes and products, made no reference to PM methods, but PM activities and processes. Hence, these issues were included in the category 'other QMS processes' (see Figure J.1 Audit+ Procedure)
C8	**Section 1.** Management review is not a measurement method but a decision making activity, being on a "higher level" of activities than PM activities – delivering inputs for management review.	Due to the ISO 9000 core of standards not specifically having a PM system (it should be remembered that in fact the term 'performance' is not defined in the ISO 9000 standard of vocabulary), one of aims of the Audit+ procedure is precisely to propose that system. In order to do this, all of the clauses of the core were analysed according the spirit of the standards. Management reviews were

		identified as a PM method because its objective is to assess the QMS and to propose changes for its improvements (see Chapter 2 regarding the discussion of these PM methods).
C8	**Section 1.** Strict use of terms: a) Monitoring of customer satisfaction (is a PM activity) b) PM of QMS instead of: a) Customer satisfaction b) Performance of QMS	This suggestion was applied
C8	**Section 2.** Change "evaluate the effective development of business measures and targets" to "development or deployment of targets and measures"	This suggestion was applied
C8	**Section 1.** Model with 3 triangles is very nice. Some adaptations are interesting to consider in: a) Categorisation of product, b) Categorisation of processes. Suggestions: a) Product could be categorised by: functionality, cost-price and quality (for more information see book: R Cooper When Lean Enterprises Collide ISBN 0-87584-540-1) b) Process could be categorised by: effectiveness, efficiency and flexibility (or agility)	The proposed changes are interesting, nevertheless due to Neely *et al.* (1995) and Rohleder & Silver (1997) having become standard definitions in the literature, it was decided to maintain the approach of the Audit+ triangle (Figure 1.2)
C8	**Section 1.** "It is mentioned three levels of scrutiny …. Do we speak about levels or areas, focuses? Management review is on one level and performance measurements are on another level (lower level)".	Clarifications regarding the three levels of scrutiny were included in Section 1.
C8	**Section 1.** "Missing aspect is risk management. Auditors should look through the glasses of "risk management" (Murphy and his family are still alive!)"	The author of the procedure recognises the current importance of 'risk management' in quality management as well as quality audits and found these suggestions pertinent. Nevertheless, due to this being the first version of Audit+ and needing to be easy-to-understand for auditors, it was decided to include this new body of knowledge in the next version of the procedure
C8	**Section 1.** "Missing area is attention for the availability and adequate functioning of resources, especially infrastructure. Also here risk management should play an important role during audits following Audit+ approach"	
C8	**Section 1.** In many cases low performance of an organisation could be related to problems caused by poor working interfaces between the processes and/or between organisations and their customers and/or suppliers. This aspect needs	This suggestion was applied in Section 1

	more emphasis in Audit+.	
C8	**Section 2.** This procedure can be used in all three types of audits, not only 1st party audits (internal audits) and 3rd party audits (independent audits – like certification audits)	This comment was included in Section 2
C8	**Section 9.** Reference is made to ISO 19011:2002, there is a new version.	When the Audit+ procedure was developed the current version of the standard was 2002
C8	**Section 4.** Audit team should work in conjunction with top management	This suggestion was applied
C8	**Section 4.** There is a missing activity: evaluation of audit process (as performed) with audit team.	A specific Clause, 5.37, regarding this issue was included in the procedure
C8	**Section 5, Clause 5.** Missing inputs: mission, vision and strategy	The outputs were included in section 5
C8	**Section 5.** Maturity level diagnosis: term "diagnosis" is going too far because the causes of situation as it could be still "hidden" after performing such assessment. Suggestion: use maturity level assessment term.	The suggestion was applied in Section 5
C8	**Clause 5.2, Note.** "Tasks – it is not always necessary to use written description of tasks – it depends on necessary capabilities to perform certain task, currently present capabilities and risks involved".	This suggestion was applied and a clarification note was included in Clause 5.5
C8	**Table 5.1.** Assigning an order number to a call received from a client is not a task without value added (missing this step could disturb process and cause failures) Suggestion: a better example could be: internal check if the client call has the correctly assigned order number (if an organisation is performing well, such steps could be skipped without introducing extra risks).	For pedagogical purposes, it is important that there are some examples of tasks which do not add value to processes. Hence, it was clarified in Table 5.1 that only for the purposes of this particular example, this task does not add value to the process.
C8	**Table in Appendix A.** There are some other usable matrixes suitable for presentation of relations given. Suggestion: a) Agility / reliability matrix: horizontal axis: process reliability low <> high vertical axis: agility low <> high b) Customisation / reliability matrix: horizontal axis: process reliability low <> high vertical axis: customized product <> catalogue product Value for the customer depends on his needs (from own, unique specification via customized product till fully	It was decided to use the Hall & Johnson (2009) classification due to its roots in the literature.

	standardized (catalogue) product. This in relation to functionality, price, delivery conditions / flexibility in delivery and required quality	
C8	**Table B.1.** Features are not quality characteristics. The product quality of a Fiat Panda could be as good as that of a Bentley, but the features (functionality) are totally different (and some differences in price)	The classification was taken from Neely *et al.* (1995) and due to it being a standard in the PM field, it was decided to leave it in the appendix as in the literature
C8	**Table B.1.** Cost: missing non quality costs	
C8	**Table B.1.** Details of this table are very confusing: What is output quality and why is this a part of flexibility?	
C8	**Figure C.1.** Management review is not a PM method. Suggestion: Management review could be placed in the middle of this drawing, visualising that all inputs are coming into management review and resulting in decisions regarding to what action to take with the aim of improving performance of an organisation and increasing customer satisfaction	It was decided to maintain the current approach of the figure for this first version of the procedure in order to keep it simple. An extra figure with the suggestions of the reviewer will be included in the next version of the document
C8	**References section.** Missing: Reference to ISO 31000 standard on Risk management	It was decided not to include risk management in this version of the procedure
C8	**General comment.** Use of term ISO 9000 could be better reserved only for the referencing to issues being described in this standard like QMP's, process model and terminology. When speaking about requirements only the ISO 9001:2008 standard should be mentioned, to avoid misunderstandings	This suggestion was applied
B10	**Section 1, Figure 1.2.** It would be useful to have a general indicator for top management about the performance of the QMS	Currently, it is not possible to provide a general indicator of the performance of the QMS due to the different levels of scrutiny of the ISO 9001 standard. Also, the current performance framework for improvement of ISO 9004 establishes a classification of 1-5 regarding different concepts of the standard. Hence, a different approach of QMS measurement will be difficult to implement
B10	**Clause 5.25.** It is not clear in Figure 2.25 how the non-conformities regarding the examples stated in clauses 5.1 – 5.4 should be documented	Figure 5.25 was improved in order to make it clear
B10	**Appendix C.** Guidelines regarding how to implement and evaluate KPIs, benchmarking and risk analysis should be added to the procedure	It was considered that with Appendix B, organisations will be able to identify KPIs. Regarding benchmarking and risk analysis, due to this is a first version of

		the procedure and it is important to keep it simple, these two issues will be included in a next version of the procedure
A7	**General comment.** "I think you have very interesting material to be used by auditors. Regarding the procedure itself and its readiness to go for trials I think it is ok and you can do it straight away and then see what can be improved or better clarified, improved".	---
A7	**General comment.** "My main doubt/concern relates to the approach of three QMS performance methods where you include management review as a performance measurement method (I confess I never thought of it conceptually as a measurement method) and the total omission of process and product monitoring and measurements (9001:2008 4.1, clause 8.1, 8.2.3 and 8.2.4) required by 9001, that is the central tool in 9001 to measure performance and provide information to top management".	Because PM is defined as "the process of quantifying the efficiency and effectiveness of an action" (Neely et al., 1995), it was considered that management reviews were a PM method due to its objective being to ensure the suitability, adequacy and effectiveness of the QMS (Clause 5.6.1, ISO 9001). The monitoring and measurement of processes and products were considered as PM 'processes' not as PM methods. Hence they were included in the procedure in the section 'other QMS' processes' (see Figure 1.1). A new section explaining this was included in Appendix C of the procedure and a clarifying note was included in Figure 1
C6	**Section 4.** Paragraph related to responsibility and authority of the audit team leader: top management representative needs to be included in the development of this stage	This suggestion was applied
C6	**Section 4.** Paragraph related to responsibility and authority of the top management representative. Top management representative should be more involved in the planning stage (e.g. He/she needs to provide feedback to the audit team about business objectives, strategies and policies in order they would be correctly assessed).	This suggestion was applied
C7	**General.** The document seems to switch from internal to second party to third party audits. There is some confusion throughout the document	Section 2 "Purpose of the procedure" was updated to state that the procedure was intended to be used for both types of audits. Also, some clauses were re-written to avoid confusion
C7	**General.** There does not seem to be anything special about this auditing process that would give it the status of 'Audit+'. The parameters included in this document are those that would be	The author agreed with the opinion of the expert that all the concepts of the Audit+ procedure should be used in an ISO 9001 audit. Nevertheless, the results of the mixed methods study stated in

	expected from any system that was set up in accordance with the requirements of Clause 8 of ISO 9001	Chapter 5, show this is not the case and that ISO 9001 organisations need more help for conducting effective audits
C7	**Section 1.** 'Customer Satisfaction' should not be used by itself. You should use 'Customer Satisfaction Measurement'. This also occurs in many other places throughout the paper.	This suggestion was applied
C7	**Section 1.** The concepts of Performance Measurement, Business Process Improvement, Business Process Re-engineering and Resource-Based View should be explained briefly so that people can understand them	Due to the length of the procedure, it was decided to include the definition of these concepts in the next version
C7	**Section 4.** Why do you need a 'follow-up group of experts'? Each process owner should be responsible for implementing the audit improvement actions for their own process(es)	The current approach of 'processes owners' being in charge of implementing the audit improvements is not working according the results of the mixed methods study stated in Chapter 4, hence the author believes that this groups of experts may be able to help not only the owners of the processes but the Top Management to conduct an effective follow-up of the audit findings.
C7	**Section 4.** 'Follow-up Group of Experts' should not be part of the document	One of the most important findings of the mixed methods study was that organisations are facing a lot of problems with the follow-up of the audit findings. Hence, the author believes that more guidelines regarding with this topic is needed and should be included in the document because otherwise may be omitted by organisations as currently happens with ISO 19011
C7	**Clause 5.3**. Why does the Audit Team identify the processes to be audited? Shouldn't that be up to the client?	A clarification note stating that this clause is to be used in internal audits was added
C7	**Clause 5.7.** Why is it highly recommended that other management systems are included in the Audit+ plan after the first Audit+ has been declared 'closed'? It is much more efficient to audit the different systems together if possible	The author believes that due to this being a new way to audit a QMS, auditors should focus only on ISO 9001 in the first Audit+ and when they have more experience with the methodology they can include other MS in the scope of the next audit
C7	**Clause 5.9.** Why will the auditors review the design, implementation and use of the processes? The audit is designed to ascertain whether the processes are in place and whether they are being implemented effectively	The Audit+ procedure was designed to increase the approach of the current ISO 9001 audit process in order to detect improvements to the QMS. This is why auditors should review the design, implementation and use of the processes, to review that processes are not only effective but to detect improvements

C7	**Clause 5.16**. This only talks about the interaction with other processes of the QMS and business goals & targets. What about interaction with other management systems, e.g., OHS/EMS?	Due to the current approach of the Audit+ being ISO 9001, this suggestion will be included in the next version of the procedure which will target management systems
C7	**Clause 5.18.** "Auditors should be careful that an element, activity or task will not be required in the future before discarding it." Auditors do not discard anything. They can make recommendations to the auditee. It is up to the auditee whether they change a process	The clause was re-phrased in order to state this discarding is only for the audit exercise and that the owners of the processes will decide if the activities/tasks are redundant during the follow-up of the audit
C7	**Clause 5.18 (Note).** These may be questions that internal auditors could ask but I doubt that 3rd party auditors would have the time to carry out such investigations. In any case process owners must be involved in such detailed investigations	A clarification was added to state, this is only in the case of 'internal audits'
C7	**Clause 5.20.** Can't 'continuously improve' the performance measures as the processes need to be stable for some time so that the measures can be compared. Then changes can be made and more measurements taken to determine whether the changes have lead to an improvement	A clarification note was added to make auditors aware that performance measures have to be stable in order to compare them
C7	**Clause 5.24.** This clause relates specifically to Certification Bodies. Other parts of the document relate to internal audits. This could be confusing to the overall discussion	The author believes, internal auditors should also be aware of what audit findings during internal audits would become 'non-conformities' in external audits

Table H.1 Feedback from ISO 9000 experts regarding the Audit+ procedure

APPENDIX I
CASE STUDY PROTOCOL OF THE PILOT CASE

Company X1

Objective of the case study
To test the audit+ procedure in real conditions to determine its degree of applicability in industry

Theoretical framework
Contained in the Audit+ procedure

Data collection procedure
The data collection procedure includes the following stages and activities to be performed:

1. **Internal auditors' training about the Audit+ procedure**
   17th August 2011 during the workshop at the Council for Culture and Arts (Mexico City)

2. **Planning the Audit+**
   18th August 2011 at X1's Mexico City headquarters. This stage includes the following activities and tasks:
   - *Determination of the audit team*
     The audit team shall consist of:
     - B2, Director of Quality of X1, who will act as audit team leader;
     - C6, Consultant, who will act as internal auditor; and
     - The author, Researcher NUBS
   - *Determination of the scope of the Audit+*
     The processes to be assessed using the procedure will be:
     - sea-freight (realisation process[47]);
     - air-freight (realisation process);
     - insurance (realisation process); and
     - internal audit (analyse, measurement and improvement process)[48]

     These processes will be audited only at Mexico City, the operations at Guadalajara and other parts of Mexico are not included in the scope of this Audit+

   - *Carry out the Audit+ checklist of the processes to be assessed*

[47] Classification of processes according to ISO 9001:2008
[48] The scope of the audit does not include the QMS

- *Create the Audit+ plan*
- *Request access to Mexico City International airport to conduct the on-site audit for the air-freight process*

3. **Doing the Audit+**
   The on-site audit is planned as follows:
   - 1st September 2011 – auditing the processes of sea-freight and air-freight at Mexico City Airport
   - 2nd September 2011 – auditing the processes of insurance and internal audits at X1 headquarters

   The on-site audit will be conducted according to the Audit+ plan. The audit team leader will be in charge of sending the audit plan to the personnel in charge of receiving the audit.

4. **Verifying the Audit+**
   2nd September 2011 at X1 headquarters at Mexico City with the audit team. This stage includes the following activities:
   - determine the Audit+ findings to be reported to Top Management; and
   - draft the Audit+ report.

5. **Acting on the Audit+**
   From 5th to 9th September 2011 at X1 at Guadalajara with B2 and the Top Management of X1. This stage includes the following activities:
   - determine the root cause of the Audit+ findings; and
   - create the Audit+ action plan for conducting the follow-up to solve the audit+ findings.

Chain of evidence

The records to be used for producing a 'chain of evidence' will be:

- Audit+ plan;
- Audit+ checklist;
- Audit+ report; and
- Audit+ action plan (follow-up on audit findings)

During the Audit+, different documents will be reviewed and contrasted with facts by the audit team. However none of these documents will be copied or retained by the researcher due to the confidentiality principles of the audit process stated in ISO 19011:2002 and ISO 17021:2008.

Outline of the case study report

1. The rationale of the procedure
2. The Audit+ triangle
3. The stage of planning the Audit+
4. The stage of doing the Audit+
5. The stage of verifying the Audit+
6. The stage of acting on the Audit+
7. General problems of the Audit+ procedure

Case study questions (interview protocol)

1. How did you feel using the audit+ procedure? Do you think it helped you to improve your competences as auditor?
2. What do you think about the audit results obtained using the procedure? Do you believe the procedure enabled you to take into account relevant factors that otherwise could have been overlooked?
3. What do you think about the approach of dividing the audit measurement elements into: products/services, processes and QMS? Do you think it helps you to better auditing?
4. How do you feel using the audit performance triangle? Are you happy with all of the measurement elements proposed? (**product/service:** quality, time, flexibility and cost; **processes:** effectiveness, efficiency and adaptability; **QMS:** audits, management reviews, measurement of customer satisfaction)
5. What do you think about the structure of the document? Do you think it is easy to follow and understand?
6. Do you have any suggestions for improving the procedure?

The interview will be conducted with B2 on 12th September by telephone when the Audit+ process has finished.

APPENDIX J
CASE STUDY REPORT OF THE PILOT CASE

Company X1

Organisation's background

X1 is an international company dedicated to providing logistics services which include maritime and air transportation. The company is an Italian family business with 32 years in the market. It has 241 offices in 80 countries and transports more than 100,000,000 kilos by air and 260,000 TEU's on the oceans per year. X1 has more than 3,000 employees around the world, 100 of them in Mexico. The company has its Mexican headquarters in the City of Guadalajara in Jalisco State and has another two operations offices in Mexico City and Monterrey. It also has sales offices in Queretaro, Aguascalientes and Puebla.

The top management of the company decided in 2000 to achieve the ISO 9001 certification in all of their branches. The Mexican branches certified their operations processes (sea-freight and air-freight exports and imports) in 2002.

Due to the constant change of personnel, X1 has only one certified internal auditor who is also the quality director and top management representative. Currently, the company is training a group of internal auditors.

Stage of Planning the Audit+

Date: 18th August 2011 from 10.00 to 17.30h
Place: Headquarters at Mexico City
Audit Team: B2 (audit team leader); C6 (internal auditor); and the researcher
Tasks of the stage:

1. Determine the scope of the Audit+ (processes and locations)
2. Carry out the Audit+ checklist of the processes to be assessed
3. Draft the Audit+ plan report
4. Request access to Mexico City international airport to conduct the on-site audit for the air-freight process

Report of activities:
Scope of the Audit+

As a first activity, the audit team determined that the scope of the internal Audit+ will only include the processes which are performed in Mexico City. Hence, the processes to be assessed using the Audit+ procedure will be: sea-freight (realisation

process[49]), air-freight (realisation process), insurance (realisation process), and internal audits (analysis, measurement and improvement process).

Hence, the operations at Guadalajara and other parts of Mexico are not included in the scope of this Audit+.

It was also noted by the audit team leader that the company's QMS has two permitted exclusions to ISO 9001:2008: clause 7.3 design and development and clause 7.5.5 preservation of products.

Identification of business goals and targets

The top management has not documented a balanced scorecard but the company has a quality policy which outlines five business objectives to be achieved in five years:

- reduce the number of non-conformities by 5% (service and process non-conformities);
- increase sales by 25%;
- achieve 80% customer satisfaction (measured through an annual survey);
- increase the efficacy of the QMS as a result of training personnel (10 courses per year); and
- achieve 80% of internal satisfaction with suppliers (supplier's QA).

Classification of Processes

Following the sequence of clauses of the Audit+ procedure, the audit team determined the business processes which interact with the processes to be audited (clause 5.3). Hence, two business processes were identified: sales and customer services.

[49] Classification according to ISO 9001:2008

Also according to clause 5.4, the artistic processes were identified using the classification of Hall & Johnson (2009) provided in Appendix A of the Audit+ procedure. Sales, customer services and internal audits were identified as artistic processes.

Finally, the audit team discussed the type of processes of the realisation processes to be audited, according to Hall & Johnson (2009). The audit team agreed that insurance, sea-freight and air-freight are processes of mass customisation. Auditors B2 and C6 were happy with this classification because it allowed the identification of which processes are more difficult to audit and thus demand more resources.

Construction of the Audit+ checklist

In order to build the Audit+ checklist, the audit team identified the elements, activities, task, inputs and outputs of each process to be audited[50]. To facilitate the creation of the checklist, the audit team leader created a table, using Microsoft Excel, where the auditors were able to state for each activity and task of the processes:

- if tasks were adding value to the processes;
- their KPIs (if applicable);
- type of KPIs (quality, cost, time and flexibility); and
- the ISO 9001:2008 clauses which apply to each task.

The construction of the checklist allowed the audit team to indentify some key activities and tasks which were not monitored or controlled by any indicator. In order to propose to the top management indicators for these activities, the internal auditors were encouraged by the researcher to use an adapted version of the Neely *et al.* (1995) key questions for implementing individual measures:

- What needs to be measured?
- How much will it cost?; and
- What will be the possible benefits?

When the indicators were identified, the audit team classified them as metrics of quality, cost, time and flexibility. Almost all of the indicators were classified as quality, cost and time. The concept of 'flexibility' defined by Cox (1989) was difficult to understand for auditors B2 and C6 because many flexibility metrics are related to cost and time. The flexibility concept created a lot of confusion amongst the auditors.

[50] This identification was conducted in accordance with the quality manual, procedures, work instructions and records of the company

During the creation of the checklist, the audit team leader pointed out that the records of results of the previous audit findings (internal and external) were omitted as an input of the Audit+ procedure and that it was important that this record was included in the checklist, otherwise the audit team would omit it during the on-site audit.

Also, during the revision of the internal audit process it was found that the design of its procedure may not be adequate for the needs of the organisation. The personnel do not perform an analysis of the causes about why non-conformities are being generated; this is the responsibility of the quality director. When a non-conformity is identified during an audit, the personnel simply correct the failure without asking themselves why it was produced in the first instance. The audit team identified this as one of the potential reasons why some non-conformities are recursive.

Finally, the audit team leader requested clearance permission with the Mexican Customs Agency for the other internal auditors in order that they would be able to enter the Mexico City international airport to conduct the on-site Audit+ (stage of doing the Audit+).

In the opinion of auditors B2 and C6, the identification of KPIs was the most added value activity of the planning the Audit+ stage.

Stage of Doing the Audit+

Date: 1st September 2011 from 9.30 to 17.30h
Place: Mexico City international airport
Audit Team: B2, audit team leader; C6 internal auditor; and the researcher
Interviewed personnel: air manager and imports air supervisor

Tasks of the stage:

1. Conduct the Audit+ opening meeting;
2. Evaluate the compliance with the ISO 9001:2008 standard in the processes of air-freight exports and imports;
3. Assess the performance of processes of air-freight exports and imports according to the Audit+ procedure, Audit+ plan and the Audit+ checklist; and

4. Detect the audit findings (non-conformities, observations, improvement opportunities and performance findings).

Report of activities

Conducting the Audit+ opening meeting

The audit team leader conducted the opening meeting with all of the customs office personnel at Mexico City international airport, following the ISO 19011:2002 guidelines. The audit team leader explained to all of the personnel that the internal audit would be conducted with a performance approach using a special methodology developed by researchers at Nottingham University. She introduced the audit team and explained that the top management was very interested in testing this methodology in order to determine the performance of the QMS. The audit team leader also encouraged the personnel to be open and answer auditors' questions with complete honesty in order to take advantage of the opportunity of having two experienced auditors helping with this internal audit. Finally, she stated which people would be in charge of receiving the audit and where the audit would be conducted.

The on-site Audit+ at Mexico City International Airport

The on-site Audit+ started with a revision of the activities conducted by the air manager regarding air-freight exports.

As suggested in clause 5.18 of Audit+, the audit team leader asked the air manager if the documented process of air-freight exports was understandable and easy-to-follow in order to know if the document reflected the activities conducted in the area. The air manager explained that during July all of the national managers and supervisors of the company had attended a meeting in Guadalajara in order to review the realisation processes (sea-freight and air-freight exports and Imports). During this meeting some changes had been made to improve the processes, thus the air-freight procedure was clearer now than in the past. However, the document as well as its work instructions were relatively new and the personnel needed more time to know if they were in accordance with all of the activities they perform. In order to check the personnel's level of understanding of the procedure, the audit team leader asked the air manager to explain to the audit team, the flow chart of the process of air-freight and how it interacted with other processes.

Continuing with the Audit+ plan, the audit team asked the air manager about the most recent data of the KPIs of the air-freight exports and imports processes. She had difficulties to address the question but managed to give auditors a list of targets for her department. When the audit team contrasted the KPIs previously identified in the Audit+ checklist with the air-freight department's targets, it was found that

some KPIs were not in accordance with the departments' targets. Thus, the organisations' personnel were not aware about they needed to control and measure other activities.

The next activity in the Audit+ plan was assessing suppliers' performance. The audit team asked the air manager how the department was evaluating its suppliers and what the criteria were. She explained that quality, response time and price were the criteria used to assess suppliers. However, when the audit team reviewed how the contracts are granted, it was found that the main criterion used was price. The documented assessment showed that the criteria of quality and time of response were evaluated in a subjective manner. From a deeper investigation, the audit team found that several suppliers that received a good qualification in the assessment had faced considerable problems to provide services to the company. For example, the audit team, using audit sampling techniques, identified a supplier who was assessed as 'excellent' but that when he was asked to provide a transport service, did not have the infrastructure to provide the service. In order to overcome this problem, the audit team asked the air manager if it would be a good idea to include specific individual metrics of quality, time, cost and flexibility (as stated in Appendix B of the Audit+ procedure) in the suppliers' evaluation in order to make it less subjective. She was happy with this classification and said she would ask the quality director to conduct a deep revision of the suppliers' assessment procedure.

Finally, in order to assess the design, implementation and use of the QMS's processes, the audit team asked the air manager about the results of her department regarding previous audit findings and management reviews (stated in clause 5.20 of the Audit+ procedure). The air manager declared that she did not know this information. Because communication between all levels of the company regarding audit and management reviews results is a mandatory requirement of ISO 9001:2008, the audit team decided to investigate the reasons for this lack of knowledge. Hence, the audit team found that the internal audit procedure of the company stated that audit results would be only informed to the members of the staff of the organisation during a staff meeting; then the staff members had the obligation to inform their personnel. Auditors noted that some managers may not have been informing their personnel about audit results and questioned if the design of this processes was correct.

The second part of the audit was planned to be conducted with the imports air supervisor. As with the air manager, she was also asked by auditors if the process of air-freight was correct and easy to follow. She stated that the new version of the procedure was better than the previous one and that she would not change anything.

In order to learn how the personnel determined the performance of processes, the audit team asked the air supervisor how she assessed if the air-freight process was efficient. She answered that she would be able to know if the number of non-conformities of the procedure was less than 12% per month. However, when the

audit team questioned her about how this average was measured, it was found that the efficiency of this process was not measured at all.

The next activity in the Audit+ plan was to corroborate with the air supervisor the no-added value activities identified by the audit team in the planning stage of the Audit+. After reviewing the list with the auditors, the air supervisor noted that a whole department was recently hired to exclusively re-work client's contracts because 90% of the contracts suffered modifications after being agreed with the client. The audit team leader (who was also the director of quality) was surprised to realise that the company had created a new area in the accountancy division to re-work contracts (they had not seen it in this way).

The on-site Audit+ at Mexico City international airport finished at 17.30h.

Date: 2nd September 2011 from 9.30 to 18.00h
Place: X1 headquarters at Mexico City
Audit Team: B2, audit team leader; C6, internal auditor; and the researcher
Interviewed personnel: sea-freight manager; sea-freight supervisor; chief of sea imports; director of quality (responsible for the insurance and internal audit processes)

Tasks of the stage:

1. Conduct the Audit+ opening meeting;
2. Evaluate the compliance with the ISO 9001:2008 standard in the processes of sea-freight exports and imports, insurance and internal audit;
3. Assess the performance of processes of sea-freight exports and imports, insurance and internal audit according to the Audit+ procedure, Audit+ plan and the Audit+ checklist; and
4. Detect the audit findings (non-conformities, observations, improvement opportunities and performance findings).

Report of activities

Conducting the Audit+ opening meeting

Because the Audit+ was planned as a multi-site audit, it was necessary to conduct an opening meeting at the Mexico City headquarters as well. Hence, the audit team leader also conducted the Audit+ opening meeting. She introduced the audit team to the personnel and explained that the objective of the audit was to determine the performance of the QMS. She also noted that top management was very interested in learning the results of the Audit+. Finally, the audit team leader detailed the Audit+ plan and asked all the personnel to answer all the audit questions with honesty in order to have a real picture of the performance of the QMS.

The on-site Audit+ at the Mexico City headquarters

As with the air-freight process, the audit team asked the sea-freight manager and the sea-freight supervisor if the sea-freight process was easy to understand and follow. The sea-freight manager answered that the operations personnel did not have problems with the new version but customer service personnel were facing many problems to understand all of the activities of the process. He also explained that the sea-freight process was particularly difficult for customer service personnel due to all the complex activities that needed to be done for sea exports and imports. He added that if the customer service personnel were correctly trained in this process, it would be very valuable to the company due to them having direct contact with clients and being able to more easily promote this service than operations personnel. The sea-freight manager argued that because the sea-freight process was not well understood by the customer service personnel, it was not effectively promoted to clients and the company was probably losing market share. Moreover, the sea-freight supervisor also highlighted that the 'instructions letter' (the form where all the client requirements and needs were stated) had several parts which were difficult to understand not only for clients but also for X1 personnel. Hence, the audit team reviewed the document and found that there were no instructions about how to fill out the document and there were several sections which were very technical for the lay person. The audit team suggested the inclusion of help boxes in the form in order that clients and the personnel of X1 would be able to correctly fill out the document.

Auditors also questioned the sea-freight manager and sea-freight supervisor about the activities which were detected during the planning stage as not-adding value to the process. The sea-freight supervisor confirmed that in the 'shipping run' area, re-working was a very common activity and that personnel wasted a lot of time in doing things two or three times. The audit team suggested that the sea-freight personnel use sampling methods to chose a couple of shipping run orders and trace all of the processes' activities needed to fill out the order to determine the problems causing re-work in the first place. The audit team pointed out that the Audit+ procedure includes in its clause 5.18 some guidelines which address the topic of re-work.

Regarding the activities of supplier evaluation, both the sea-freight manager and the sea-freight supervisor stated that 'cost' was the most important factor in the evaluation and there were many examples of suppliers who charged a low rate for their services but could not provide them due to lack of infrastructure. They added that the current process for assessing suppliers did not

allow for the identification of problems with suppliers. Hence, personnel of X1 were not being informed about these problematic suppliers.

Finally, the sea-freight supervisor was asked if the number of non-conformities was a good indicator for determining the performance of the sea-freight process. She answered that non-conformities were not usually reported because they were something very damaging for the QMS that may cause the organisation to lose its certification, but that failures in the process and services were corrected on a daily basis. Due to ISO 9001 encouraging the detection of non-conformities and this not being a cause for losing certification, the audit team asked the sea-freight supervisor how many errors or problems were detected during the last month and if they were treated as non-conformities (in the X1 quality manual it stated that non-conformities had to be analysed using a root-cause analysis). It was found that even if the sea-freight personnel had controlled and solved most of the failures detected during the last month, but they were not reported and treated as non-conformities. And due to the personnel not conducting a root-cause analysis, some problems were repeating again. The audit team leader explained to the sea-freight manager and sea-freight supervisor that detecting and preventing non-conformities is one of the most important processes of any ISO 9001 QMS and companies are not penalised nor lose their certification because they have a high number of non-conformities. The audit team suggested conducting a workshop about non-conformities with all the X1 personnel in order to clarify why it is important to report and how to handle non-conformities. The sea-freight supervisor also highlighted that most of the failures that their department had recently detected were concerned with financial loses and that there was not any apparent reason for this happening. The audit team suggested that the sea-freight personnel as well as the quality director review all these failures and try to classify them in order to conduct a root cause analysis to determine the reasons for these loses. In order to conduct this review and classification they were encouraged to use the guidelines provided in clauses 5.31-5.35 of Audit+.

The next department to be audited according to the Audit+ plan was sea imports. In order to gather more information regarding how the personnel were handling non-conformities, the audit team asked the chief of sea imports about the number of non-conformities detected in his area during the last month. He answered that they did not detected any non-conformity in his area during the last month. However, he stated that they had a lot of failures in delivering some services related to the instructions letter. He added that the customer service personnel usually did not carefully check the instructions letter with clients and this caused a lot of delays and problems. For example, they had a case were the weight of an item was incorrect in the instruction letter and the customs department of a European country accepted a tax exemption. Nevertheless, when the item arrived in the country and it was correctly measured the client had to pay taxes and an extra charge for storage of the item. Naturally, this caused a complaint from the client who felt he was not correctly advised. The audit team asked the chief of sea imports to what extent the delivery of

late goods was causing client dissatisfaction. He answered that his department always warned clients that their imports may be late by up to 2 days from the promised delivery date, so clients were aware of possible delays. However, the department did not have a statistic about how many times this agreement is broken. But he estimated that between 5-10% of the total of client complaints were related to failures in the sea-freight process. From a deeper interrogation by the audit team, it was also found that problems were also being caused because each country has different requirements for exporting and importing goods and sometimes these requirements were not well understood by X1's personnel. The audit team suggested to the chief of sea imports to make statistics about the number of problems by country, so his department would be able to determine different levels of inspections for the documents that need to be completed to import or export to each country.

Finally, auditors asked the chief of sea imports about the performance of his department in achieving the company's organisational goals. He pointed out that they had some problems in increasing sales and suggested that the company should state sales goals by department because the customer services' area was mainly the one in charge of the business goal of increasing sales.

The on-site Audit+ continued with the audit team interrogating the quality director about the internal audit process of the company. Firstly, auditors questioned the lack of trained auditors for conducting internal audits. Currently, there were only two qualified internal auditors. The quality director stated that due to the continuous change of personnel, the company has lost many qualified internal auditors. The audit team suggested implementing a programme to train internal auditors on a continuous basis.

Auditors also asked the quality director why the company personnel were not informed about the results of internal audits. She explained that the current internal audit process stated that audit reports would be distributed only between the top management. Thus, managers were not informing their personnel about audit results. After a deeper review by the audit team about the internal audit process, it was concluded that the design of the process was causing this problem. Hence, the auditors suggested using the guidelines included in Clause 5.20 of the Audit+ procedure to correctly design a new version of the internal audit process.

The final task of the Audit+ plan was reviewing the insurance process. After conducting an investigation of this process, auditors found that the main problem of the area was claiming the insurance from insurance companies, each claim taking a lot of time due to incomplete documentation. The auditors suggested that the quality director implement a checklist in order that each area wanting to claim insurance would be informed about all of the necessary documents they would need to provide to claim it.

Finally, auditors also found that the insurance area did not have a catalogue of the most frequent claims. The auditors also suggested creating this catalogue, so the company would be able to detect risks and reduce costs.

Stage of checking the Audit+

Date: 3rd September 2011 from 10.00 to 19.00h
Place: X1 headquarters in Mexico City
Audit Team: B2, audit team leader; C6, internal auditor; and the researcher
Tasks of the stage:

1. Determine the non conformities, observations, improvement opportunities and performance findings; and
2. Draft the Audit+ report

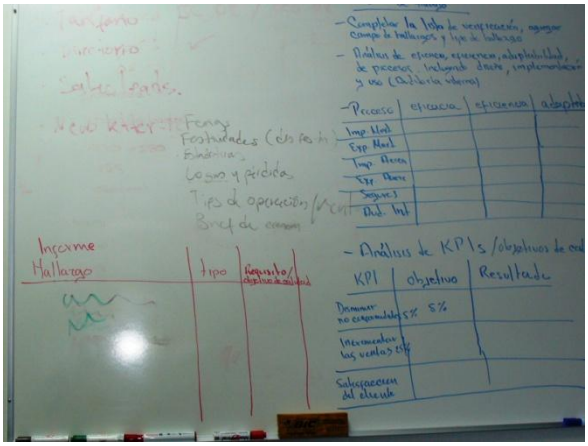
Report of activities:

Drafting the Audit+ report

The first activity conducted by auditors was to determine the non conformities and observations detected during the on-site Audit+. After three hours of discussion auditors stated 9 findings:

- 1 non-conformity; and
- 8 performance findings or observations

In order to create an Audit+ report easy-to-follow for X1's top management, the auditors improved the *Table 5.5 Example of audit+ report- Internal process assessment* of the Audit+ procedure and created a table only with the columns: finding, type of finding (non-conformities, observations or performance findings), ISO 9001 requirement and possible benefits.



When the table was completed and auditors agreed on all of the Audit+ findings, auditors B2 and

C6 pointed out that all the performance findings were 'improvement opportunities'. Thus, the auditors concluded, the Audit+ procedure is an improvement tool which permits not only the checking of conformity but also the detection of possible improvements.

The next activity in drafting the Audit+ report was conducting the internal and external assessment of the performance of the processes according to Clause 5.22 of Audit+. This task was difficult for auditors because there were no guidelines included in the procedure about how to write this assessment in the report (The *table 5.5 Example of audit+ report- Internal process assessment* relates exclusively about how to state audit findings). Hence, the researcher created a couple of tables where the assessment of processes and business goals could be stated. In this way, the effectiveness, efficacy and adaptability of the realisation processes were assessed according to Clause 5.22 and stated in the new tables. Also, due to the internal process being a PM method of the QMS, the auditors reviewed the design, implementation and use of this process according to Clause 5.20.

Moreover, auditors assessed the KPIs of the processes and company according to Clause 5.26. This task was slightly difficult for auditors due to the most important KPIs of the organisation being stated in quality and business goals and the scope of the Audit+ included only the assessment of the realisation processes. Thus, two quality objectives could not be assessed.

Finally, it is important to point out that due to auditors B2 and C6 facing some problems to understand how to draft the Audit+ report, they suggested the following improvements for this section of the procedure:

- clarify the distinction between the internal and external assessment of processes;
- state that organisations may have macro KPIs stated in business goals and quality objectives that have to be specially assessed (improve Clause 5.26 of the Audit+ procedure);
- provide more guidelines about how to assess efficiency, efficacy and adaptability in processes, the current guidelines stated in Clause 5.22 are still subjective; and
- provide more tables which help to create the Audit+ report in an easy-to-follow way for top management.

APPENDIX K
SUMMARY OF THE CASE STUDIES

Case X1

Company profile	
Type of company	Multinational
Year of certification	2002
Industry sector	Logistic services
Scope of the Audit+	-Sea-freight exports and imports -Air-freight exports and imports -Insurance -Internal auditing
Maturity level of the QMS	3

Application of the Audit+ procedure

Stage of auditor's training

The training of internal auditors B2 and C6 was conducted during the Audit+ workshop on 17th August 2011 at the Culture and Arts Council of Mexico. The workshop lasted 8h and was divided into three main stages. During the first stage, each section of the Audit+ procedure was reviewed in detail. In the second stage, auditors were provided with exercises in order to put the PM concepts of Audit+ into practice. Finally, in the last stage participants were asked to assess the procedure with a questionnaire.

Stage of planning the Audit+

This stage was conducted on 18th August 2011 and auditors had the following difficulties with some of the activities stated in the procedure:

- translating the quality objectives into business objectives, there was little connection between the strategy of the organisation and the QMS;
- identifying the artistic and customised processes as defined by Hall & Johnson (2009);
- identifying KPIs, the audit team found several activities which did not have any control at all;
- understanding the concept of 'flexibility' by Cox (1989) in order to classify KPIs; and
- the records of the previous audit findings were omitted as an input of the Audit+.

The audit team also found the following activities of great value:

- the identification of business goals at the planning stage of the audit allowed the audit team to more clearly define the objective of the audit;
- the identification of artistic and customised processes permitted for planning the level of inspection needed for processes during the on-site audit;
- the review of the design of the processes allowed the audit team to anticipate possible failures; and
- the classification of KPIs allowed the determination of new KPIs.

Stage of doing the Audit+

The stage was conducted on 1st and 2nd September 2011 and during this stage auditors had some problems with the process assessment. The definitions of Roehleder & Silver (1997) regarding the effectiveness, efficiency and adaptability of processes were ambiguous for

auditors. Also, there was confusion between the concepts of 'adaptability' and 'flexibility'.

The audit team also found the following activities of great value:

- the assessment criteria for QMS processes (design, implementation and use) allowed the improvement of processes;
- the approach of making the audit a 'learning exercise' allowed auditees to be more open with auditors and this permitted the detection of improvements in the QMS; and
- the Neely *et al.* (1995) classification of individual metrics allowed the detection of KPIs.

Stage of checking the Audit+

This stage was conducted on 3rd September 2011 and auditors had the following difficulties with some of the activities stated in the procedure:

- assessing the processes according Roehleder & Silver (1997) criteria, Audit+ did not provide an example about how to state this assessment in the Audit+ report;
- creating the Audit+ report, the procedure did not include a full example of the report; and
- stating 'performance findings', the audit team identified that 'performance findings' are 'improvement opportunities'. Hence, there was confusion about what to state in the Audit+ report.

The audit team also found the following activities of great value:

- assessing KPIs and processes in addition to compliance with the ISO 9001 standard was found very useful by auditees and top management;
- changing of the approach of this stage from an activity of ticking boxes into an audit assessment was found of great value by auditors; and
- evaluation of business goals in addition to the QMS

Case X2

Company profile	
Type of company	SME – Family business
Year of certification	2010
Industry sector	Medical care
Scope of the Audit+	QMS
Maturity level of the QMS	3

Application of the Audit+ procedure

Stage of auditor's training

The training of internal auditors was conducted on 5th September 2011 at the headquarters of the company. The training lasted 4h and was divided into three main stages. During the first stage, each section of the Audit+ procedure was reviewed in detail. In the second stage, auditors were provided with exercises in order to put into practice the PM concepts of Audit+. Finally, in the last stage participants were asked to assess the procedure with a questionnaire.

Stage of planning the Audit+

This stage was conducted on 6th September 2011 and auditors experienced the following problems with Audit+:

- identifying the 'artistic' processes;

- categorising the activities and task of processes, some processes did not have a task level;
- allocating the ISO 9001:2008 requirements in the checklist according to the activities/task of each process;
- identifying KPIs of administrative processes and relating them to business goals; and
- understanding the concept of 'flexibility' in the classification of individual measures.

The audit team found the following activities of great value:

- identifying activities and tasks allowed the detection of failures in processes;
- allocating the ISO 9001:2008 requirements allowed personnel to understand the standard; and
- indentifying KPIs allowed the detection of activities which were not controlled.

Stage of doing the Audit+

The stage was conducted from 7th – 8th September 2011 and the audit team had the following problems:

- interpreting with clarity some ISO 9001:2008 requirements;
- conducting the assessment of processes, the concept of 'adaptability' was not fully understood;
- understanding the concept of 'flexibility' in the individual measures; and
- assessing KPIs.

Internal auditors found the following activities of great value:

- assessing KPIs allowed the detection of inconsistencies with business goals;
- evaluating the design, implementation and use of the QMS processes allowed the detection of failures; and
- using a customised checklist divided into activities/tasks/KPIs/ISO 9001:2008 requirement allowed auditors to have better control during the audit.

Checking the Audit+

This stage was conducted on 9th September 2011 and auditors experienced the following problems:

- identifying the ISO 9001:2008 requirements associated with non-conformities;
- assessing the processes according to the Roehleder & Silver (1997) criteria;
- creating the Audit+ report, the procedure did not include a full example of the report; and
- stating 'performance findings', the audit team identified that 'performance findings' are 'improvement opportunities'. Hence, there was confusion about what to state in the Audit+ report.

Auditors found the following activities of great value:

- top management was very satisfied with the results of the audit;
- assessing KPIs and processes in addition to compliance with the ISO 9001 standard was found very useful by auditees and top management; and
- changing of the approach of this stage from a box ticking activity to an audit assessment was found of great value by auditors.

Case X3

Company profile	
Type of company	Large – State owned
Year of certification	2006
Industry sector	Higher education
Scope of the Audit+	Teaching, research and purchasing processes
Maturity level of the QMS	3

Application of the Audit+ procedure

Stage of auditor's training

The training of internal auditors was performed on 23th August 2011 at the headquarters of the organisation. The training lasted 8h and was divided into three main stages. During the first stage, each section of the Audit+ procedure was reviewed in detail. In the second stage, auditors were provided with exercises in order to put into practice the PM concepts of Audit+. Finally, in the last stage participants were asked to assess the procedure with a questionnaire.

Stage of planning the Audit+

This stage was conducted on 13th September 2011 and the only problem that auditors faced during this stage was identifying KPIs of 'flexibility'.

Stage of doing the Audit+

The stage was conducted from 19th – 20th September 2011 and auditors experienced problems with the process assessment. It was difficult for auditors to assess the adaptability of processes using only the Roehleder & Silver (1997) definition. Also, there were problems with the definition of 'flexibility'.

The audit team also found the following activities of great value:

- classifying individual metrics as metrics of quality, cost, time and flexibility allowed the detection of inconsistencies in some KPIs;
- assessing the effectiveness and efficiency of processes allowed the identification of failures in processes; and
- conducting the audit as a learning exercise for auditees allowed organisation's personnel to be more open during the audit and this permitted auditors to detect inconsistencies in processes and services.

Stage of doing the Audit+

The stage was conducted on 29th September 2011 and auditors faced the following problems:

- assessing the 'adaptability' of processes, the Roehleder & Silver (1997) criteria was confusing;
- creating the Audit+ report, the procedure did not include a full example of the report; and
- stating 'performance findings', the audit team identified that 'performance findings' are 'improvement opportunities'. Hence, there was confusion about what to state in the Audit+ report.

The audit team also found the following activities of great value:

- assessing KPIs and processes in addition to compliance with the ISO 9001 standard was found to be very useful by auditees and top management; and
- changing the approach of this stage from a box ticking activity to an audit assessment.

Suggested improvements for Audit+

During the three in-depth case studies, internal auditors suggested the following improvements to Audit+:

- including the results of previous audit findings in the input section of the procedure;
- adding the Neely *et al.* (1995) questions for determining the assessment of PM systems in the planning and doing the Audit+ stages;
- clarifying the criteria for assessing the effectiveness, efficiency and adaptability of processes;
- including criteria to classify individual measures as 'measures of flexibility';
- adding a full example of the Audit+ report, integrating the assessment of processes, KPIs and business goals;
- changing the requirement of the level of maturity of the QMS to 3-5;
- clarifying that 'performance findings' can be 'improvement opportunities; and
- including an example of an executive presentation of the Audit+ report for top management.

APPENDIX L

FEEDBACK QUESTIONNAIRE FOR AUDIT+ WORKSHOPS

Criteria for evaluation

(A)	Feasibility
(B)	Usability
(C)	Utility
(D)	Additional information

Usability and utility of the procedure

PLANNING THE AUDIT+ STAGE

Please tick (✓) your answers in the following questions:

1.1 (B) ¿Was the stage of '**planning the Audit+**' easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

1.2 (B) ¿Was the activity of '**processes identification**' (Clause 5.4) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

1.3 (B) ¿Were the activities of building the **'checklist for the assessment of the Audit+ based on processes, KPIs, type of metrics and ISO 9001 clauses'** (Clauses 5.5 – 5.10 of the Audit+ procedure) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

1.4 (C) ¿Has the stage of '**planning the Audit+**' enable to take into account relevant factors that otherwise you could have been overlooked with the traditional approach of auditing?

_____ Yes _____No _____I don't know

1.5 (D) What are the main problems that you identify in the stage of '**planning the Audit+**?

_____
_____
_____
_____

DOING THE AUDIT+ STAGE

Please tick (✓) your answers in the following questions:

2.1 (B) ¿Was the stage of '**doing the Audit+**' easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

2.2 (B) ¿Was the activity of '**assessing if the elements of processes are adding value to the QMS'** (Clause 5.18) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

2.3 (B) ¿Was the activity of **'assessing KPIs'** (Clause 5.19) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

2.4 (B) ¿Was the activity of **'assessing PM processes/methods of the QMS'** (Clause 5.20) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

2.5 (C) ¿Has the stage of '**doing the Audit+**' enable to take into account relevant factors that otherwise you could have been overlooked with the traditional approach of auditing?

_____ Yes _____No _____I don't know

2.6 (D) What are the main problems that you identify in the stage of '**doing the Audit+**?

_____
_____
_____
_____

CHECKING THE AUDIT+ STAGE

Please tick (✓) your answers in the following questions:

3.1 (B) ¿Was the stage of '**checking the Audit+**' easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

3.2 (B) ¿Was the activity of '**assessing processes externally'** (Clause 5.22) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

3.3 (B) ¿Were the activities of **'creating the Audi+ report'** (Clauses 5.23-5.26) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

3.4 (C) ¿Has the stage of '**checking the Audit+**' enable to take into account relevant factors that otherwise you could have been overlooked with the traditional approach of auditing?

_____ Yes _____No _____I don't know

2.6 (D) What are the main problems that you identify in the stage of '**doing the Audit+**?

_____

_____

_____

_____

ACTING ON THE AUDIT+ STAGE

Please tick (✓) your answers in the following questions:

4.1 (B) ¿Was the stage of '**acting on the Audit+**' easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

4.2 (B) ¿Was the activity of '**appointing a follow-up group of experts'** (Clause 5.30) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

4.3 (B) ¿Were the activities of **'creating the Audit+ action plan'** (Clauses 5.31-5.33) easy to understand and follow?

1. Very easy	*2. Easy*	*3. Neither easy or difficult*	*4. Difficult*	*5. Very difficult*	*6. I don´t know*
Comments:					

4.4 (C) ¿Has the stage of '**acting on the Audit+**' enable to take into account relevant factors that otherwise you could have been overlooked with the traditional approach of auditing?

_____ Yes _____No _____I don't know

2.6 (D) What are the main problems that you identify in the stage of '**acting on the Audit+**?

_____

_____

_____

_____

_____

_____

Feasibility of the procedure

- Name:_____
- Job title: _____ Date: ____/____/____
- Organisation:_____

Please assess the following sections of the Audit+ according to the following scale:

(1) Very good, (2) Good, (3) Needs improvement, (4) Needs re-written

If you chose options **[3] o [4] please let us know why**

(A) General assessment of each section	*Scale*	*Notes*
1) Rationale of performance auditing	1 2 3 4	
2) Purpose of the procedure	1 2 3 4	
3) Scope of the procedure	1 2 3 4	
4) Responsibility and authority	1 2 3 4	
5) Description of activities	1 2 3 4	
6) Records	1 2 3 4	
7) Appendix A- Process categorisation	1 2 3 4	
8) Appendix B – Individual measures	1 2 3 4	
9) Appendix C – The ISO 9001 PM system	1 2 3 4	
10) Identification of changes	1 2 3 4	
11) Bibliography	1 2 3 4	

Do you have any suggestion to improve the procedure?

_____
_____
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_____

APPENDIX M
QMS AND QUALITY TOOLS AND TECHNIQUES

During the last two decades, there has been a wide proliferation of QMS and quality tools and techniques.

Dale (2007) argues that the purpose of a QMS "is to establish a framework of reference points to ensure that every time a process is performed with the same information, methods, skills, and controls are used and applied in a consistent manner" (Dale, 2007, pp 280). Taking as a base this definition and the recent literature, it can be argued that the most used QMS are: total quality management (TQM), ISO 9000, business excellence models and six sigma (Zhu & Scheuermann, 1999; Kartha, 2004; Martínez-Costa *et al*., 2007; Martínez-Costa *et al*., 2009). In the following paragraphs, a description of these QMS is provided.

Total quality management (TQM)

Kartha (2004) defines TQM as "a systems approach to management that aims to enhance value to customer by designing and continually improving organizational processes and systems" (pp. 331). Whereas for Dale *et al.* (2007), it is "the mutual co-operation of everyone in an organisation and associated business processes to produce value-for-money product and services which meet and, hopefully, exceed the needs and expectations of customers" (Dale *et al*, 2007, pp. 4). Moreover, TQM focuses externally on meeting customer requirements, while internally on management commitment and employee training and education. Its main objective is to embed quality into process, products and services (Zhu & Scheuermann, 1999). Hence, TQM is a company-wide approach to quality, with improvement undertaken on a continuous basis by everyone in the organisation.

Najmi & Kehoe (2001) argue in their literature review that there is no common approach and assessment tool for TQM. However, more recently, Dale *et al.* (2007) provide a list of key elements of what constitutes TQM:

- commitment and leadership of the chief executive officer;
- planning and organisation;
- using tools and techniques;
- education and training;
- involvement;
- teamwork;
- measurement and feedback; and
- ensuring that the culture is conductive to continuous improvement activity.

Dale *et al.* (2007) also argue that the TQM philosophy involves the application of quality management principles to all the aspects of the organisation, including

customers and suppliers and their integration in key business processes. Interestingly, these authors cite the QMS principles stated in ISO 9000:2005 as the TQM management principles.

Brelin *et al*. (1996), cited by Zhu & Scheuermann (1999), suggest a list of steps that organisations should follow to implement TQM:

1. To identify important business processes by which product/services are delivered and to improve the flow of ideas and interdepartmental communication;
2. To clarify the company's mission statement into several business goals;
3. To develop statistical measurements for each of these processes;
4. To set standards of performance and evaluation of current performance within these processes so that poorly performing processes can be indentified and tackled with TQM;
5. To train employees in statistical process control and give them authority to make decisions in their daily tasks; and
6. To implement rewards for ingenuity and quality improvement.

More recently, Dale *et al.* (2007c) have suggested that for applying TQM, a company should conduct the following actions:

1. Implement methods outlining the wisdom, philosophies and recommendations of the international respected experts in the subject (Crosby, 2004; Deming, 2000; Feigenbaum, 2008; Juran, 1989);
2. Prescribe step-by-step the approaches of action 1;
3. Create a TQM plan in order to translate all the TQM principles into actions across the organisation;
4. Implement non-prescriptive methods in the form of a framework or model; and
5. Use self-assessment methods based on business excellence models such as the Malcom Baldrige National Quality Award (MBNQA) and the European Quality Award (EQA).

Also, Dale *et al.* (2007d) argue that TQM philosophy can be divided into four main areas for its implementation: organising, systems and techniques, measurement and feedback and culture change. Meanwhile, Dale and Lascelles (2007) identify the following six different levels of TQM adoption:

1. Uncommitted;
2. Drifters;
3. Tool-pushers;
4. Improvers;
5. Award-winners; and

6. World class.

These authors argue that these levels are not stages; they are characteristics and behaviours which organisations display at the point in time in relation to TQM.

It is important to highlight that TQM is a long-term process which requires dedication and hard work. An organisation should expect to get benefits from TQM after some years.

ISO 9000

The objective of the ISO 9000 family of QMS standards is to provide customers with an assurance that the quality of products and services that they are buying meet their requirements (Dale, 2007). The ISO 9000 core of standards consists of four standards:

- ISO 9000:2005 – Quality management systems – Fundaments and vocabulary;
- ISO 9001:2008 – Quality management systems – Requirements;
- ISO 9004:2009 – Quality management systems – Guidelines for the sustained success of organisations; and
- ISO 19011:2011 – Quality management systems – Guidelines for auditing management systems.

These standards are based on eight quality management principles:

- customer focus;
- leadership;
- involvement of people;
- process approach;
- system approach to management;
- continual improvement;
- factual approach to decision-making; and
- mutually beneficial supplier relationship

(ISO 9001, 2008)

To develop a QMS based on ISO 9000 standards, an organisation should identify their clients, products and processes and document a quality manual based on the ISO 9001 requirements. The quality manual should include, at least, a quality policy, six mandatory procedures and a description about how the organisation fulfils ISO 9001 requirements (see ISO 9001, 2008). Because ISO 9001 is generic standard, an organisation is free to exclude requirements from the 'product realisation' element. However, the reasons for the exclusion should be stated in the quality manual. Also, under the ISO 9000 scheme, organisations are free to develop more procedures, work instructions and as many records as they need in order to document their QMS.

Dale (2007) argues that "ISO 9001 and ISO 9004 define and set out a definitive set of features and characteristics which should be presented in an organisation's quality management system through documented policies, manual and procedures, wherever the product is manufactured or offered, or the service provided, or the technology used. In this way sound advice is provided on how an organisation may develop a quality system" (pp. 306).

Business excellence models

Dale *et al.* (2007e) state that the main reason for the increasing interest in business excellence models is the self-assessment criteria that these quality awards provide to organisations in order that they will be able to evaluate their improvement. The authors also indicate that business excellence models help organisations to develop and manage their improvement activities in a number of ways, such as:

- providing a definition and description of business excellence;
- enabling measurement of progress with business excellence;
- encouraging annual improvement;
- forcing management to think about the basic elements of their business and how it operates;
- providing an objective, fact-based measurement system using scoring criteria;
- forcing the implementation of best practices and organisational learning facilities;
- improving education of management and employees; and
- helping to develop a more cohesive company working environment.

There are several internationally recognised business excellence models, but the most prestigious are the Deming Application Prize in Japan, the Malcolm Baldrige national quality award (MBNQA) and the European quality award (EQA).

The Deming application prize in Japan

The Deming application prize was established in 1951 in honour of Dr W. E. Deming. It was created to ensure that good results are achieved through the implementation of company-wide control activities and it is based on the application of a set of principles and statistical techniques (Dale *et al.,* 2007e). The Union of Japanese Scientists and Engineers (JUSE) has identified the following results which have been achieved in applying for the prize (Dale et al., 2007e):

- quality stabilisation and improvement;
- production improvement/cost reduction;

- expanded sales;
- increased profits;
- thorough implementation of management plans/business results;
- realisation of top management's vision;
- participation in and improvement of the organisational constitution;
- heightened motivation to manage and improve as well as to promote standardisation;
- harnessing power from the bottom of the organisation and enhanced morale; and
- establishment of various management systems and the total management systems.

The Deming application prize consists of ten primary categories: policies; organisation; information; standardisation; human resources development and utilisation; quality assurance activities; improvement; effects; and future plans. Subsequently, each primary category is divided in six sub-categories, apart from quality assurance activities which is divided into twelve. In order to maintain flexibility, there are not a number of points established to qualify each sub-category (Dale *et al.,* 2007e). The examiners of the prize are selected by JUSE from quality management experts from non-for-profit organisations. To apply for the prize, organisations need to submit a detailed document arguing how they are fulfilling each of the prize's criteria. Thus, the prize committee review the document and decide if the applicant is suitable for an on-site examination. The committee chooses the experts who conduct the examination. Dale *et al.* (2007e) argue that organisations get a great deal on advice from the examination.

The Malcolm Baldrige national quality award (MBNQA)

This prize was launched by President Regan in 1987 to improve the quality management practices of US firms. The award is named in honour of the former American Secretary of Commerce in the Reagan administration, Malcolm Baldrige. The award is made by the US President and the winners can advertise their award if they agree to share information about their quality management and improvement strategies with other American organisations.

The Baldrige award is evaluated in seven major categories with a maximum total score of 1,000 points (Dale *et al.,* 2007). The categories are: leadership (120 points); strategic planning (85 points); customer and market focus (85 points); information and analysis (90 points); human resources focus (85 points); process management (85 points) and business results (450 points). These categories are divided into 18 items and the further items are defined by 29 areas to address (Dale *et al.,* 2007b). The criteria and award process is reviewed every year in order to keep them up to date.

As well as the Deming prize, the evaluation of the MBNQA is based on a written application that summarises the organisation's practices and results. The examiners use three main indicators of success: approach; deployment; and results. Approach and deployment are scored together and results are evaluated based on convincing data of improvement over time. After this document is reviewed, the selected candidates receive an on-site visit of examiners to verify information and clarify issues and questions from the documented review. Later, a panel of judges reviews all the data from the written application and on-site visit, and recommends the award winners.

The European quality award (EQA)

The EQA was established in 1991 to help the management of European organisations to understand best practice relating to quality and support them in their leadership role (Dale *et al.,* 2007e). As well as the MBNQA the EQA is evaluated based on a set of categories which total 1000 points. These categories are: leadership (100 points); policy and strategy (80 points); people management (90 points); partnership and resources (90 points); processes (140 points); customer results (200 points); people results (90 points); society results (60 points); and key performance results (150 points).

As Dale *et al.* (2007e) explain, these criteria are divided into an enables group and results group, each with a possible 500 points. The model is based on the principle that people and enablers provide results. Thus, the award is evaluated based on four indicators: results; approach; deployment; and assessment and review. The scoring is done on a scale of five levels where 0% indicates no evidence, implementation or results; 25% represents that the organisation is just starting; 50% indicates some progress; 75% considerable progress; and 100% excellence.

For the EQA, like the Deming Prize and the MBNQA, a written application needs to be submitted to apply for the prize. A team of independent assessors examines each application and decides whether or not to conduct a site visit. Dale *et al.* (2007e) clarify that the assessors are mainly practising managers, but there are quality professionals and academics too. Irrespective of whether an organisation is selected for a site visit, all of the participants receive a feedback report. However, the feedback for the visited organisations contains more detailed information. After the site review, a jury of seven examiners from business and academia reviews the findings and decides the winners of the prize.

Six sigma

In the mid-1980s, Motorola created the concept of 'six sigma' to improve its performance. The goal of Six sigma is creating value through quality improvement.

Van Der Wiele *et al.* (2007) state "six sigma makes use of quality engineering methods within a defined problem-solving structure to identify and eliminate process defects and solve problems and in this improves yield, productivity, operating effectiveness, customer satisfaction, etc." (van Der Wiele et al., 2007, pp. 469). Six sigma is a relatively new QMS whose benefits are currently being researched.

As van Der Wiele *et al.* (2007) point out, many objectives of this QMS are similar to those of TQM, such as, customer orientation and focus; team based activity; comprehensive education and training; and problem solving methodology. These authors also argue that six sigma is not a universal success and that organisations that want to achieve success using it need to have reached high levels of quality maturity.

The 'six sigma' name comes from the statistical variation in terms of the standard deviation applied to quality control. The higher the sigma value, the lower number of defects associated with the process, the lower the cost of rework and scrap and the lower the cycle time of the process. Thus, six sigma is 3.4 defects per million.

Also, van Der Wiele *et al.* (2007) identify four prerequisites to implement six sigma:

- high level of commitment and involvement of the management;
- high level of QMS sophistication, six sigma needs to be treated as a quality philosophy;
- high commitment to reducing defects; and
- business focus.

The following can be considered as the central elements of six sigma:

- focus on customer;
- data and fact-driven management;
- specific training;
- structured approach;
- quality engineering;
- process focus, control and improvement;
- proactive management;
- 'boundary-less' collaboration;
- drive for perfection;
- cost saving of each project; and
- short-term improvement projects.

van Der Wiele *et al*. (2007)

Six sigma's concept is based on problem-solving approaches for process improvement; process design/redesign; and process management. Depending on the organisational process, the cycles 'define-measure-analyse-improve-control' or 'define-measure-analyse-design-verify' need to be used in order to apply Six sigma. Van Der Wiele *et al.* (2007) argue that this QMS has been criticised because its

approach has not been successful. However, six sigma has proven its financial benefits.

Quality tools and techniques

Dale (2007b) argues that the most popular and known quality management tools and techniques are:

- checklists;
- flowcharts;
- the seven quality control tools (QC7: cause and effect diagram, check sheet, control chart, graphs, histogram, Pareto diagram and scatter diagram);
- quality costing;
- statistical process control;
- failure mode and effects analysis;
- fault tree analysis;
- design of experiments;
- quality function deployment;
- the seven management tools (M7: affinity diagrams, relations diagrams, systematic diagrams, matrix diagrams, matrix data analysis, process decision programme chart and arrow diagrams);
- departmental purpose analysis;
- mistake- proofing;
- benchmarking;
- total productive maintenance; and
- housekeeping.

Dale (2007b) also argues that these tools and techniques are mainly for improving processes and products and summarises their benefits as follows:

- summarising data and organising its presentation;
- data-collection and structuring ideas;
- identifying relationships;
- discovering and understanding a problem;
- implementing actions;
- finding and removing the causes of the problem;
- selecting problems for improvement and assisting with the settings of priorities;
- monitoring and maintaining control;
- planning; and
- performance measurement and capability.