We shall *not cease from exploration*
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time.

T.S. Eliot

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Information systems and quality management systems: researching lifecycle synergies

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"Men and women confronting change are never fully prepared for the demands of the moment, but they are strengthened to meet uncertainty if they can claim a history of improvisation and a habit of reflection (...). Learning to savor the vertigo of doing without answers or making shift and making do with fragmentary ones opens up the pleasures of recognizing and playing with pattern, finding coherence within complexity, sharing within multiplicity"

Mary C. Bateson, Peripheral Visions: Learning Along the Way, 1994

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Abstract

We propose an approach for the synergistic development of the information system (IS) and the quality management system (QMS), in the context of ISO 9001.

ISO 9001 is a quality standard adopted by more than one million organizations worldwide. Compliance with standards and their regulations is a foremost concern for ISO 9001-certified organizations. They are asked to plan, document, audit, and continuously improve their business processes. Moreover, QMS development comprises the internalization of quality principles into daily practice, fostering a quality culture in the entire organization.

An information system is a socio-technical construct that usually includes information technologies (IT) in support of the business processes. Additionally, standards and regulations become a vital source of information to define the context in which the IS operates. In this complex scenario, IS development (ISD) lifecycle calls for a comprehensive design and support for continuous change. It must ensure conformity to the organizational goals and rules, aligned with the organizational policies.

The IS and the QMS depend on each other; however, they are different in nature and their integration can be problematic. Especially, if each field sees the other as a mere way to solve their own needs: the IS in providing tools and information for quality management; the QMS in providing normative guidance with principles and practices that apply to the IS. We argue that a third perspective is possible and desirable. The one which combines efforts within the IS/QMS development lifecycle, addressing five interrelated dimensions: (1) a *context* that is shaped by quality principles; (2) the *people* involvement in the IS/QMS development lifecycle; (3) the formal and informal business *processes*; (4) the formal and informal *IT* that supports them; and (5) the flows of *information/data*.

The main outcome of this thesis is an approach that we named ISO_2. It was first drafted from a systematic literature review, interviews with quality auditors, and fourteen case studies. We then validated and refined ISO_2 in three action research projects. We gathered evidence in our research that ISO_2 can: (1) provide a step-by-step guide to assist the synergistic development of the IS and QMS; (2) facilitate a common understanding by the IS/QMS experts about the interdependence between their systems within the lifecycle; (3) define goals and rules for the systems development, considering five main dimensions: *context*, *people*, *process*, *IT*, and *information/data*; (4) integrate regulations in the joint development of the IS and the QMS; (5) create artifacts that link each of the five main dimensions identified – the O_2 artifacts; (6) assess and improve IS quality culture; (7) assess and improve the business processes quality culture.

According to the organizations in our study, the ISO_2 approach is simple to use at design-time, integrating the viewpoints of IS/QMS stakeholders. Moreover, at run-time, it backs the audit and improvement of the IS and the QMS, suggesting a unified action plan that explores synergies. ISO_2 can also offer a key contribution in the transition to the new version of ISO 9001, to be released in 2015, which anticipates (1) the increasing importance of quality principles; (2) a broader evaluation of organizational context; (3) the need of documented information; and (4) advanced evidence of improvement.

Resumo

Propomos uma abordagem para o desenvolvimento sinergístico do sistema de informação (SI) e do sistema de gestão da qualidade (SGQ), no contexto da ISO 9001.

A ISO 9001 é uma norma da qualidade adotada por mais de um milhão de organizações em todo o mundo. A conformidade com normas e as regulamentações associadas é uma prioridade para as organizações certificadas pela ISO 9001. Estas necessitam de planear, documentar, auditar e melhorar continuamente os processos de negócio. Adicionalmente, o desenvolvimento do SGQ compreende a internalização dos princípios da qualidade na prática diária, envolvendo todos na promoção de uma cultura da qualidade. O sistema de informação é uma construção sociotécnica que usualmente inclui as tecnologias de informação (TI) para suportar os processos do negócio. Também as normas e regulamentação constituem uma fonte de informação para definir o contexto do SI. Neste cenário complexo, o ciclo de vida do desenvolvimento de SI (DSI) requer um desenho abrangente e suporte para a mudança, em conformidade com os objetivos, regras e políticas organizacionais.

O SI e o SGQ são mutuamente dependentes, contudo, têm natureza diferente e a sua integração pode ser problemática. Especialmente se cada área vir a outra como uma mera forma de resolver as suas próprias necessidades: SI a disponibilizar ferramentas e informação para gestão da qualidade; SGQ a proporcionar orientação normativa com os princípios e práticas aplicáveis ao SI. Defendemos que uma terceira perspetiva é possível e desejável. A que combina os esforços ao longo do ciclo de desenvolvimento do SI/SGQ, abordando cinco dimensões interrelacionadas: (1) um *contexto* delineado por princípios da qualidade; (2) o envolvimento das *pessoas* no ciclo de desenvolvimento do SI/SGQ; (3) os *processos* de negócio formais e informais; (4) as *TI* formais e informais que os suportam; e (5) os fluxos de *informação/dados*.

O principal contributo desta tese é uma abordagem que designámos por ISO_2. Foi delineada a partir de uma revisão sistemática da literatura, entrevistas com auditores da qualidade e catorze estudos de caso. Posteriormente, validámos e refinámos a ISO_2 em três projetos de investigação ação. Obtivemos evidências que a ISO_2 pode: (1) proporcionar um guia passo-a-passo para assistir ao desenvolvimento sinergístico do SI/SGQ; (2) facilitar uma perceção comum acerca das interdependências entre os sistemas ao longo do ciclo de vida, pelos especialistas do SI/SGQ; (3) definir objetivos e regras para o desenvolvimento do SI/SGQ, considerando cinco dimensões principais: *contexto, pessoas, processos, TI e informação/dados*; (4) incluir a regulamentação no desenvolvimento conjunto do SI e do SGQ; (5) criar artefactos que interligam cada uma das cinco dimensões identificadas – artefactos O_2; (6) aferir e melhorar a cultura da qualidade do SI; (7) aferir e melhorar a cultura da qualidade dos processos de negócio.

De acordo com as organizações no nosso estudo, a ISO_2 é simples de utilizar na fase de desenho, integrando os pontos de vista de várias partes interessadas do SI/SGQ. Adicionalmente, na fase de operação, ajuda na auditoria e melhoria do SI e do SGQ, sugerindo um plano de ação unificado que explora sinergias. A ISO_2 pode dar um contributo relevante na transição para a nova versão da ISO 9001, esperada para 2015 e que antecipa (1) a importância crescente dos princípios da qualidade; (2) uma avaliação mais abrangente do contexto organizacional; (3) a necessidade de ter informação documentada; e (4) uma melhor evidência de melhoria.

Table of contents

List of figures

List of tables

Glossary of Key Terms and Abbreviations

AR   The abbreviation of Action Research. A research approach developed in a client setting with the active participation of the researcher. There are different forms of action research, involving cycles of diagnosing, action taking, and reflection conducing to learning. Action research is used to solve problematic situations whilst contributing to enhance the body of knowledge on the topic.

BPM   The abbreviation of Business Process Management. It involves the activities of analysis, design, execution, monitoring and measurement, as well as continuous improvement of business processes.

CAR   The abbreviation of Canonical Action Research. It is one of the forms of Action Research.

D&D   The abbreviation of Design and Development. There are specific requirements in ISO 9001 for the process of design and development.

IS   The abbreviation of Information System. It is a socio-technical construct that usually includes information technologies (IT) in support of the business processes.

ISO   The abbreviation of International Organization for Standardization. It is a network of national standards institutes with the purpose of developing and publishing international standards.

ISO 9001   A quality standard developed by ISO. It is a voluntary form of regulation, focusing on customer satisfaction and the continuous improvement of business processes.

ISO$_2$ An approach proposed in this thesis for the joint design and management of information systems (IS) and quality management systems (QMS). It is structured in seven steps, supported by a set of artifacts (e.g., tables and diagrams), that can be used to design, implement, and continuously improve both systems comprehensibly and simultaneously.

IT   The abbreviation of Information Technologies. It includes the hardware and software used to support business processes within a specific context.

MUVE   A socio-technical approach to improve business processes by taking into account the perspectives of the participants. MUVE suggests four dimensions that must be improved to remove process friction, namely, Motivation, Understanding, Value, and Effort.

O$_2$ An information system design framework proposed in this thesis. It suggests that a comprehensive study of the information system should consider at least five dimensions: People, Processes, Information Technology (IT), Information/Data, and Context. Changing one of the dimensions can affect how information flows within, inside-out and outside-in the boundaries of the system.

ORS
The abbreviation of Organizational Regulatory Space. It can be defined as a combination of public and private characteristics that involve dynamic relations between people and organizations and within the latter, sharing a common space of specific regulatory issues.

QIS
The abbreviation of Quality Information System. It is defined in this thesis as a system that intertwines people and IT, in a context that is influenced by quality policies, procedures, standards, the organizational infrastructure, and its external environment, processing information in cycles of planning, execution, monitoring, measurement, and improvement of the organizational processes.

QMS
The abbreviation of Quality Management System. ISO 9001 is one of the most popular references to create, maintain, and improve a QMS. An ISO 90001-based QMS includes the resources and processes that an organization adopts to manage quality.

Regulations
All the principles, codes, and rules that must be followed. The regulations may be enforced or adhered to voluntarily.

Regulatory Compliance
To act according to the principles, codes, and rules applied to a specific activity. Processes may play a role in achieving compliance with regulations that include identifying, interpreting, diffusing, adopting regulations, and providing evidence of the compliant behavior.

Chapter 1

Introduction

This chapter presents the introduction to the research that we conducted in this thesis. Our contribution addresses the synergistic development of two critical organizational systems: the Information System (IS) and the Quality Management System (QMS) in the context of the ISO 9001 standard (ISO, 2008b). We begin by framing the problem space and the motivation to embark on a Ph.D. journey. Next, we present the purpose and the objectives of our research, as well as a summary of the research strategy. Then, we discuss the importance of our work for both academics and practitioners. We then follow with a list of publications related to this dissertation. The introduction ends with the thesis outline, presenting the synopsis of the remainder chapters.

1.1   More than the sum of the parts

"More than the sum of the parts" is a vision presented by Cunha and Figueiredo (2005) for the joint development of the IS and the QMS. Their work was an inspiration and a starting point to increase the body of knowledge with this thesis. The QMS – concerned with the principles, policies, processes and procedures required for ensuring the quality objectives (Zhu & Scheuermann, 1999) – and the IS – consisting of technology, data, and people involved in delivering information and communication services (Davis, 2000) – are two main pillars of effective organizations. We begin by presenting each *"part"* addressed in our research. Then, we summarize the opportunity to explore the synergies between these two important organizational systems.

ISO 9001 is a standard for quality management, adopted by more than one million organizations worldwide (ISO, 2012b). It requires the internal development of management procedures, work instructions, improvement plans, and a demanding measurement system (ISO, 2008b). Moreover, ISO 9001 requires the development of external information flows (Forza, 1995b). Therefore, the QMS becomes a tool to manage the relations between the organization and its environment (Singh, Power, & Chuong, 2011). ISO 9001 is one of the most popular programs to implement a QMS (Sampaio, Saraiva, & Rodrigues, 2011; Zhu & Scheuermann, 1999), guiding the organizations in the creation of a documented system to manage their quality efforts (ISO, 2008a).

The greatest challenge that organizations face in their effort to implement ISO 9001 is making quality a daily practice, internalizing the quality principles in the development of a quality culture (Briscoe, Fawcett, & Todd, 2005; Ishikawa, 1984; Kanji & Yui, 1997; Kanji, 1998). ISO 9001 suggests eight essential quality management principles, namely: customer focus; leadership; involvement of people; process approach; system approach to management; continual improvement; factual approach to decision-making; and mutually beneficial supplier relationships (ISO, 2008b). A detailed presentation of the clauses of requirements and principles suggested by ISO 9001 is offered in Chapter 2. To conquer the ISO 9001 challenge, the IS becomes vital (Forza, 1995a, 1995b; Hemsworth, Sánchez-Rodríguez, & Bidgood, 2008).

The IS can be researched in a socio-technical perspective (Bostrom & Heinen, 1977), involving several interrelated dimensions, that may be technical, organizational, and semiotic (Lyytinen & Newman, 2006). These dimensions have influenced the *"glorious history"* of the IS field (Hirschheim & Klein, 2012), allowing researchers to holistically understand what emerges from the people use and adaptation of information technologies and organizational processes (Paul, 2007). During IS development (ISD), an organization embarks on a change process that may reorganize and expand the IS dimensions to serve an organizational purpose, in complex and dynamic environments (Lyytinen & Newman, 2006). Therefore, ISD must also consider the influence of the business environment and internal characteristics of the company, such as its policies, processes, and procedures (Böll, 2012; Curtis, Krasner, & Iscoe, 1988; Kautz, Madsen, & Nørbjerg, 2007).

IT is one of the important dimensions that we can address in IS research (Orlikowski & Iacono, 2001; Zhang, Scialdone, & Ku, 2011); however, it is not the only one as we can confirm in the definitions available (Alter, 2008; Böll, 2012; Carvalho, 2000; Davis, 2000; Lee, Thomas, & Baskerville, 2015). Moreover, information systems are multidisciplinary (Avison, Fitzgerald, & Powell, 2001; Hirschheim & Klein, 2012). The possibility of interrelating different dimensions, namely Context, People, Processes, IT, and Information/Data, allows us to find added value in IS research *"in asking questions that other disciplines are not asking or in addressing problems that others are incapable of addressing"* (Hassan, 2014, p. 41).

The literature shows that the IS has a significant impact on quality management and performance (Delić, Radlovački, Kamberović, Vulanović, & Hadžistević, 2014; Dewhurst, Martínez-Lorente, & Sánchez-Rodríguez, 2003; Sánchez-Rodríguez & Martínez-Lorente, 2011; Wai, Seebaluck, & Teeroovengadum, 2011). Information management can develop quality management capabilities such as customer management, process management, and performance management (Mithas, Ramasubbu, & Sambamurthy, 2011). The reverse is also true as argued by Delić et al. (2014), who highlight the role of quality management for overcoming the shortcomings of IT impact on organizational performance. A number of authors focused on the influence of quality principles in IS quality (Dahlberg & Jarvinen, 1997; Prybutok, Zhang, & Ryan, 2008; Ravichandran & Rai, 2000a; Wang, 1998). Other authors have studied the positive impact of quality principles in ERP – Enterprise Resource Planning (Li, Markowski, Xu, & Markowski, 2008; Lin, 2010; Schniederjans & Kim, 2003) and IS adoption (Hartman, Fok, Fok,

& Li, 2002). Yet, there is a lack of approaches to explore the mutual benefits of the IS and the QMS within their development lifecycle.

Information systems and quality management systems are mutually dependent and important for organizations' competitiveness worldwide (Au & Choi, 1999; Cunha & Figueiredo, 2005; Delić et al., 2014; Sampaio, Saraiva, & Rodrigues, 2009a). On the one hand, ISO 9001 requires the design of business processes and the creation of documented templates and procedures for their execution (Gingele, Childe, & Miles, 2002; Iden, 2012; ISO, 2008b). Moreover, some authors such as Au and Choi (1999) suggest the involvement of IT professionals in quality development efforts. On the other hand, the organizational IS deals with the information flows of the processes that the organization develops, with the supporting involved technologies and how users adopt and use them (Briggs, Nunamaker, & Sprague, 2011; Davis, 2000; Paul, 2007). However, we gathered evidence during our research that their design and operation is frequently disconnected, performed by different teams, with unrelated tools and methodologies. We confirmed previous findings that the IS and quality departments do not usually leverage the synergistic potential in combining their efforts (Cunha & Figueiredo, 2005; Spencer & Duclos, 1998). Several authors including Kumar and Balakrishnan (2011), Poksinska et al. (2006), and Withers and Ebrahimpour (2000) state that the increased demand of information is one of ISO 9001's problems, but the adoption of IT in support of quality efforts is not enough to overcome it (Forza, 1995a, 1995b; Morabito, Themistocleous, & Serrano, 2010). In fact, each of these two fields traditionally sees the other as a mere way to solve their own needs: the IS in providing tools and information for quality management (a mere supplier); the QMS in providing normative guidance with principles and practices that apply to the IS (a difficult regulator). In this type of perspective, each system expert sees the *foreign system* through his or her own lenses, focusing on the impact it has in his or her daily work. According to Pérez-Aróstegui, Bustinza-Sánchez, and Barrales-Molina (2015, p. 11) "*managers are able to take advantage of the synergies derived for implementing both QM* [quality management] *and IT programs*".

Joseph Campbell, a famous mythologist, writer, and lecturer, said that "*if you want to change the world, you change the metaphor*" (Moyers, 2008). We argue that the metaphor in which one system sees the other as foreign entity could be replaced by *an innovative breath of oxygen* for the joint development of the IS and the QMS. If we want to change this metaphor, we must understand the connections and the complementarities between the IS and the QMS. Connections may provide opportunities to create development partnerships between both systems experts and users; for example, in process improvements and documentation efforts. The complementarities may be explored to enhance the combination of outcomes; for example, the QMS can complement the IS with its principles and culture (Fok, Fok, & Hartman, 2001; Leidner & Kayworth, 2006), while the IS can enrich QMS efforts with well-structured development methods and information technologies (Ivanova, Gray, & Sinha, 2014). We can also find in the work of Joseph Campbell an appealing quote about IT: "*Computers are like Old Testament gods; lots of rules and no mercy*" (Campbell, 2003, p. 201). This sentence was cited by Richard Mason (2009) while explaining his personal interest in studying how people could use computers. We share the interest of Mason (2009) and agree with his view that an holistic IS should consider the

combination of people and technology to implement the optimal information flows, in a specific context. In our research, ISO 9001 and its interconnected regulations shape the context.

There is an opportunity to study the IS and the QMS as a whole, creating synergies in their lifecycle, throughout their development phases of design-time and run-time. The first phase addresses the systems design, while the second phase improves the operation of both the IS and the QMS. However, we found multiple obstacles in the course of our research. For example, modeling processes as required by ISO 9001 do not deliver a complete set of requirements for the IS (Okawa, Hirabayashi, Kaminishi, & Koizumi, 2011); permanent change and the internal policies developed in a QMS may create difficulties for the IS requirements identification and constant adjustments (Attaran, 2004; Spencer & Duclos, 1998); and there is a distinct vocabulary between the stakeholders that are involved in compliance to standards and other regulations (Abdullah, Sadiq, & Indulska, 2012). We must remove these obstacles, suggesting guidelines and artifacts (Lee et al., 2015; Pentland & Feldman, 2008; Zhang et al., 2011) to assist practitioners in their joint work.

The proposal of an approach to jointly develop the IS and the QMS in ISO 9001-certified organizations is a vast and complex assignment. One of its main difficulties is to assist both systems holistically and provide effective help to their users. Yet, it must be simple enough to be adopted by different systems stakeholders, whether IS/QMS experts or non-experts. The findings from the literature provide a strong motivation to create a new approach for the integrated lifecycle of IS and QMS. There are also personal reasons, as we bring in the next section.

1.2   Personal motivation

There are potential synergies to explore in the development of the IS and the QMS. We found that evidence in multiple sources: in the literature (Cunha & Figueiredo, 2005; Ferreira, Carvalho, & Sampaio, 2012) and in contacts with ISO 9001 auditors and consultants, academics, and IS/QMS managers in ISO 9001-certified organizations. In addition, the sixteen years of industrial engineering experience of the author in over 150 client organizations also underlined this perception. The blend of these facts was a strong motivation to propose a contribution to science in the form of a Ph.D. The research work was done in parallel with the professional activity of the author as consultant and invited lecturer in the area of IS. It was a challenge to combine three activities as important as the ones in attendance, but it was also an opportunity to evolve as an action researcher that must serve the interest of the academia and industry (Susman & Evered, 1978).

A contribution to science that addresses the development of two important organizational systems is a comprehensive task. A researcher with a background on IS and QMS activities was a potential advantage to accomplish such task, but there were additional variables in the problem space (e.g., regulatory compliance, social aspects, technological concerns). Nevertheless, during the research work, we understood that it was not possible to simply exclude *"parts"* in such a holistic purpose to joint develop the IS and the QMS. We addressed different dimensions of both

systems development: Context, People, Processes, IT, and Information/Data (Barata & Cunha, 2013a). Therefore, when we needed to opt, we decided to include rather to exclude areas that could potentially create synergies for the IS and the QMS, in the limits of time and resources that a Ph.D. allowed us to attempt it.

As research evolved, new aspects emerged in our course of discovery. We will present the details of the research progression to the reader, how the ideas materialized, which interpretations we used to guide our actions, the publications we have read, the ones we prepared, and the conclusions taken. We recognized the difficulties and embraced this challenge with transparency, *learning along the way*, improving techniques, creating a frame of reference (Checkland & Holwell, 1998b; Lau, 1999; Shrivastava & Mitroff, 1984), adopting the criteria and recommendations suggested by different scholars, specifically the ones made for the research approach that we have chosen (Davison, Martinsons, & Kock, 2004; Runeson & Höst, 2008).

1.3   Research purpose and objectives

This research intends to contribute for the realization of lifecycle synergies in the joint development of the IS and the QMS. Its relevance, pointed out in the literature, was confirmed by our preliminary contacts with IS/QMS practitioners, and it was observed by the author throughout several years of IS consulting in quality management contexts. Hence, to address this opportunity, our research purpose is to:

> *"Propose a synergistic approach for the joint development of the Information System and the Quality Management System, in the context of ISO 9001"*

To achieve this purpose we formulated the following research objectives (RO):

RO1. Compile relevant literature about IS and QMS synergies by means of a systematic literature review.

RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors.

RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations.

RO4. Outline the main steps of the synergistic approach for the phases of design-time and run-time in the joint development of the IS and the QMS.

As research evolved, we found problems and opportunities that led us to identify the additional research objectives:

RO5. Clarify the concept of quality information system in the selected organizations and propose a definition for our work.

RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles.

RO7. Contribute to the development of a business process quality culture in the selected organizations, in the context of organizational policies and ISO 9001 principles.

Several researchers and practitioners called for an approach capable of exploring synergies in the joint development of the IS and the QMS (Cunha & Figueiredo, 2005; Ferreira et al., 2012). Such an approach was not available before and it was our intention to make it accessible to the core actors of IS and QMS development: IS and QMS managers and consultants. Moreover, both, systems design and operation should also involve the process participants. People involvement is one of the quality principles of ISO 9001 (ISO, 2008b). It can be used for integrating stakeholders' concerns and viewpoints in IS development (Sommerville & Sawyer, 1997), and to reduce process friction while promoting process improvement (Antunes, Cunha, & Barata, 2014; Antunes & Cunha, 2013). Therefore, people learn and develop a quality culture, which exists trough the values defended by the organization, the ways of working, and the collective learning (Gallear & Ghobadian, 2004). In our research, three concepts emerge from the synergies that we found between the IS and the QMS, namely: quality information systems, IS quality culture, and business process quality culture.

We named our approach for the joint development of the IS and the QMS as ISO_2.

1.4 Research strategy

The research strategy is a general plan of how to address the research objectives, providing a guide to the researcher efforts (Saunders, Lewis, & Thornhill, 2009). We present our overall research strategy in Figure 1-1.
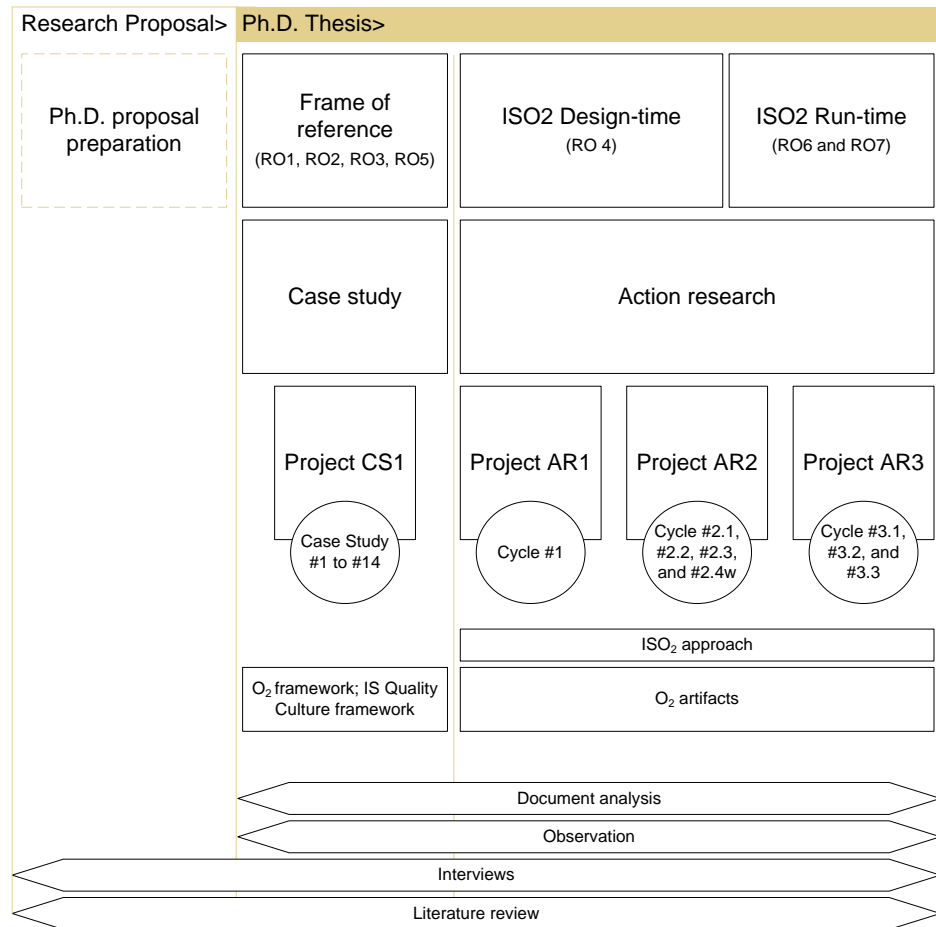
Figure 1-1. Overall research strategy

Figure 1-1 summarizes the evolution of our research regarding the different phases and its underlying research objectives represented in line 1, the approaches we selected in line 2, and the projects conducted in different organizations that we represent in line 3 (Lindgren, Henfridsson, & Schultze, 2004; Saunders et al., 2009). The figure also synthesizes the artifacts we developed and the data gathering techniques adopted while executing our research tasks (Myers & Newman, 2007; Myers, 1997; Walsham, 2006; Webster & Watson, 2002).

Our work started with a research proposal that is a requirement of the doctoral program. It is represented on top of Figure 1-1, as an exploratory phase of our research program to define the research purpose and objectives. To carry out the research proposal, we have interviewed five ISO 9001 auditors to understand the potential synergies between IS and QMS. Simultaneously, we performed the opening literature review about IS and ISO 9001-based QMS. We were able to consolidate ideas about the steps of an approach to assist IS and QMS professionals in their work. We proposed a first draft for the approach that was inspired in the literature review, the interviews, and projects that we had with companies at that moment.

Then, the research program aimed at the clarification of our frame of reference (Checkland & Holwell, 1998b; Lau, 1999; Shrivastava & Mitroff, 1984) for synergies in IS and QMS development. The Merriam Webster dictionary defines a frame of reference as "*a set of ideas,*

conditions, or assumptions that determine how something will be approached, perceived, or understood" (Webster, 2014). Shrivastava and Mitroff (1984) proposed a concept of frame of reference (FOR) for organizational research that includes analyzing practitioners' assumptions and concerns. We performed multiple case studies at this program phase. A case study is "*an empirical enquiry that investigates a contemporary phenomenon within its real life context*" and it "*relies on multiple sources of evidence*" (Yin, 1994, p. 13). We had the opportunity to study what happened in fourteen ISO 9001-certified organizations, before, during, and after the development of the IS and the QMS. Our sources of evidence were interviews with the IS and QMS managers, observation of the systems that they implemented and the processes they supported, and document analysis. During this period, we continued our literature review that is an important part of any research project (Tranfield, Denyer, & Smart, 2003), ensuring that our frame of reference was built from theory and practice.

Subsequently, to shape and refine our approach for the joint development of IS and QMS, we selected action research (AR), more specifically its canonical format described by Susman and Evered (1978). Among the multiple forms of action research (Baskerville & Wood-Harper, 1998), the Canonical Action Research (CAR) is characterized by five phases of *Diagnosing, Action planning, Action taking, Evaluating, and Specifying learning* (Susman & Evered, 1978).

We followed specific principles and criteria for CAR rigor and validity that were proposed by Davison et al. (2004). The principle of theory is one that Davison et al. (2004) describes, suggesting a thorough review of the existing literature to identify specific aspects of the focal problem. According to the authors, theory "*provides a basis for delineating the scope of data collection and analysis*" (Davison et al., 2004, p. 74), allowing the creation of frameworks to inform the process of research and guide the intervention. Earlier studies presented by Checkland and Holwell (1998) and Lau (1999) also stated the importance of creating a theoretical frame of reference before starting action research. According to Shrivastava and Mitroff (1984, p. 24), researchers need "*methods with qualitative approaches and action-oriented research design*" to produce more useful results to managers. The findings from the literature review, interviews with auditors, and fourteen case studies allowed us to create a first draft of the ISO_2 approach to use and refine in the initial action research cycle. We conducted action research in different organizations in a cyclic and iterative way. In each organization we learned different things, in different moments. The combination of cycles composed what we represent as an action research project (Holwell, 2004; Lindgren et al., 2004). An example of presenting one action research project with more than one CAR cycle can be found in Lindgren, Henfridsson, and Schultze (2004), that also evaluated their action research project with the criteria proposed by Davison et al. (2004). These authors inspired the structure that we selected for this thesis.

We differentiated three action research projects (Lindgren et al., 2004) involving one or more cycles, either parallel or sequential. Those projects had specific purposes for the ISO_2 evolution that are:

1. Project AR1 to shape and use ISO_2 for the first time, establishing a sequence of steps and the initial artifacts to assist its application;

2. Project AR2 to refine the ISO_2 design-time, when we wanted to improve the modeling of the systems in a way that different stakeholders could participate, involving multiple regulations;

3. Project AR3 to refine ISO_2 run-time, assisting the ISO_2 users in the evaluation and improvement of their joint developed systems.

1.5   Significance of the study

Our research is relevant for the synergistic development of two organizational systems: IS and QMS. From a theoretical perspective, it contributes to: (1) understand the auditors perspective of the IS in the context of ISO 9001; (2) identify the problems that exist in the lack of integration between the IS and QMS from the perspective of IS and QMS managers; and (3) propose of a joint development approach that holistically addresses the IS and QMS integrated lifecycle. From a practical perspective, our approach can contribute to: (1) improve the mutual understanding that both IS and QMS practitioners should have of each other's work; (2) guide auditing practices in the context of ISO 9001; and (3) provide artifacts that IS/QMS managers and consultants can use in daily practice.

Conducting action research promotes relationships between academia and industry. This effect is created when the researcher simultaneously works to increase the body of knowledge and solve concrete industrial problems (Baskerville, 1999). Our work adds to the literature of IS and QMS synergies, going beyond the mutual impact proof (Delić et al., 2014; Hartman et al., 2002; Li et al., 2008; Perez-Arostegui, Benitez-Amado, & Tamayo-Torres, 2012; Sánchez-Rodríguez & Martínez-Lorente, 2011). It provides a solution to improve compliance with regulations at design-time (Bonazzi, Hussami, & Pigneur, 2010; Julisch, Suter, Woitalla, & Zimmermann, 2011; Sadiq, Governatori, & Namiri, 2007; Wagner & Klueckmann, 2006) and run-time (compliance auditing, improvement), while exploring the synergies between IS and QMS. Moreover, the proposed approach offers a way of internalizing high-level quality principles in daily practice of business processes (Schmiedel, vom Brocke, & Recker, 2014; vom Brocke & Schmiedel, 2011), and quality management (Kanji & Yui, 1997; Kanji, 1998; Philip & McKeown, 2004). There is a mutual influence of quality culture and IS (Leidner & Kayworth, 2006; Philip & McKeown, 2004), but the literature has been inclined toward studying the unidirectional impact of culture values on IT outcomes (Leidner & Kayworth, 2006). Our contribution for the run-time phase of the IS and the QMS development addresses an holistic IS quality culture inspired by the distinct views proposed by Stylianou and Kumar (2000), and to foster quality principles at a process level.

We propose that the joint development of IS and QMS becomes a continuous endeavor. Quality and IS development should not be a concern in the days that precede the certification audit, as we sometimes found in organizational practice. The use of an approach that is not excessively formal may make it more accessible to both IS/QMS experts and non-experts, suitable for the majority of small and medium size companies that are ISO 9001-certified. Using a synergistic approach to design and run both systems promotes learning of process participants about their goals and rules, in a context shaped by regulations. This task may be slow, continuously seeking opportunities to incorporate high-level quality principles in daily practice, trough the IS and the QMS. Then, it is a shared organizational view that may shift the development of both systems from a matter of mere compliance to genuine change (Ogbonna & Harris, 1998).

1.6 Publications associated with this thesis

The outcome of our work was published as follows. On the left, when applicable, we indicate the chapters of the thesis in which we addressed the subject of the publication in depth.

1.6.1 Conference presentations

Chapter 4

Barata, J., & Cunha, P. R. (2013). Five Dimensions of Information Systems: A Perspective from the IS and Quality Managers. In Proceedings of the 10th European, Mediterranean and Middle Eastern Conference on Information Systems (EMCIS). Windsor, UK.

Chapter 4

Barata, J., Cunha, P. R., & Costa, C. C. (2013). The Foundations for an IS Quality Culture in the Context of ISO 9001. In Proceedings of the 10th European, Mediterranean and Middle Eastern Conference on Information Systems (EMCIS). Windsor, UK.

Chapters 4, 5

Barata, J., & Cunha, P. R. (2014). ISO2: A New Breath for the Joint Development of IS and ISO 9001 Management Systems. In M. Escalona, G. Aragón, H. Linger, M. Lang, C. Barry, & C. Schneider (Eds.), *Information Systems Development: Improving Enterprise Communication.* Proceedings of the 22nd International Conference on Information Systems Development (ISD) 2013, Seville, Spain (pp. 499–510). Springer International Publishing Switzerland.

Chapter 5

Barata, J., & Cunha, P. R. (2013). Modeling the Organizational Regulatory Space: A Joint Design Approach. In J. Grabis, M. Kirikova, J. Zdravkovic, & J. Stirna (Eds.), *6th IFIP WG 8.1, The Practice of Enterprise Modeling (PoEM 2013), LNBIP 165* (pp. 206–220). Springer Berlin Heidelberg.

Chapter 5

Barata, J., Cunha, P. R., & Costa, C. C. (2013). Developing an IS Quality Culture with ISO 9001: Hopefully, a Never Ending Story. In Proceedings of the 24th Australasian Conference on Information Systems (ACIS). Melbourne, Australia.

Chapter 5

Barata, J., & Cunha, P. R. (2014). Towards a Business Process Quality Culture: From High-level Guidelines to Grassroots Actions. In Proceedings of the 23nd International Conference on Information Systems Development (ISD). Varazdin, Croatia.

1.6.2 Journal publication

Chapters 5, 6

Antunes, A., Cunha, P. R., & Barata, J. (2014). MUVE IT: Reduce the Friction in Business Processes. Business Process Management Journal, 20(4), 571–597.

1.6.3 Book chapter

Chapter 6

Barata, J., Cunha, P. R., & Barata, S. (2014). ICT Management and Compliance: An Action Research Project. In J. Ariza-Montes & A. Lucia-Casademunt (Eds.), *ICT Management in Non-Profit Organizations* (pp. 242–264). IGI Global.

1.6.4 Poster for doctoral consortium

Barata, J., & Cunha, P. R. (2013). Information Systems and Quality Management Systems: Researching Lifecycle Synergies. 13ª Conferência da Associação Portuguesa de Sistemas de Informação (CAPSI). Universidade de Évora, Portugal.

1.6.5 Submitted journal papers (under review)

Chapter 2

Barata, J., & Cunha, P. R. (conditionally accepted with minor revision in Total Quality Management & Business Excellence (TQM&BE); resubmitted in January 2015). Synergies Between Quality Management and Information Systems: A Literature Review and Map for Further Research.

Chapters 5, 6

Barata, J., & Cunha, P. R. (submitted to Journal of Information and Organizational Sciences (JIOS); February 2015). Do You Walk the Talk in Quality Culture?

1.7 Dissertation structure

We organized the next chapters of this thesis as follows:

Chapter 2: Literature review. We present the background literature of quality management systems according to the ISO 9001 standard and its quality principles. Next, we review essential topics of information systems, introducing its main dimensions, the role of IT as one of those dimensions, as well as the history and challenges of information system development. We also seek inspiration in fields of study such as enterprise architectures and business process management. At the end of the IS section, we introduce two subjects that initiate our incursion on synergies between the IS and the QMS, namely the concept of quality information systems (QIS) and an examination of IS quality, in the scope of ISO 9001. Then, we review the concepts of organizational culture and quality culture. After exploring the foundations of each system separately, this chapter offers a systematic literature review to identify development synergies. The conclusions present a research map for the design-time and run-time synergies, summarizing the literature contributions to our research purpose.

Chapter 3: Research strategy. The chapter begins with the philosophical assumptions in which we base our research. Next, we present case studies, the principal method used in the creation of our frame of reference for action research. Then, we discuss action research, its rigor and validity, and how we adopt it in our quest for an approach to promote synergies between the IS and the QMS. We conclude by portraying the overall research program and explaining how we addressed each of our research objectives.

Chapter 4: Theory building: a frame of reference for action research. Our first contribution to IS and QMS synergies was the conception of a frame of reference. This was achieved by complementing the literature review with the inputs obtained from interviews with ISO 9001 quality auditors and the study of fourteen organizations in their development of IS and QMS, in the context of ISO 9001. This chapter presents the insights that we gathered from the auditors and the experience of the selected organizations in the problems and opportunities of integrating the IS and the QMS. The chapter concludes with a narrative of the path that conducted to the proposal of ISO_2.

Chapter 5: Theory building: the ISO_2 proposal. We used the frame of reference from chapter 4 to guide the first action research project, structuring the first version of the ISO_2. Then, we detail the refinement of ISO_2 for the design-time and run-time phases, accordingly to the two additional action research projects that we conducted. Particular attention is given to rigor and validity in each one of our action research projects, taking into account the criteria proposed by Davison et al. (2004).

Chapter 6: ISO_2 in practice: an application case. We illustrate the adoption of ISO_2 in a process of one of our client settings for action research. We detail the use of ISO_2 approach in all of its extension to the Design and Development (D&D) process of the organization, allowing future users of ISO_2 to know how they can employ it in their processes.

Chapter 7: Conclusions. We start by presenting the contribution of this thesis according to each of the research objectives. Then, we discuss the limitations. Finally, we point out avenues to be explored for future studies.

Chapter 2

Literature review

This chapter presents fundamental concepts and inspiring theory in quality management and information systems domains. The next section begins with an historical perspective of quality, followed by the presentation of Total Quality Management (TQM), a management approach to Quality and continuous improvement. We explored the concept of TQM due to the relevance of its principles for modern quality management. Next, we explore the context of quality based on the ISO 9001 international standard, that we will adopt in the proposed research. A review of information systems theory follows, with the identification of its five key dimensions: Context, People, Processes, IT, and Information/Data (Alter, 2008; Carvalho, 2000; Laudon & Laudon, 2007; Paul, 2007). We also searched for inspiration in the literature about enterprise architecture (EA) and business process management (BPM), so we introduce this in sequence. Afterwards, we explain and distinguish the concepts of quality information system and IS quality. Section 2.3 describe the concepts of organizational and quality culture, which we explored in our quest for synergies. Then, we address the multi-dimensional relation of the IS with quality management. IS and quality synergies have been studied by several authors since at least two decades. In fact, this connection is recurrent in the literature from two viewpoints: the IS support to the QMS and vice versa; section 2.4 details these interdependencies, adding a third perspective: the shared view of the IS and the QMS in the organization. We conclude by summarizing the results of the literature review and the gaps that motivated our contributions.

At the end of the chapter, the reader should:

1. Have an introductory background in quality management theory, the specificities of the ISO 9001, and the foundational quality principles;

2. Have an understanding of key aspects of IS and the five IS dimensions that we use in the development of our proposal;

3. Be aware of related concepts in our literature review that influenced our research, namely the organizational regulatory space, quality culture, enterprise architectures, business process management, quality information systems, and IS quality;

4. Recognize the opportunities created by developing a quality culture in IS, namely in the scope of holistic IS quality and business processes;

5. Understand a category of potential synergies for the IS and QMS extracted from the literature;

6. Identify intersection points to address by IS and QMS experts within a joint development lifecycle.

2.1   Quality management systems (QMS)

Quality management is a priority for organizations worldwide (ISO, 2012b), increasingly concerned with continuous change and aggressive competition. This section provides a review of quality management , namely in Total Quality Management and standards such as the ISO 9001 (ISO, 2008b), two globally accepted programs to implement a QMS (Zhu & Scheuermann, 1999). TQM is a philosophy that adopts a systemic view of the organization and focuses its interest on maintenance and continuous improvement of the processes (Hackman & Wageman, 1995). In turn, the ISO 9000 family (ISO, 2005b, 2008b, 2009b) encompasses a series of quality management standards, developed and published by the International Organization for Standardization (ISO).

2.1.1   Defining quality: an historical review

Quality has accompanied humans since they started to build utensils for personal use. In this case, the artificer, single intervenient on the product lifecycle, also executed control activities (Ross, 1995). The correction of defects inspired a generic definition of "*fitness for use*", later developed by Juran (1974). After several design cycles of the same artifact, the artificer started to think about improving it, sharing the work with others, and allowing future generations to learn what he had already learned by trial and error. As societies increased their need of products, small groups of artificers slowly replaced individual production. Industrial revolution was a mark for quality history and the concept of quality control (Juran & Godfrey, 1998). In that period, larger production units were organized in several departments and each manager was also responsible for product inspectors. Products were developed with non-standard materials using irregular methods and, as a result, achieving variable characteristics. Knowledge was easier to share in small organizations, but as they started to grow, knowledge dilution implicated more verification activities and the development of the first product specifications. Quality control was essentially a responsibility of the customer (Ross, 1995).

In the early XXth century, Frederick Taylor (1856-1919) proposed new theories for work organization known as "*Scientific Management*". A clear distinction between administration and work force was present in those principles, also demanding higher specialization of the employees, as technical improvements increased complexity of processing tasks. Productivity focus and reduced inspection criteria are in the origin of critical quality problems recorded in that period. The risk of uncontrolled work also generated serious quality problems during the First World War, because of products outside their specifications. The solution was to separate

inspection from the production team, aiming to achieve more independence for quality function concerned with defect identification. Later, inspection started to include the management of product defects, metrology, maintenance and calibration control, inspection planning, and the beginning of fault prevention activities. Inspection was the most relevant function to quality in the first half of the XXth century, mainly due to the generalization of statistical methods (Shiba, Graham, & Walden, 1997). Defect prevention started in 1930s and spread during the Second World War, due to the need to define quality patterns and the evidence that specifications were not enough to prevent faults if the control activities failed to be rigorous. The studies demonstrated that even within tolerance, product faults could derive from control deficiencies and the selection of their characteristics near the lower limits (Feigenbaum, 1991). After the war and with the transition from military to civil production, the quality of products manufactured in the United States of America decayed. This scenario induced more planning and monitoring activities in this country, which promoted research in quality management and the development of methodologies to process control and improvement (Juran & Godfrey, 1998).

In the literature, we can identify two main perspectives of quality management (Ross, 1995): managerial and technical (tools and techniques). The pioneers of quality management saw their names and theories generalized all over the world. Several authors suggested that quality problems were not an employee problem, but a system management problem. For example, Demming (1988) argued that around 85% of the quality and productivity problems have management issues at their origin. Ishikawa (1984) proposed several statistical tools for quality control. Demming (1988) developed methods for determining the variance of a production process, aiming at detecting causes for lack of quality and dividing common causes from the ones specific to process variance. This author also proposed a vision of organizations as systems, open to the environment, and sensitive to their customer's information (Crépin & Robin, 2001). Juran (1974, 1983) put an emphasis on establishing annual objectives and teaching corporate teams to achieve them. Philip Crosby (1979) introduced the "*zero defects*" program. Feigenbaum (1991) proposed TQC – Total Quality Control, in 1956, aiming at the adoption of statistical and engineering methods in organizations. These ideas supported quality as a system, not as a simple control process to be applied after the production phase. The ideologies for quality management address different managerial and technical aspects, although a convergence can be found in the following concepts (Ross, 1995):

- Inspection is never the method for quality improvement (it is a method for quality control);

- Leadership and top management involvement are essential for developing a culture of quality;

- A quality program requires efforts from the organization as a whole, long-term commitment, and competence improvement;

- Quality is a priority and production becomes second.

In 1960's the demand for quality assurance was emphasized. With the increase of competitiveness and product complexity, customers also wanted to be assured of product behavior and "trust" their characteristics. A new movement was then created with the contribution of Juran (1974, 1983), the first author to propose a global management of quality and sustain that improvement efforts must be translated into concrete projects (Crépin & Robin, 2001). Juran (1983) argued that quality management is similar to financial management and that both share three stages:

- Planning – Establish the objectives and appropriate actions. Planning should consider the input from the consumers, parameterize those needs, and implement appropriate actions to achieve proposed targets;

- Control – Compare with the objectives, identify sporadic problems, and correct them. This stage accomplishes multiple actions to assure that what has been planed is being achieved;

- Improvement – Identify chronic problems, diagnose them, and propose solutions. The prevention and anticipation leads to improvement.

The economy stagnation of the 1970's motivated companies to implement diversification strategies, with even greater concerns for product quality as a competitive advantage. Diversification strengthened the idea of quality as a management tool to compete and anticipate problems (instead of inspection to identify problems). This strategy increased the adoption of TQM principles (Hackman & Wageman, 1995; Juran & Godfrey, 1998).

Quality as a management activity is nowadays consolidated in standards, but it has been researched according to different views (Reeves & Bednar, 1994):

1. Quality as excellence, suggesting that quality is assessed against some specific standard;

2. Quality as value, extending the excellence view and introducing the cost-benefit of quality implementations (Nelson, Todd, & Wixom, 2005);

3. Quality as conformance with specifications, requiring one to consider whose needs are being satisfied and through which product (Kanungo & Bhatnagar, 2002);

4. Quality as meeting expectations, the most pervasive perspective (Reeves & Bednar, 1994), including conformance with specifications as proposed by Kahn, Strong, and Wang (2002).

Conforming and even exceeding expectations enables the perception of quality as a judgment by the customer and not a simple standard evaluation. The definition provided by ISO 8402 interprets the view of the customer satisfaction: "*The totality of features and characteristics of a product or service that bear on its ability to satisfy specified or implied needs*" (ISO, 1994, p. v).

Many things changed since quality was mainly a customer's responsibility (Ross, 1995). First, problem prevention is now a priority to quality managers, requiring detailed and rigorous information about their products and their organizational processes (Addey, 2004). Moreover, quality involves everyone in the organization and not only the quality manager (ISO, 2008b). Second, information has an increasing importance for quality management, in the form of product specifications, process measurements, and customer requirements (Reeves & Bednar, 1994). Third, quality can no longer be the result of trial and error, it requires planning, control, and improvement (Juran, 1983). Forth, quality management is now a system that involves quality techniques and methods, but also social aspects regarding leadership and people involvement (Feigenbaum, 1991; Juran & Gryna, 1993). Fifth, quality management involves the creation of a culture of quality (Ross, 1995). That culture is based in principles that are distinctive of quality efforts (ISO, 2012a).

2.1.2 *Total quality management (TQM)*

TQM is a philosophy that adopts a systemic view of the organization, focusing on continuous improvement (Li et al., 2008). It is the quality approach chosen by several IS researchers (Au & Choi, 1999; Khalil, 1994; Prajogo & Sohal, 2006; Siddiqui & Rahman, 2006; Stylianou, Kumar, & Khouja, 1997; Valmohammadi, 2011). It has similarities with ISO 9000's principles, safeguarding differences in implementation (Heras-Saizarbitoria, Casadesús, & Marimón, 2011). In a study with independent quality auditors of QMS models, Heras-Saizarbitoria et al. (2011) found that ISO 9000 and TQM shared similar motivations leading to their implementation, mostly due to internal improvement. Khalil (1994) synthesizes the principles of TQM as:

- Total satisfaction of customers needs (implicit or explicit);

- Problem prevention;

- Monitoring of all organizational activities;

- Effort of continuous improvement;

- Responsibility of all the company stakeholders for pursuing excellence.

The principles of TQM are precedents of current excellence models, for example, the European Prize of Quality, implemented by the European Foundation for Quality Management (EFQM), the Deming Prize, and the Malcolm Baldrige National Quality Award, which explicitly addresses IS issues in its assessment criteria (Bou-Llusar, Escrig-Tena, Roca-Puig, & Beltrán-Martín, 2009; Cragg, 2005). These prizes provide a referential model for improvement and point out elements to establish the key dimensions that condition competitiveness. We exemplify the TQM impact with the EFQM model, constituted by two parts, enablers and results, divided in the nine evaluation criteria of Figure 2-1.
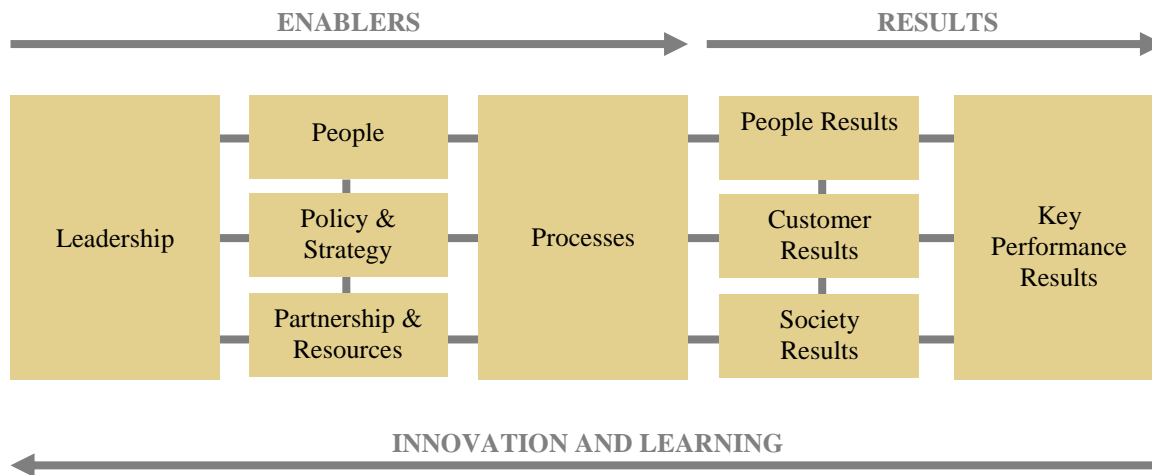
Figure 2-1. EFQM excellence model (adapted from EFQM (2003))

The EFQM model represents a broad definition of quality management systems, applicable to all types of organizations and heavily dependent on the underlying information system. Moreover, excellence models such as EFQM are considered to be operational frameworks to implement TQM, incorporating its principles and constructs (Bou-Llusar et al., 2009; Corredor & Goñi, 2011). Therefore, we include in this section a summary presentation of each enabler and result of EFQM (EFQM, 2003), to clarify how this model can guide TQM adoption in practice.

The EFQM is committed to help organizations improve their performance, with a non-prescriptive framework that recognizes the existence of many approaches to achieve sustainable organizational excellence. Within this non-prescriptive approach, there are some basic concepts that underpin the model. Behaviors, as well as activities or initiatives based on these concepts are often referred to as quality management, described below (EFQM, 2003, pp. 6-8):

- *"Results Orientation"*: Excellence is dependent upon balancing and satisfying the needs of all relevant stakeholders (this includes employees, customers, suppliers and society in general, as well as those with financial interests in the organization);

- *"Customer Focus"*: The customer is the final arbiter of product and service quality. Customer loyalty, retention, and market share gain are best optimized through a clear focus on the needs of current and potential customers;

- *"Leadership & Constancy of Purpose"*: The behavior of an organization's leaders creates a clarity and unity of purpose within the organization and an environment in which the organization and its people can excel;

- *"Management by Processes & Facts"*: Organizations perform more effectively when all inter-related activities are understood and systematically managed. Moreover, decisions concerning current operations and planned improvements are made using reliable information that includes stakeholder perceptions;

- *"People Development & Involvement"*: The full potential of an organization's people is best released through shared values and a culture of trust and empowerment, which encourages the involvement of everyone;

- *"Continuous Learning, Innovation, and Improvement"*: Organizational performance is maximized when it is based on the management and sharing of knowledge within a culture of continuous learning, innovation, and improvement;

- *"Partnership Development"*: An organization works more effectively when it has mutually beneficial relationships, built on trust, sharing of knowledge and integration, with its partners;

- *"Corporate Social Responsibility"*: The long-term interests of the organization and its people are best served by adopting an ethical approach and exceeding the expectations and regulations of the community at large.

Each enabler of this model is detailed in different sub-criteria and some of them take into account specificities of the IS and process oriented approach, as described below (EFQM, 2003):

- *"Leadership"*: Leaders develop and facilitate the achievement of the mission and vision, develop values required for long-term success and implement these via appropriate actions and behaviors. They are personally involved in ensuring that the organization's management system is developed and implemented.

  o Leaders are personally involved in ensuring the organization's management system is developed, implemented and continuously improved;

  o Leaders are involved with customers, partners, and representatives of society.

- *"Policy and Strategy"*: The organization implements its mission and vision via a clear stakeholder focused strategy, supported by relevant policies, plans, objectives, targets, and processes.

  o Policy and strategy are based on information from performance measurement, research, learning and creativity related activities.

- *"People"*: The organization manages, develops and unleashes the knowledge and full potential of its people at an individual, team-based and organization-wide level. The organization plans these activities in order to support its policy and strategy and the effective operation of its processes.

- *"Partnerships and Resources"*: The organization plans and manages its external partnerships and internal resources in order to support its policy and strategy and the effective operation of its processes.

  o Technology is managed;

  o Information and knowledge are managed.

- *"Processes"*: The organization designs, manages, and improves its processes in order to support its policy and strategy. It generates increasing value for its customers and other stakeholders.

A study developed by Prajogo and Sohal (2006) demonstrates that TQM is positively related with differentiation strategies, and that it only partially mediates the relationship between differentiation strategy and other three performance measures evaluated: product quality, product innovation, and process innovation. They conclude that "*when pursuing quality performance under the context of a differentiation strategy, organizations also need to furnish certain resources that are not accommodated by TQM, such as technology management*" (Prajogo & Sohal, 2006, p. 48). Nevertheless, the adoption of new tools and technology can be more successful after the creation of a quality culture (Gore, 1999). TQM is also suggested to achieve process improvement (Kanji, 1998), contributing to organizational competitiveness and excellence (Irani, Beskese, & Love, 2004).

The following core concepts that shape TQM may be found in the literature: process management; management leadership; fact-based management; continuous improvement; design quality; speed and prevention; customer focus; information and analysis; employee participation; suppliers, tools and technologies (Bou-Llusar et al., 2009; Tummala & Tang, 1996; Valmohammadi, 2011). Because of its common roots, the current version of ISO 9000 shares the majority of these concepts as principles for quality management.

Some authors, for example Martínez-lorente and Martínez-costa (2004) and Rahman (2001), do not find benefits in combining ISO 9000 and TQM implementation. Nevertheless, the most common perspective argues that ISO 9000 is a good first step toward TQM (Gotzamani & Tsiotras, 2001), as concluded by Sampaio, Saraiva, and Rodrigues (2009). There are also suggestions that TQM and ISO 9000 should be simultaneously implemented, concluding about the independency of both QMS contexts (Sampaio et al., 2009b). Other authors (Soltani & Lai, 2007) consider ISO 9000 as a TQM model, presenting the minimum requirements to practice an excellence approach. In this perspective, the ISO 9000 series may be construed as a sub-system of TQM or excellence models (Bou-Llusar et al., 2009), with positive influence in their success (Gotzamani, Tsiotras, Nicolaou, Nicolaides, & Hadjiadamou, 2007). Bayo-Moriones, Merino-Díaz-de-Cerio, Escamilla-de-León, and Selvam (2011) present benefits in combining ISO 9000 and TQM in work practices: with ISO 9000, this effect occurs through improvement groups and the implementation of suggestion systems; with TQM, this effect occurs with the incentive of work teams for new project development (D&D) and on the organization of informative meetings between top management and employees (management responsibility).

Process management, information management, and IT are three important aspects to consider when implementing TQM models (EFQM, 2003; Woodall, Rebuck, & Voehl, 1997). TQM is based in core concepts that shape that behaviors and activities for quality management (Bou-Llusar et al., 2009; Tummala & Tang, 1996; Valmohammadi, 2011). Moreover, those principles remind that quality system is not only a matter of requirements and obligations; it is a

system that involves people goals for the organizational processes (Bayo-Moriones et al., 2011; Simon, 1964). That is also the case of ISO 9000 family of standards that we discuss in the next section.

2.1.3 ISO 9000: quality management standards

International Organization for Standardization (ISO) has published a series of standards for quality management systems, named ISO 9000. The first version of this standard was published in 1987, and later revised in 1994, 2000, and 2008 (ISO, 2008b; Karapetrovic, Fa, & Saizarbitoria, 2010). By the end of 2011, this standard had been adopted in 180 countries, by 1.111.698 organizations (ISO, 2012b). It allows organizations to implement a quality management system, which can optionally be certified by an external entity. When adopting the standard, organizations must carry out an internal and external audit program. Audits are more than simple nonconformity identification; their purpose is to keep the system "alive" and suggest improvement opportunities (ISO, 2011).

ISO 9001 guides companies to improve business quality and adopt continuous improvement as a strategy (Sampaio, Saraiva, & Rodrigues, 2009; Ward & Peppard, 2002). To be certified by an external audit, organizations must provide evidences of compliance with the standard requirements. Moreover, ISO certification requires the creation of documented procedures, specifications, templates, and other support information to ensure that processes are properly executed in a consistent manner (Cunha & Figueiredo, 2005). There is also a need for a quality measuring and monitoring system (ISO, 2008b). Therefore, it is a tool for organizations to demonstrate to their customers that they have the capability to produce consistently to their requirements (Cianfrani, Tsiakals, & West, 2000). However, obtaining the certificate should not the sole objective of implementing ISO 9001. The real value lies in the adopting continuous improvement as a strategy (ISO, 2008b; Ward & Peppard, 2002). Quality becomes a strategic objective that should be regarded as a set of characteristics, intrinsic and extrinsic, concrete or abstract, which result in the consumer giving preference to a particular product or service (Fey & Gogue, 1989). As a strategic objective, quality is a journey, not a destiny (Chang, Labovitz, & Roskansy, 1993).

The ISO 9000 series is made up of three basic standards. The ISO 9000:2005 contains all the fundamentals or principles of quality management that constitute the philosophy that has served as an inspiration for the requirements of the ISO 9001 standard. It also contains all the vocabulary used in the ISO 9000 series (ISO, 2005b). In turn, the ISO 9001:2008 is the reference by which organizations mainly establish, document, and implement their quality management systems oriented toward customer satisfaction (ISO, 2008b). Finally, the ISO 9004:2009 standard appears in the 2000 version and aims at establishing guidelines that enable an organization to evolve from a customer focus to a system oriented toward all the interested parties in an organization (customers, shareholders, alliances, employees, and ultimately the entire society). Moreover, the ISO 9004 standard is concerned with the overall improvement of the organization's

performance, both in terms of effectiveness and efficiency, not just toward achieving desired results (objectives), but accomplishing them using the least possible resources (ISO, 2009b).

Current version of ISO 9001 is supported on eight quality management principles conferring it a managerial nature that should follow a process approach. Management by processes is explicitly included in ISO 9001, requiring process identification, modeling, documentation, execution, and improvement (ISO, 2008b).The eight principles on which the ISO 9000 series are based are shown in Table 2-1.

Table 2-1. Quality management principles (ISO, 2008b, 2012a)

Quality principle	Description
Customer focus	Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.
Leadership	Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
Involvement of people	People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
Process approach	A desired result is achieved more efficiently when activities and related resources are managed as a process.
System approach to management	Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
Continual improvement	Continual improvement of the organization's overall performance should be a permanent objective of the organization.
Factual approach to decision-making	Effective decisions are based on the analysis of data and information.
Mutually beneficial supplier relationships	An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

According to ISO, senior managers can use the principles presented in Table 2-1 as a framework to improve organizational quality and performance (ISO, 2012a). Although the designations may vary – for example, *"factual approach to decision-making" vs. "decisions based in facts"* – all the ISO 9001 principles defined by ISO Technical Committee ISO/TC 176 can be found in the TQM literature presented in the previous section (Bou-Llusar et al., 2009; Tummala & Tang, 1996; Valmohammadi, 2011). Next Section presents the ISO 9001 structure and its clauses of requirements.

2.1.3.1 ISO 9001 structure

The quality management model presented in Figure 2-2 is included in the introductory section of ISO 9001.
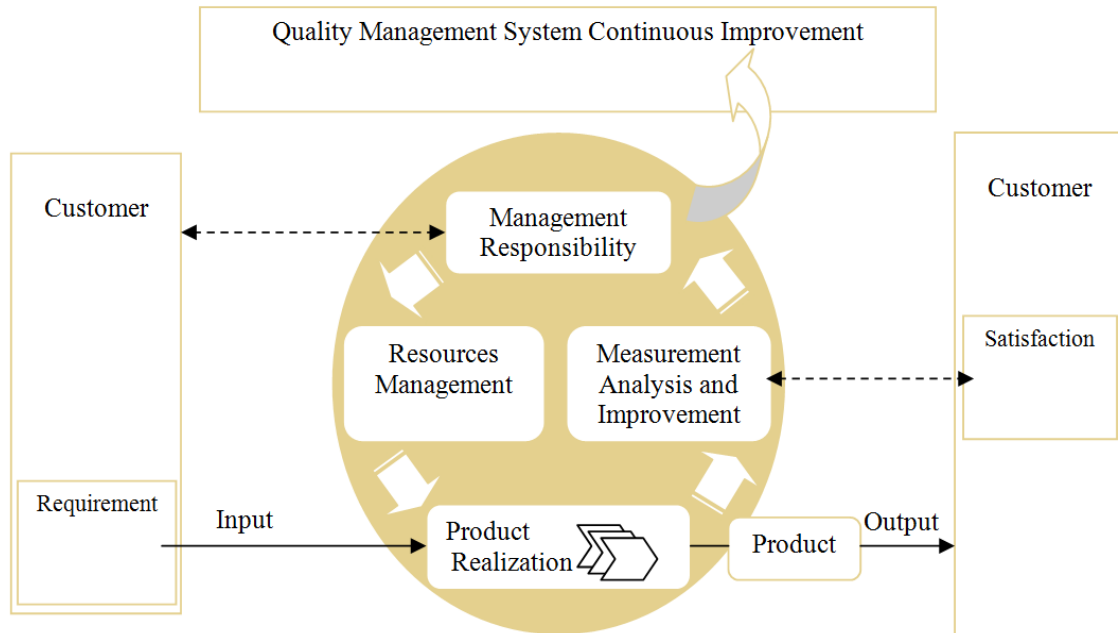
Figure 2-2. ISO 9001 quality management model (adapted from (ISO, 2008b))

Figure 2-2 depicts a model where the organization is represented by the circle in the middle. The organization receives the input from the customer requirements (on the left), and supplies its products to achieve customer satisfaction (on the right). The continuous improvement represented in the top of this model is completely oriented towards the customer (ISO, 2008b). The diagram blocks that appear in the figure above are the clauses of the standard, namely Management Responsibility; Resource Management; Product realization; and Measurement, Analysis and Improvement. Moreover, there are additional clauses to the standard requirements that we briefly present below (ISO, 2008b).

Introductory clauses (0-3): Clause 0 introduces the process approach. Clause 1 presents the purpose and application of the standard. Clause 2 is the normative reference of ISO 9001 and clause 3 defines the terms used. The initial three clauses of the standard are a general introduction, making it evident that the adoption of a quality management system must stem from a strategic decision and, therefore, must count on the support of management boards. It makes clear that the standard establishes requirements that each company must fulfill with the systems and methodologies that it prefers (is not mandatory to use a specific methodology). Another of the aspects that the organization must establish is the scope (field of application) of the quality management system that is to be applied, for example, limiting the certification to the administration, product lines, or other specific areas of the organization.

The process approach of the standard is demonstrated in these introductory clauses, and the requirements themselves have been conceived as if they were "macro processes", which later

facilitates the definition of the company's process structure. ISO 9001 is applicable to all types of organizations, basing its continuous improvement model in PDCA – Plan, Do, Check, Act cycles (illustrated in

Figure 2-3), originally proposed by Shewhart (1939) and later popularized by Edward Deming.
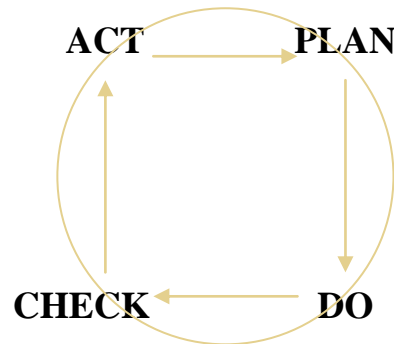
Figure 2-3. Shewhart/Deming plan-do-check-act cyclic model (ISO, 2008b)

This methodology for continuous improvement has the following steps:

- Plan – Establish objectives and processes to achieve results according with customer requirements and organizational policy;

- Do – Execute the processes;

- Check – Monitor and measure processes and product relating with policies, objectives, and requirements (explicit or implicit);

- Act – Execute actions to continuous improve process performance.

Next, we will introduce clause 4, which cover the requirements of the quality management system.

Clause 4 – Quality management system

Establishes general requirements and presents the steps that must be taken in documenting, establishing, implementing, and maintaining a quality management system. This clause encourages the organization to build a process map, considering the interrelationships between processes, the operating criteria, and the methods for monitoring and measuring (Euro-Symbiose, 2001). It includes sub clauses: 4.1 General requirements; and 4.2 Documentation requirements. According to clause 4.1, companies must:

a. Identify the processes needed for the quality management system and their application throughout the organization;

b. Determine the sequence and interaction of these processes;

c. Determine criteria and methods required to ensure that both the operation and control of these processes are effective;

d. Ensure the availability of resources and information needed to support the operation and monitoring of these processes;

e. Carry out monitoring, measurement, and analysis of these processes;

f. Implement the actions needed to achieve the planned results and their continual improvement.

The availability of documentation that facilitates and favors the application, maintenance and effectiveness of the system must be ensured (clause 4.2). There is also a need to create systems for controlling both the documentation and the records that are generated (ISO, 2008a). It is important to understand that – contrary to a common erroneous interpretation – the documents do not need to be paper-based, as explained by the technical committee ISO/TC 176, which is responsible for ISO 9000 series of standards (ISO, 2008a). According to ISO 8402 (ISO, 1994), a document consists on information and its support medium, where the medium may be paper, magnetic, electronic or optical computer disk, photograph, master sample, or a combination thereof. The required document organization for implementing a ISO 9001-based QMS may be represented by a pyramid (Cianfrani et al., 2000), starting with the quality manual as the top level document that states which company processes are considered under quality management (e.g., procurement, sales, and after sales service), the interactions between these processes, and the procedures that constitute them. This manual must be aligned with the business strategy, mission and aims (Ward & Peppard, 2002). The document pyramid of ISO 9001 is presented in Figure 2-4.
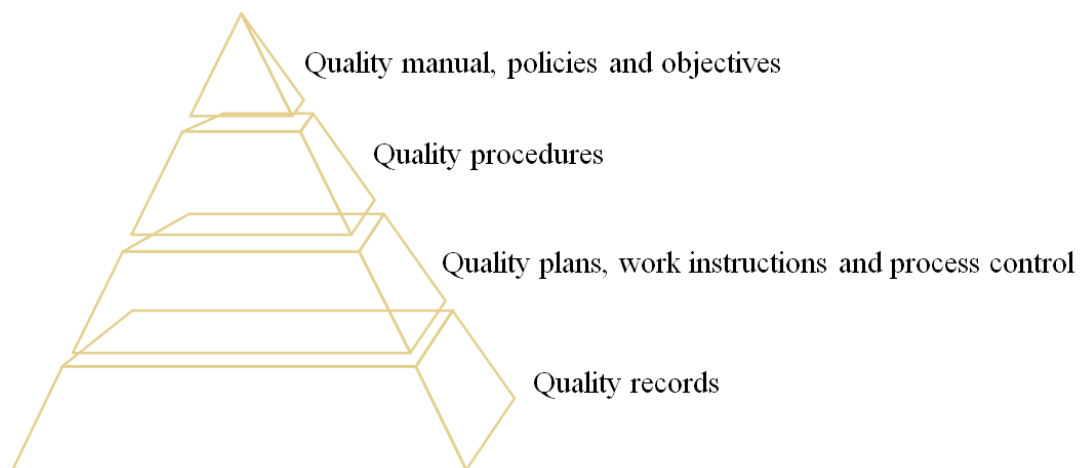
Figure 2-4. Quality documents hierarchy in ISO 9000 (adapted from Cianfrani et al. (2000))

Additionally, each document must be based on approved templates, to ensure consistency. The last kind of required documents are records, consisting of the filled-in templates that result from the normal operation of the procedures, according to the descriptions that were written

down. Records of are key importance, since they represent evidence, to the auditors, that the procedures are, in fact, being followed (Cunha & Figueiredo, 2005; Kasim, 2011).

Clause 5 – Management responsibility

In clause 5, the responsibilities in the organizational structure must be defined, and these communicated to the company. Usually, this involves creating an organizational chart where the responsibilities are shown (in particular, those related to quality), and that can be included in the quality manual (although it can also be documented separately and referred to in the manual). The functions of each of the positions in the organizational chart are also often specifically documented, which facilitates their assignment to the corresponding persons. Clause 5 includes the following sub clauses: 5.1 Management commitment; 5.2 Customer focus; 5.3 Quality policy; 5.4 Planning; 5.5 Responsibility, authority and communication; and 5.6 Management review. Sub clause 5.1 implies that management must be involved in the complete system review. Management review evaluates the system to ensure that it is appropriate and effective. It also addresses the need to analyze the opportunities for improvement, and establish the guidelines for enhancing the effectiveness of the processes and the system as a whole. ISO 9001 indicates what information is necessary to consider and obtain for its review. It is essential to plan some type of meeting where management can carry out this review, at least annually.

Clause 6 – Resource management

This clause focuses on how to manage organizational processes to provide the necessary resources. Sub clause 6.1 asks to identify, maintain, and improve the resources to enhance customer satisfaction. Resources are understood as pertaining to three clearly differentiated types, included in sub clauses 6.2 Human resources; 6.3 Infrastructure; and 6.4 Work Environment:

- Human resources (sub clause 6.2). The organization must ensure that the persons who participate in the processes are competent (that is, for instance, have required experience in a specific activity, or have a particular degree, or have taken a certain course, or have undergone a trial period in a certain position).

- Infrastructure (6.3). All the equipment, facilities, auxiliary services, including computer equipment and applications, necessary to obtain the product. The infrastructure must be determined, placed at the disposal of the processes, and then adequately maintained;

- Work environment (6.4). The work conditions (directly influencing product), such as the adequacy of the infrastructure can and do influence the final product obtained.

Clause 7 – Product realization

Clause 7 consists of requirements that are directly related to the activities to be performed to create the organization's product(s). There are prior definitions to understand this clause:

- A "*product*" as defined in ISO 9000:2005 is the "*output of any process*" and must also be understood as a "*service*" (ISO, 2005b);

- A "*project*" is a unique set of processes, activities or coordinated and controlled tasks, with start date and end date, performed with innovation to achieve objectives, according to specific requirements and including restrictions of time, cost, and resources (Capelas & Paiva, 2005).

Clause 7 includes the following sub clauses: 7.1 Planning of product realization; 7.2 Customer-related processes; 7.3 Design and development; 7.4 Purchasing; 7.5 Production and service provision; and 7.6 Control of monitoring and measuring equipment. The requirements in this clause encompass such aspects as:

First, planning. The organization plans what it is going to produce, how, what processes are necessary, and how it controls them. Therefore, this planning involves the definition of the products to be realized or the services to be delivered, as well as identification of the necessary realization processes, documents, and monitoring and measurement activities. In engineering companies, where construction and/or projects are carried out, it is common to show this planning in so called quality plans, which are a particularization of the quality system for the specific construction site, project or contract. Quality plans make it possible to account for the particularities of the execution processes, identify requirements and objectives to achieve (to comply to contract stipulations), define inspections to be done (particularizing the "*inspection point programs*" to apply), and classify new parameters to be controlled.

Second, customer relations. The organization communicates with the customer, determines what she or he wants, and sells its products. Requirements may be directly related to the customer (including those requirements not expressed but necessary for use of the product) or indirectly, for example by legal and regulatory requirements.

Third, design and development (D&D). The organization, if necessary, designs the product to conform to what the customer requires. The design activities of a product involve the transformation of the requirements into specified product characteristics or specifications. This means that the organization must assess to what extent they perform activities of this type, since if they do not perform design activities, this section of the standard does not apply (sub clause 7.3). Depending on how complicated the design is, the number of development stages may differ. However, one inescapable step is that, once the final specifications are obtained for the product, their verification and validation must be performed, and there must be evidence (records) of both activities. According to the verification of design and development is necessary "(…) *to ensure that the outputs of design and development meet input requirements.*" (ISO, 2008b), while the validation is required "(…) *to confirm that the resulting product is capable of meeting the requirements of its specified application or expected use*" (ISO, 2008b).

Fourth, purchasing. To comply with this requirement, purchasing management concentrates on three essential points, as summarized below:

- To know the ability of the supplier to offer good products (evaluation of suppliers). A record should be kept of this evaluation;

- To ensure that the purchasing documents (the orders) are properly written so that there is no doubt as to what is being purchased;

- To verify the products when they are placed at the disposal of the organization.

Fifth, production and service provision. The organization must control the processes necessary to obtain the product or deliver the service. Organizations usually have supporting documents that describe the activities and the important process parameters, thus ensuring that people perform the operations systematically and consistently (may be called technical instructions, because of the specific nature of the document). They also establish monitoring and measurement methods in the processes. Product traceability (identification and production history) is included in this clause.

Sixth, control of monitoring and measuring equipment. This type of devices may be necessary for monitoring and measurement (e.g., manometers, sensors), commonly requiring calibration and/or verification by comparison with measurement standards. Thus, calibration may be outsourced to a laboratory or done in-house using reference equipment, although this, in turn, must also be calibrated, necessarily, by an outside laboratory.

Clause 8 – Measurement, analysis and improvement

Clause 8 of the ISO 9001 standard encompasses all the QMS requirements oriented towards measuring the effectiveness of the organization's processes and the system, enabling data to be collected and compiled for later analysis. It also requires establishing and planning actions for improving processes and the system as a whole. It includes the following sub clauses: 8.1 General; 8.2 Monitoring and measurement; 8.3 Control of nonconforming products; 8.4 Analysis of data; and 8.5 Improvement. The data provided by the monitoring and measurement of product conformance and other relevant sources must be analyzed. For example, the data from the surveying customers; the data from the findings of the internal audits (in their reports); the data from the measurements of the processes. However, these sources can contribute little to the system if they are not analyzed, compared, added, and converted into relevant information. The required sources of information for monitoring and measurement are mentioned in Table 2-2.

Table 2-2. Monitoring and measurement requirements (adapted from (ISO, 2008b))

Monitoring and measurement	Purpose
Customer satisfaction (Sub clause 8.2.1)	Measure and obtain information on the customer's perception of how the organization (and the specific products) comply with what they need (customer requirements), establishing suitable methods to obtain such information (surveys, studies, customer panels).

Monitoring and measurement	Purpose
Internal audit (Sub clause 8.2.2)	Determine the degree of conformance of the quality management system with the applicable requirements (ISO 9001:2000 and others), and find out whether the system is implemented and maintained effectively. The audits are a tool for improving the system and they must be planned. The people that conduct them (auditors), who, in most cases, pertain to the organization itself, must have sufficient competence for it.
Monitoring and measuring of processes (Sub clause 8.2.3)	Determine the ability of processes to achieve planned results and whether they are effectively accomplished. Monitoring and measuring is based on established indicators (which include ratios, for example the % of conformance in delivery), for which a control value, or an objective, may also be defined for comparison with the real value and thereby find out process effectiveness.
Monitoring and measuring of product (Sub clause 8.2.4)	The purpose is to verify whether the characteristics of the products comply with applicable requirements, that is, check product conformance ("*fulfillment of a requirement*" according to ISO 9000).

The "*analysis*" in clause 8 seeks to convert data into information (which is meaningful data), and finds out how satisfied the customer is, how effective the processes are, and how the developed products are like. Thus, opportunities for improving can be identified. Based on the elements collected, appropriate actions must be pursued (clause 8.5):

- Corrective actions (reactive): after detecting a nonconformity in the process and to prevent future occurrences;

- Preventive actions (proactive): to prevent a potential nonconformity in the process.

The information flows involved in continuous improvement based in actions is presented in Figure 2-5.
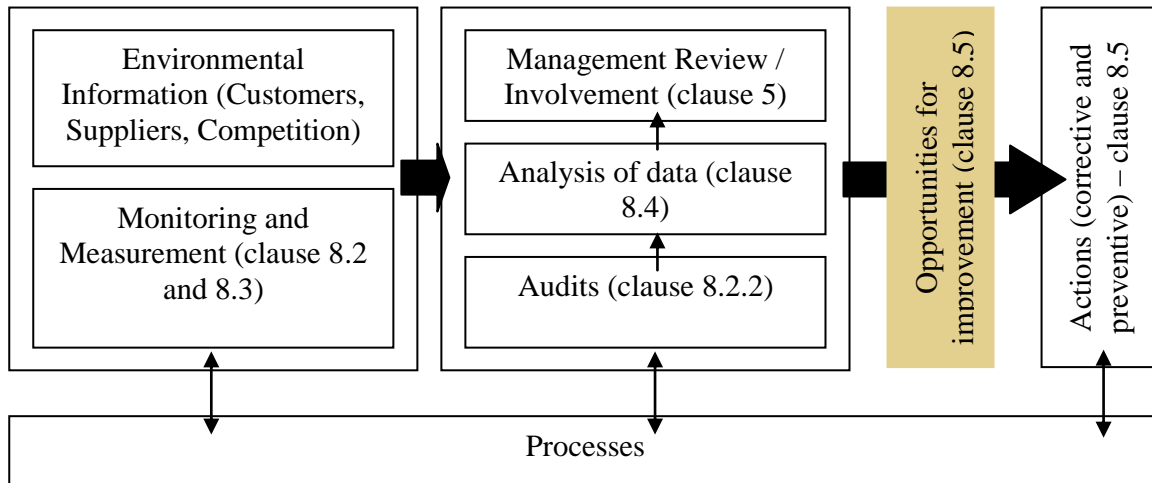
Figure 2-5. Information flows for continuous improvement in ISO 9001: process "voices"

(compiled from ISO (2008b))

Figure 2-5 includes distinct clauses and illustrates actions triggered by evaluation of data. In both corrective and preventive actions, the same sequence is followed by ISO 9001 standard (PDCA cycle): determine the causes of the problems; evaluate the need to take action; decide the actions necessary; implement the actions; and identify new actions as a consequence of review. Continuous improvement also includes actions not determined by nonconformities. Those are the improvement actions to increase QMS effectiveness (ISO, 2011). In this case, the source of information may be data analysis (internal or external sources, for example market needs) or suggestions from the entities in the environment: customers, suppliers, and internal employees. At the enterprise level, quality management in ISO 9000 must be integrated with business global management (Euro-Symbiose, 2001; Lascelles & Dale, 1990), as illustrated in Figure 2-6.
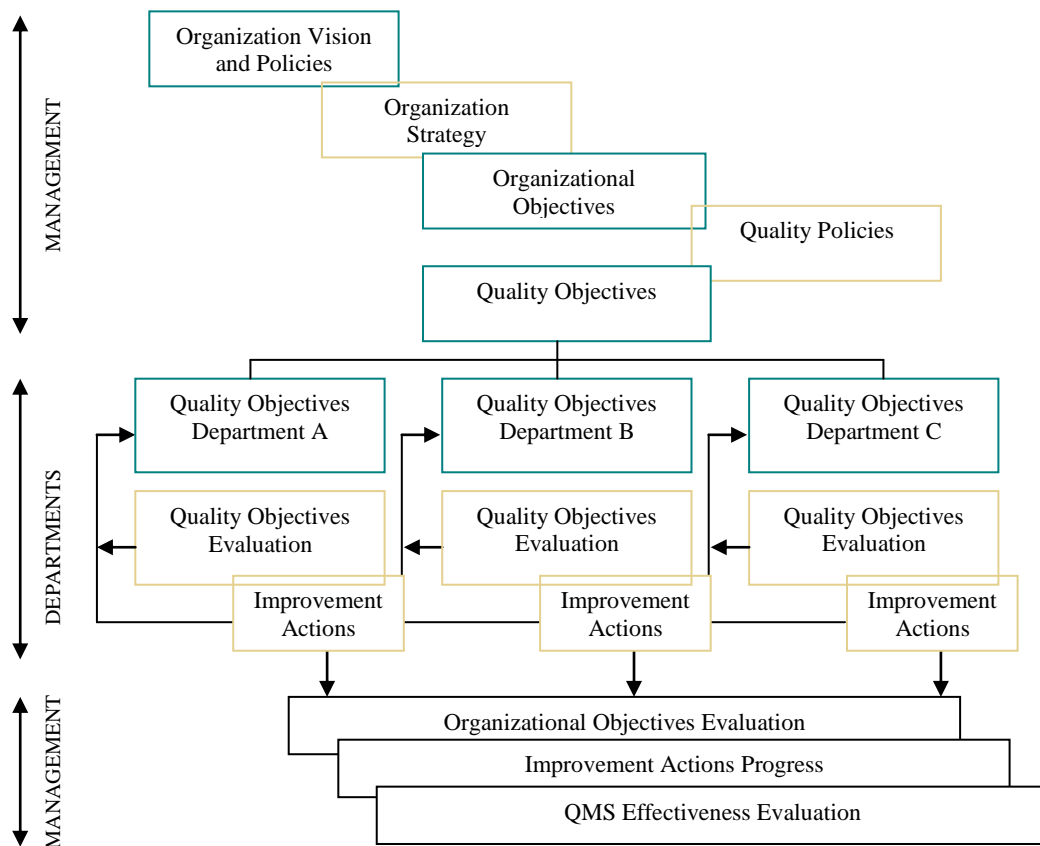
Figure 2-6. QMS integration with the organizational management system (adapted from Euro-Symbiose (2001))

Although Figure 2-6 does not adopt a process-oriented view, because it only refers to the departments, we may observe the quality objectives deployment in the entire structure. The audit process of ISO 9000 systems is a noteworthy occurrence in continuous improvement activities, with potential connections with IS. Quality auditors address internal and external elements when auditing ISO 9001 in specific organizational contexts. According to Bell and Omachonu (2011), the development of a documented ISO 9001-based QMS follows the following steps : (1) gaining management commitment; (2) employing external consultants; (3) conducting an awareness campaign; (4) creating a QMS manual; (5) developing a documentation system; (6) training employees on the system; (7) creating work processes and procedures; (8) conducting system wide reviews; and (9) pre-assessment audit.

Considerable parts of the documents produced in ISO 9000 are records, the filled-in templates that must be created as evidence (ISO, 2008a, 2009a). In this case, some overhead is introduced when paper-based solutions are used, as some excerpts of information that could otherwise be retrieved from a database have to be written by the user for every instance of a record (Cunha & Figueiredo, 2005).We started this section by introducing the quality principles that guided ISO 9001. They suggest that QMS should be implemented by a system of interrelated processes, focusing the customer. People involvement is critical for quality management, from top manager to process participants; quality is only possible if everyone participates. Moreover,

continuous improvement must be a permanent objective of all the stakeholders, including suppliers. Information systems are essential for the QMS, for example on the factual approach to decision making. Quality principles are the framework for the distinct clauses that we detailed afterwards (ISO, 2012a).

Clause 4 followed the three initial clauses that presents the purpose, definitions, and application of the standard, highlighting the importance of the IS and its supporting documents. clause 5 stress the necessity to involve top management in the QMS, the requirement to plan, review the system, and ensure an effective communication within the company and with external parties. Then we presented the resources for ISO 9001-based QMS, namely human resources, infrastructure (including IT), and the work environment. This clause offers another opportunity to recognize the focus on people and how they work. Clause 7 is concerned with the product development and finally clause 8 includes the requirements for measurement, analysis, and improvement. Once again, the importance of data appears directly in the last clause of the standard.

Distinct dimensions of the system that compose the QMS emerge in the clauses we studied, for example the context of the organization, people, processes, quality documents, and quality information (ISO, 2008b). The standard is written with a simple vocabulary, not restrictive in their practices, and not prescriptive in their approaches. Perhaps the simplicity is one of the reasons for ISO 9001 success, but there are also reported problems in its use. This discussion is presented in the next section.

2.1.4 The benefits and pitfalls of ISO 9001

The motivation to implement a QMS compliant with ISO 9001 may vary in nature. As presented by Heras-Saizarbitoria, Casadesús, and Marimón (2011), there are external motives such as customer demand and improving public image. Internal motives are the improvements in systematization, efficiency, and internal control of the firm. A study by Pekovic (2010) has revealed that certification determinants in the public sector may vary with organization characteristics between manufacturing and service firms. The probability of certification increases with firm size and if the firm belongs to a group. The existence of international activity and the experience with similar standards also have positive effect on the probability of certification. Although recognizing the importance of external arguments, several authors (Boiral & Amara, 2009; Briscoe et al., 2005; Brown, Wiele, & Loughton, 1998; Curkovic & Pagell, 1999; Gotzamani & Tsiotras, 2001; Pan, Lin, Tai, & Tseng, 2010; Rao, Ragu-Nathan, & Solis, 1997; Sampaio, Saraiva, & Rodrigues, 2009) suggest that to achieve a competitive advantage, companies must internalize the quality principles. Standards requirements may be easily copied by competitors and the differentiation advantage decreases in importance as other companies in the same industry achieve the same certifications (Karapetrovic et al., 2010). As shown by Prajogo (2011), strengthening internal motives have a positive impact in ISO 9001 implementation and operational performance.

The majority of studies made so far attest the positive organizational impact of ISO 9001 (Karapetrovic et al., 2010). They have concluded that organizations achieve a distinct operating advantage from implementing the standard when they accomplish to use it in daily practice (Naveh & Marcus, 2005; Sroufe & Curkovic, 2008), with customer focus, and a continuous improvement strategy (Terziovski, Power, & Sohal, 2003). These impacts may also be clustered in internal and external to the organizations. Internal impacts are related with organizational improvements, such as the quality system, communication, service, competitiveness, financial performance, and human resource/organizational climate (Boiral, 2011; Cagnazzo, Taticchi, & Fuiano, 2010; Naveh & Marcus, 2005). Further, Walgenbach (2001) reported that ISO 9001 was an opportunity for structuring and achieving a better clarity in the organizational processes: documenting know-how, systematization, the standardization and improvement of processes, procedures, and interdepartmental relations. External impacts are related with international trades, suppliers, customers, and stakeholders (Cagnazzo et al., 2010). According to Singh, Power, and Chuong (2011), ISO 9001 focuses on internal processes but also on the coordination with external stakeholders. Singh et al. (2011) purport that organizations use ISO 9001 as a holistic tool to manage organizational environment, involving the internal processes and external relationships with suppliers and consumers.

ISO 9001 is also a subject of criticism. Kumar and Balakrishnan (2011) identify four categories of problems:

- Leadership related issues (inadequate commitment by top management, lack of motivation, recognition, organizational learning, and long term focus);

- Strategy related Issues (poor alignment between the quality management system and the organizational strategy, KPIs and initiatives);

- Quality system related issues (weak PDCA cycle, generic system, internal audit not in depth, non-value adding meetings/trainings, and excessive paperwork);

- Society oriented gaps (insufficient social concern, for example, corporate social responsibility, environmental management, and sustainability).

The most cited barriers to effective ISO 9001 implementation and use are insufficient top management involvement, excessive documentation, considerable implementation time and cost, system change, and incorrect interpretation of the standard (Poksinska et al., 2006; Withers & Ebrahimpour, 2000). The information support to ISO 9001 is a common cause for criticism in increasing bureaucracy (Seddon, 1997) and lack of flexibility. Some of the weak points may be illustrated by the following expressions (Euro-Symbiose, 2001):

- Weak correspondence between the standard requirements and organizational dynamics;

- Isolation of the QMS function originating a deficient evaluation/treatment of functional connections in the business;

- Companies do not exploit all the sources of progress if regarding only the basic requirements of 9001;

- Quality systems, even ISO 9001-certified, do not systematically prove its effectiveness and performance;

- Customer is not always present as it should, in all organizational processes and acknowledged by all organizational actors.

There is also evidence that ISO 9001 perceived benefits may decrease over time (Franceschini, Galetto, Maisano, & Mastrogiacomo, 2010; Karapetrovic et al., 2010), as described by the longitudinal studies made by Casadesús and Karapetrovic (2005a, 2005b). There are also risks of decreasing process compliance over time, after achieving a certificate (Gray & Roth, 2014). Additionally, a phenomenon of "*decertification*" has emerged in some developed countries, as presented by Franceschini, Galetto, Maisano, and Mastrogiacomo (2011). Previous studies have identified the decrease of ISO 9001 certificates, for example, Marimon, Heras, and Casadesús, (2009) and Sampaio, Saraiva, and Rodrigues (2009). Franceschini et al. (2011), present three possible causes for the saturation and initial decline in some countries: the perception of little incentive towards improvement; the bureaucratic burden in the application of ISO 9001 standards; and the apparent lack of advantages for organizations with a well-rooted quality culture.

There are a number of studies concerning the benefits and difficulties of ISO 9001, however, how to use ISO management systems in practice remains an opportunity for research (Boiral, 2011). We strengthened our idea that an approach to joint develop the IS and the QMS should contribute to internalize quality principles in daily practice (Naveh & Marcus, 2005; Prajogo, 2011). Moreover, there is a need to consider internal and external stakeholders needs to reach the potential benefits of ISO 9001 (Boiral, 2011; Singh et al., 2011; Walgenbach, 2001). Nevertheless, the potential problems of ISO 9001 can also be addressed by integrating the IS and the QMS with (Kumar & Balakrishnan, 2011; Poksinska et al., 2006): (1) increased correspondence between the standard and the organizational processes; (2) improved top management involvement; (3) in-depth audit support; (4) reduced paperwork by resorting to IT; and (5) reduced societal gaps, by addressing the requirements of the organizational context, external stakeholders, and different regulations.

A quality management strategy must be defined prior to the decision of certifying the company and can be combined with other technologies or systems to enhance firm performance within a context of multiple regulations. This context is described by Hancher and Moran (1989) as a space that affect how organizations develop their processes, as we introduce in the next section.

2.1.5 Organizational regulatory space: multiple sources of goals and rules

The ISO 9001 is a popular standard (ISO, 2012b; Sampaio et al., 2011), however, there are several regulations that affect the organizational context. Moreover, the need to meet "*statutory and regulatory requirements*" applicable to the organizations is stated in ISO 9001, for example in clause 0.1 "*This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.*" (ISO, 2008a, p. v). According to ISO 9001, statutory and regulatory requirements "*can be expressed as legal requirements*" (ISO, 2008a, p. 1). The regulations are mentioned in different pages of ISO 9001 (ISO, 2008b), for example regarding business processes compliance (p. 2), management commitment (p. 4), establishing the product related regulations (p. 7), and inputs for design and development (p. 8).

The term "*regulatory space*" was introduced by Hancher and Moran (1989). The authors define regulation as a combination of public and private characteristics that involve dynamic relations between and within people and organizations, sharing a common space of specific regulatory issues. According to Shearing (1993), the regulatory space is a social space "*in which different regulatory schemes operate simultaneously* [… and] *the state must compete for control of regulation with other regulatory entities*". In this sense, private regulators, interest groups, and distinct business experts also influence the regulatory space. In Hancher and Moran (1989), the "*space*" metaphor is in the scope of national regulation. For this research, we have mobilized and restricted the concept of Hancher and Moran (1989) to an organizational level, representing the entire set of regulations, either imposed or voluntary, that an organization decides to implement.

The organizational regulatory space (ORS) includes standards, which are voluntary regulations, increasingly adopted worldwide to implement management systems. There are standards for different topics, for example quality that is our focus in this thesis (e.g., ISO 9001), environmental management (e.g., ISO 14001), health and safety regulations (e.g., OHSAS 18001), and corporate responsibility (e.g., SA 8000). They also cover specificities of sectors such as food (e.g., ISO 22000), laboratorial (ISO/IEC 17025), or aeronautical (e.g., AS 9100). When multiple standards exist, Jørgensen, Remmen, and Mellado (2006) outline three possible levels of integration: (1) "*compatibility with cross-references between parallel systems*"; (2) "*coordination of business processes*"; and (3) "*an organizational culture of learning, continuous improvements of performance and stakeholder involvement related to internal and external challenges*".

To separate the IS from the ORS is unfeasible. On the one hand, the ORS is designed with regulatory information; on the other hand, the IS design must attend to the stakeholders viewpoints, the technology, and the nature of the strategic and operational activities involved (Baxter & Sommerville, 2011; Curtis et al., 1988). Business process management presents solutions that can guide the design of IS and organizational rules (Zairi, 1997). Nevertheless, we must take into consideration that not all the regulations are "process-friendly" (e.g., several financial regulations), and, even when they are, problems can still exist by adopting a process

approach in regulatory contexts (Iden, 2012). The list of problems increases if we consider the distinct vocabulary among the ORS experts (Abdullah et al., 2012); the diversity of the external legislation and standards, such as the Sarbanes-Oxley act, ISO management standards, codes of practice or business partners contracts; the need to translate the external requirements into internal procedures and practices; and the difficulty in integrating and evidencing regulatory compliance (Abdullah, Sadiq, & Indulska, 2010a, 2010b) in audits, and voluntary or statutory reporting. The design of the ORS is critical for organizations operating in distinct regulatory spaces around the globe, each one with a specific set of rules, norms, and cultural characteristics.

The regulatory space is a socio-technical space combining people, processes, and information (Shearing, 1993). According to Baxter and Sommerville (2011), a socio-technical system design must consider human, social, organizational, and technical factors. An "outside-in" perspective is needed to define the organizational regulatory context of the business. Standards and laws, combined with contract agreements, policies and norms, are then translated in procedures that regulate the "within" behavior of people, processes and information. Finally, the regulatory space also demands an "inside-out" perspective, concerning customer relationship, legal and financial information, or statutory reporting. It is critical that there is an agreement between the technical and social elements of the system among its stakeholders, that requires a joint optimization (Baxter & Sommerville, 2011).

2.2   Information systems (IS)

IS, in the sense of Management Information Systems (Davis, 1974; Mason & Mitroff, 1973), is a field of research that started in the 1960's, nevertheless it may already claim "*a glorious and not-so-short history*" (Hirschheim & Klein, 2012). The IS field has many achievements and evolved over the last half century (Davis et al., 2010), however there are recurring difficulties in the proposal of a unanimous definition for IS (Paul, 2007). This field was born from the nexus of other disciplines, such as computer science, management, and operations research, with the purpose of addressing the application of computers in organizations (Davis, 2000; Hirschheim & Klein, 2012). One example is the definition of IS as proposed by Mason and Mitroff (1973) that explicitly focus the organizational context.

According to the general systems theory (Bertalanffy, 1973), IS can be presented as a response to the mechanistic and reductionist approaches to scientific studies. This theory can provide a high level way of thinking about the IS as a set of interrelated parts or dimensions (Gregor, 2006), which properties may be lost if the phenomena is isolated from its environment (Mora, Gelman, Cervantes, Mejía, & Weitzenfeld, 2003). This is the case of IS that includes different dimensions such as people and technology (Bostrom & Heinen, 1977). As a "system" the IS may be studied as a whole of its interacting parts, that, in turn, interacts with the environment. As an open system, the interactions may occur outside-in, within, and inside-out of its boundaries, influencing the system state (Ackoff, 1971). These ideas are reflected in the work systems theory

that was suggested to improve the communication and alignment between the business and IT (Alter & Wright, 2010; Alter, 1999, 2008).

Information Technology is an important dimension of IS, although it is not the only one (Bostrom & Heinen, 1977; Davis, 2000; Paul, 2007). According to Alter (1999), the IS is a work system that processes information, by performing various combinations of six types of operations: capturing, transmitting, storing, retrieving, manipulating, and displaying information. Additionally, the use of information in a human context and its alignment with strategies in a business case sustain that technological aspects are only a part of this system. Checkland and Holwell (1998) have pointed out that many people have a common difficulty in distinguishing IS and IT, thus providing a clue as to why organizations may fail their investments in technology if adopted without understanding the nature of the strategic and operational activities (Gorry & Morton, 1971; Ward & Peppard, 2002). Many people think of computers when confronted with the word "information", but the answer would be considerably different if time goes back to 1946 before the computer was invented (Hsieh, 2006).

A relation of supply and demand is projected by Edwards, Ward, and Bytheway (1995), where IS determines the need for information (demand) and IT the offer available to those needs (supply). This definition encourages the alliance between IS and business strategies, orienting the applications at IT layer to contribute in changing environments and especially global competition scenarios (Clemmons & Row, 1991; Ives, Jarvenpaa & Mason, 1993; Rodrigues, 2002). According to Briggs, Nunamaker, and Sprague (2011, p. 14), *"IS solutions must therefore be not only technically feasible but also economically, politically, socially, cognitively, emotionally, and physically acceptable to stakeholders. These aspects of feasibility and value interact in complex ways"*.

An IS is a technical system, since some of its dimensions may be technical (IT), but it is also a social system, with formal and informal human activities for processing and representing data (Alter, 2009). The vision proposed by Paul (2007) conceives the IS as a social constructed system, emerging from the use and adaptation of IT and of the business processes developed in the organization. The processes may be formal, as defined for example by a process chart, but also the informal ones, created by the users to accomplish their work, and, therefore, in constant change. This holistic perspective is reinforced by the Ph.D. thesis presented by Böll (2012) that discusses the concepts of information and information system, highlighting the technological and social perspectives of the IS. This author argues that the IS can be viewed as an ongoing entanglement of different aspects that include social actors, technology, data, information, IS development, organizations, and practices.

One of the problems that was pointed to the IS field is that it constitutes an ambiguous discipline that could benefit from a greater focus on IT-based systems (Benbasat & Zmud, 2003). Nevertheless, this perspective has been criticized for not recognizing the transdisciplinarity of IS (Galliers, 2003). According to Hassan (2014), the close relationship between IS and other disciplines raises the risk of duplicating IS research, consequently declining its value. However, the author states that it is also that transdisciplinarity that allows the IS to provide solutions to the

issues that other disciplines by themselves cannot solve. The IS evolved and is now facing new challenges and raising doubts about the future. "*Is IS dead?*" was the defying title of the keynote speech presented by Zahir Irani at the EMCIS 2013 conference. We agree that the combination of multiple dimensions is an additional value of the IS discipline, that IT is one of the important dimensions of the IS core, since its beginning (Hirschheim & Klein, 2012), and that change in the IS field is an opportunity for growth, as suggested by Galliers (2003). Our view of IS is in agreement with the conclusions of Zahir Irani and the thought-provoking debate that occurred from questioning the IS future: IS is alive and essential for "*transforming the future*" (the theme of the ACIS 2013 conference), and also "*transforming organizations and society*" (the theme of the ISD 2014 conference). The challenges that technology brings to organizations are even more complex than the ones we could found in the 1960's, with information and its related technologies being a part of our daily lives, in our work, entertainment, or family life. Nowadays IS embraces more than the internal organizational users, it involves the customers, the society at large, interacting in a wider context (Hirschheim & Klein, 2012). Moreover, the IS may be the cause of success or failure of important pillars of our organizations and society, (Davis et al., 2010). One of those pillars is quality management, which we selected to address.

We agree that IS emerges from the usage and adaptation of IT by its users (Paul, 2007), as an ongoing endeavor that entwines different dimensions such as information, social aspects, and business processes. Designing such a system must represent the interactions of its internal dimensions, such as IT artifacts, but also the interactions with the environment of the system, representing a mutual influence (Böll, 2012). The history of IS research is bound with the notion of IT artifacts, and how those artifacts fit in the holistic IS (Orlikowski & Iacono, 2001). The IT artifact in this angle becomes more than a mere technological object, it is a key social phenomena for IS research (Lee et al., 2015; Zhang et al., 2011), as discussed in the next section.

2.2.1 The IT artifact

There are different definitions for IT artifact and different opinions concerning its relevance in the IS field. For example Orlikowski and Iacono (2001, p. 121) define it as "*bundles of material and cultural properties packaged in some socially recognizable form such as hardware and/or software*", while Benbasat and Zmud (2003, p. 186) as "*the application of IT to enable or support some task(s) embedded within a structure(s) that itself is embedded within a context(s), (...)* [hardware/software design] *encapsulates the structures, routines, norms, and values implicit in the rich contexts within which the artifact is embedded*".

The definition of the IT artifact as the core of IS discipline (Benbasat & Zmud, 2003) has been criticized by other scholars (Alter, 2008, 2015), and may be seen as a limited perspective for IS (Lee et al., 2015). According to King and Lyytinen (2004, p. 541), the IS has "*has an identity gathered from the consistency of its focus on the systematic processing of information in human enterprise*". Galliers (2003) goes even further and defends the IS transdisciplinarity, with a broad scope of research that reaches the entire society, focused on information and people. Defining an IT artifact is somewhat contradictory regarding the importance that IT should have in IS research

(Zhang et al., 2011). Hassan (2014, p. 802) argues that these problems *"are manifestations of an underlying problem in the degree of importance or worth of the product of IS research* [much of them…] *located at the boundaries between knowledge and disciplines"*. Our research is located at the boundaries of the IS and Quality, seeking an holistic development of both systems. It must involve distinct experts with different viewpoints and vocabulary. For these reasons we adopted the following definition for IT artifact (Zhang et al., 2011):

> *"An IT artifact is an entity/object, or a bundle thereof, intentionally engineered to benefit certain people with certain purposes and goals in certain contexts. It is developed, introduced, adopted, operated, modified, adapted, discarded, and researched within contexts and with various perspectives"* (Zhang et al., 2011)

We can complement this sentence with the definition of context-aware systems proposed by Dey (2001), which includes the information that can be used to characterize the situation of our entity/object.

> *"A system is context-aware if it uses context to provide relevant information and/or services to the user, where relevancy depends on the user's task"* (Dey, 2001)

We agree with Hassan (2014), who claims that the future of IS research is not exclusively technological nor it is exclusively a managerial issue. We believe in the opportunities that future IS research may offer, both social and technological, as presented at ICIS 2009 panel that Davis et al. (2010) portray: for the work of organizations as stated by Gordon Davis; studying the impact of IS in society and in other fields, as defended by Paul Gray; addressing interdisciplinary studies as argued by Jay Nunamaker and Andrew Whinston.

We saw that information systems are socially constructed and IT is one of its important dimensions (Paul, 2007; Zhang et al., 2011). In our opinion, a holistic and context-aware perspective of IS in organizations has a higher potential to create synergies between the IS and the QMS. Also, the QMS is socially constructed by everyone in the organization, as suggested by the quality principles (ISO, 2008b, 2012a). The use of IT has an important effect on the QMS (Sánchez-Rodríguez & Martínez-Lorente, 2011); however, we also understood that it must be complemented by additional resources (Forza, 1995b; Morabito et al., 2010). Moreover the QMS is context-aware when evaluated according to the definition of Dey (2001), using information from regulations that shape its context and multiple sources that include the customers and suppliers. Next, we describe the interconnected dimensions of an IS that forms the whole that we aim to address with our approach.

2.2.2 *Information systems dimensions*

IS research addresses subjects as diverse as information, technologies, and social aspects in organizational context (Hirschheim & Klein, 2012). However, IS may have different meanings to different people. According to Carvalho (2000, p. 277), "*any definition of information system is inevitably a general statement that can fit different instances*", and may cause confusion about the object of interest. For instance, Mason and Mitroff (1973, p. 475) state that an IS "*consists of, at least, a PERSON of a certain PSYCHOLOGICAL TYPE who faces a PROBLEM within some ORGANIZATIONAL CONTEXT for which he needs EVIDENCE to arrive at a solution, where the evidence is made available through some MODE OF PRESENTATION*". Many other definitions exist, with varying degrees of influence from the underlying IT, suggesting a combination of dimensions (Alter, 2008; Carvalho, 2000; Laudon & Laudon, 2007). To help us understand which are the fundamental dimensions we analyzed several IS definitions in the literature. Our selection was guided by two reviews that compared IS definitions, namely Carvalho (2000) and Alter (2008). A synthesis of IS definitions and the interrelated IS dimensions is presented in Table 2-3.

Table 2-3. Some IS definitions and key dimensions

IS definitions	IS dimensions
"*an integrated man/machine system for providing information to support the operations, management, and decision making functions in an organization. The system uses computer hardware, software, manual procedures, management and decision models and a data base*" (Davis, 1974); An updated definition by Davis (2000): "*information technology infrastructure, application systems, and personnel that employ information technology to deliver information and communications services for transaction processing/operations and administration/management of an organization. The system utilizes computer and communications hardware and software, manual procedures, and internal and external repositories of data. The systems apply a combination of automation, human actions, and user-machine interaction*"	Context (organizational structure, operations and decision models), People, Processes (procedures), IT (hardware, software), Information/Data
"*can in effect be considered as the memorisation system of the organisation: the system which permits it to keep in memory; its transactions with its environment; the events in its environment which it wishes to recall easily for some period; the common rationale which its members gladly share, or those which are imposed by its environment*" (Le Moigne, 1975)	Context (culture, history), Information/Data
"*a system which assembles, stores, processes and delivers information relevant to an organisation (or to society), in such a way that the information is accessible and useful to those who wish to use it, including managers, staff, clients and citizens. An information system is a human activity (social) system which may*	Context (society), People, IT, Information/Data

IS definitions	IS dimensions
or may not involve the use of computer systems" (Buckingham, Hirschheim, Land, & Tully, 1987)	
"an information system consists of five components: hardware, programs, data, procedures and people" (Kroenke, 2008)	People, Processes (procedures), IT (hardware, programs), Information/Data
"structural perspective: a collection of people, processes, data, models, technology and partly formalised language, forming a cohesive structure which serves some organizational purpose or function. Functional perspective: technologically implemented medium for the purpose of recording, storing and disseminating linguistic expressions as well as for the supporting of inference making" (Hirschheim, Klein, & Lyytinen, 1995)	Context (indirectly defined by the organizational purpose), People, Processes (procedures), IT, Information/Data
"what emerges from the usage that is made of the IT delivery system by users (whose strengths are that they are human beings, not machines). This usage will be made up of two parts: (1) First the formal processes, which are currently usually assumed to be pre-determinable with respect to decisions about what IT to use; (2) Second, the informal processes, which are what the human beings who use the IT and the formal processes create or invent in order to ensure that useful work is done" (Paul, 2007)	People, Processes (the context does not appear clearly in this definition, although may be described by the formal and informal processes), IT
"An organizational system that consists of technical, organizational and semiotic elements which are all re-organized and expanded during ISD [information system development] *to serve an organizational purpose"* (Lyytinen & Newman, 2006)	Context (indirectly defined by the organizational purpose), People, Processes, IT, Information/Data (technical, organizational, and semiotic elements)
"An organized collection of people, information, business processes, and information technology designed to transform inputs into outputs, in order to achieve a goal" (Huber, Piercy, & McKeown, 2007)	People, Processes, IT, Information/Data
"is an integrated and cooperating set of software directed information technologies supporting individual, group, organizational, or societal goals" (Watson, 2008)	Context (organizational, societal), People, IT

The selection of definitions is presented in the left column of Table 2-3. We are focusing on which are the dimensions to address and not the possible relations between them. For example, IT can support the processes but it could also overlap the context dimension if we consider the potential technologies on the market. To ensure that the dimensions in the right column of Table 2-3 were correctly extracted, we have analyzed the IS definitions with the qualitative data analysis tool NVIVO10, as Figure 2-7 illustrates.

Figure 2-7. IS dimensions extraction with NVIVO10

After eliminating the meaningless terms (e.g., *"made"*; *"may"*), we have created associations between the relevant terms. For instance, the terms "*human*", "*people*", "*participants*" where grouped in the dimension "People", while "*environment*", "*external*", "*organizational*" are encapsulated in the dimension "Context". We have finally reached five interrelated key dimensions of an IS according to our set of definitions that are: Context, People, Process, IT, and Information/Data. These five dimensions are aligned with the elements that Böll (2012) identified, namely the organizational elements (one of the context aspects), the social actors (people), practices (processes), IT, and information/data. Böll (2012) also highlights the increasing interest for ISD studies over the years, a topic that we address in the next section.

2.2.3 *Information systems development (ISD)*

According to Cunha (2000), it is possible to estimate more than one thousand IS project methodologies, with a diversity of objectives, although this number must be cautious evaluated considering: some of these methodologies are similar and, sometimes, its differentiation is due to marketing strategies; the classification as IS project methodology includes a variety of approaches with distinct objectives. They may vary from strictly technical approaches that emerged with the beginning of computer usage in organizations, to more recent approaches that include the employees and the customers concerns in organizational processes (Antunes & Cunha, 2013;

Hammer, 2010). Regarding the contingency of the IS projects, it is difficult to compare and classify this multiplicity of methodologies (Amaral, 1994; Avison & Fitzgerald, 2003; Cunha, 2000). Each context has specific characteristics that influence the choice of the methodologies that best suit them (Avison & Fitzgerald, 2003; Cunha, 2000).

The first methodologies for ISD aimed at the technological aspects of IS, usually mapping the hardware used in organizations. These initial proposals were developed to assist companies in the acquisition and usage of IT, and some proposals have almost fifty years old. For example, in 1967 Ackoff (1967, p. B-153) suggest five steps to design a management IS: *"1-Analysis of The Decision System"*, identifying the type of decisions made and its flows in the organization; *"2-An Analysis of Information Requirements"*, identifying the relevant and irrelevant information, followed by the creation of models; *"3-Aggregation of Decisions"*, grouping decisions with the same information requirements; *"4-Design of Information Processing"* that is the procedure for collecting, storing, retrieving, and treating information; and *"5-Design Of Control Of The Control System"*, controlling changes and continuous adjustments. Ackoff (1967) pointed out the benefits of managers involvement in IS design, a concern that is common to the QMS development (Boiral, 2011).

During the 1980s participative design became an area of great interest in IS research, for example for Enid Mumford, Frank Land, and Bob Bostrom that studied the importance of user participation in IS development (Hirschheim & Klein, 2012). Examples of historical IS/IT related methodologies that focus application development are the Jackson System Development (JSD) for program design (Jackson, 1982) and Structured Systems Analysis and Design Methodology (SSADM). Some methodologies include more technical perspectives such as the SDLC – Systems Development Life Cycle or the *"waterfall model"*. In contrast with the sequential waterfall model, the agile approaches advise a more iterative perspective in software development (Dybå & Dingsøyr, 2008; Larman & Basili, 2003), while other methodologies consider both technical and managerial perspectives, such as RUP – Rational Unified Process (Jacobson, Booch, & Rumbaugh, 1999) or the ISO/IEC 12207 (ISO, 2008c). ISD research has also followed sociological perspectives, for example Multiview (Avison, Wood-Harper, Vidgen, & Wood, 1998; Avison & Wood-harper, 2003), Critical Success Factors (Rockart, 1979), and Soft System Methodologies (Checkland, 1981). ISD evolved to support business needs and now includes *"heterogeneous portfolios of applications where ready-made software, such as enterprise resource planning (ERP) packages or shrink-wrapped software from various vendors"* (Cunha & Figueiredo, 2001), which can be sourced inside or outside the organization (Lacity & Willcocks, 1998; Muhic & Johansson, 2014).

The increasing importance of IS in organizations, also increases the diversity of approaches. More recently, we found ISD approaches inspired by theories such as the general systems theory (Burns & Deek, 2011), but also in-house developed methodologies that compete in industry practice, sometimes adopting more than one methodology (Griffin, Brandyberry, & Colton, 2010). There are several ISD methodologies, but problems still exist (Kautz et al., 2007). For instance, some methodologies may be too complex and inflexible, unfitting to all the possible situations (Avison & Wood-harper, 1991). Although ad-hoc and informal developments are observed in a

number of cases, methodologies are essential for ISD and can be adapted or combined into specific situations (Avison & Fitzgerald, 2003).

The analysis, design and implementation of the IS consider the technology and the nature of the strategic, as well as operational activities involved (Galliers & Leidner, 2003; Peppard, Galliers, & Thorogood, 2014; Ward & Peppard, 2002). Therefore, ISD must deal with the problems of diversity, knowledge, and structure at distinct behavior levels such as the business, company, project, team, and the individual (Curtis et al., 1988; Kautz et al., 2007). Moreover, ISD also has to tackle distinct interrelated dimensions such as the information, IT, processes, and human aspects in organizational context (Laudon & Laudon, 2007). ISD produces changes in the organization and its outcomes must be explained by (1) what is being designed and changed, and (2) how change works (Lyytinen & Newman, 2008). According to Lyytinen and Newman (2008), IS development creates and promotes the improvement of socio-technical elements and their relationships within and between the organizational tasks, structures and processes, and an organization's technological core.

Compliance is a well-known research subject in ISD. The literature addresses topics such as the requirements engineering and conceptual modeling (Ingolfo, Siena, & Mylopoulos, 2011; Sepideh Ghanavati et al., 2010), auditing IS compliance (Julisch et al., 2011; Sangkyun, 2011), and the alignment between law and IT compliance (Bonazzi et al., 2010). There are also contributions that provide automated approach for goal-modeling and reasoning (Giorgini & Mylopoulos, 2003), normative compliance (Ingolfo, Siena, Susi, Perini, & Mylopoulos, 2013), goal-process integration (Cardoso & Santos Jr., 2010), and value modeling (Schuster & Motal, 2009). However, the majority of studies focus on the perspective of modeling and checking compliance (Kharbili, 2012), lacking the human behavior in that regulatory space and the guidance to allow cooperation between different experts, not specific to a technology or IT architecture. Additionally, the IS must consider not only the "formal" IT solutions that support the processes, such as an ERP or a BPMS – Business Process Management System, but also the "informal" IT tools, such as spreadsheets and desktop databases that proliferate in the organizations (Handel & Poltrock, 2011). To design an artifact, we must be concerned with the context, the designers, and beneficiaries of the IT, processes, and the information (Laudon & Laudon, 2007; Zhang et al., 2011). These IS dimensions may be represented as layers, that interact and influence each other and their environment (Avison et al., 1998; Kautz et al., 2007). The identification of the layers can integrate multiple viewpoints, according to each system stakeholder and particular field of knowledge (Sommerville & Sawyer, 1997). According to Simon (1996, p. 111), *"everyone designs who devises courses of action aimed at changing existing situations into preferred ones"*.

There are similarities between the development methods of the IS and of specific regulatory systems of the organization, for instance the standard that we chose for our research, the ISO 9001 (Cunha & Figueiredo, 2005). Similarly to ISO 9001, there is a need to design and construct a system, understanding the application domain (Kautz et al., 2007), but also to manage the operation and change of that system (Cunha & Figueiredo, 2001; Domínguez-Mayo, Escalona, Mejías, Ross, & Staples, 2012a; Lyytinen & Newman, 2006). As stated by Bonazzi et al. (2010),

Julisch et al. (2011), and Parker (2000), both the IS and regulatory compliance should be achieved by an holistic design. Moreover, that holistic design can be viewed as a continuous improvement process (Cunha & Figueiredo, 2001), in cycles of the systems design-time and run-time.

The designations of design-time and run-time to represent different stages of development have been used by several authors (Julisch et al., 2011; Rosemann & van der Aalst, 2007; Sadiq et al., 2007), for example Garimella (2006) that consider the design-time associated with identification, modeling, conception and implementation of the business processes, while run-time occurs when they are in execution / operation. Other authors have used the two distinctions in the field of enterprise architectures (Klöckner & Birkmeier, 2010). The current concerns of organizations become more complex when compared to the technological focus of introducing computers in organizations (Hirschheim & Klein, 2012). Both the design-time and run-time of the IS evolved to address multiple dimensions, as considered by the fields of enterprise architectures and business process management that we present in the remaining of this section.

According to Rodrigues (2002), an enterprise architecture is a model constituted by representations that describe at a global level all the relevant aspects of the organizational IS. It is the result of a process to conceive the global vision of the IS and describe the IT that supports it, the applications, underlying support services, and the definition for the activities of developing applications and services. Moreover, the model aggregates multiple perspectives in a structured format that different users can understand and explains the context of the area being analyzed (Tupper, 2011). Rodrigues (2002) especially details four of the foundational methodologies, namely "Computer Architecture", "IBM BSP – Business System Planning" (IBM, 1984), "Information Systems Architecture", proposed by Kim and Everest (Kim & Everest, 1994), and the "Zachman Framework". The latter, developed by John Zachman (Zachman, 1987) has become a global reference. The result is an approach that describes the IS of an organization, according different perspectives and dimensions. The initial model included the three dimensions of data, processes, and networks. Other 3 were added in 1992, considering persons, time, and motivations. The framework relates each dimensions in a matrix, with the following perspectives: Scope (planning responsible), Business model (owner), IS model (IS responsible), Technological model (constructor) and detailed representations (sub-constructor).

Following the Zachman proposal of 1987, several enterprise architecture frameworks have appeared; for example The TOGAF – Open Group Architecture Framework (The Open Group, 2011), the FEAF – Federal Enterprise Architecture Framework of the USA government taking a cross-agency perspective (FEA, 2012), and DoDAF – Department of Defense architecture framework (DoDAF, 2010). A comparison between these frameworks can be found in the work of Urbaczewski and Mrdalj (2006). In spite of the several EA benefits reported in the literature (Tamm, Seddon, Shanks, & Reynolds, 2011), for example gaining insights in complexity of the organizations and benefiting complex projects, those benefits have less recognition by EA users when compared to EA creators (Foorthuis et al., 2010). Moreover, there are critics to the excessive technical focus of EA, number of description artifacts and, an overall complexity (Lucke, Krell, & Lechner, 2010) that can make the most widespread frameworks difficult to implement by the majority of ISO 9001-certified organizations.

As presented by Boh, Yellin, Dill, and Herbsleb (2003, p. 177), the interest in creating standards in EA field is very attractive: *"to reduce redundancy of infrastructure services provided by different IT groups, to reduce heterogeneity of infrastructure components across lines of business, and to ensure enterprise system reliability, availability, and scalability"*. Standards can be applied to the general domain of EA, for example with the IEEE P1471 standard, but also for the structure of the architecture components and for its design principles (Winter & Aier, 2011). The standards represent restrictions but also assist communication among EA practitioners. An example of architecture standardization is the ISO/IEC/IEEE 42010: Systems and software engineering – Architecture description, published by ISO in 2011. This standard is a successor of IEEE Std 1471, defining architecture by the concepts and properties of the system in its environment. According to ISO/IEC/IEEE 42010, an architecture may have different viewpoints that frame the concerns of a group of stakeholders in that system, following an idea that was previously introduced in the field of requirements engineering (Sommerville & Sawyer, 1997).

To overcome the deficiencies of EA frameworks to represent stakeholders concerns, Engelsman, Quartel, Jonkers, and Van (2010) proposed the ARMOR language, aiming to represent high level principles and their underlying goals. According to these authors, the principles can influence all the solutions in a specific context. Therefore, a principle must be decomposed in goals (Engelsman et al., 2010). Simon (1964, p. 3) defines goals as *"value premises that can serve as inputs to decisions"*. In the field of software requirements engineering we can find several goal oriented approaches (GORE), previously adopted for including stakeholders goals in EA. Examples of GORE approaches are the NFR (Mylopoulos, Chung, & Nixon, 1992), GBRAM (Antón, 1996), i* or i-star (Yu, 1997), and KAOS (Lamsweerde, 2001), proposing ways to identify and model goals to include in software requirements.

To map the reality of organizations, enterprise architectures must face the challenges of new design pressures, conciliation with legacy systems and the adoption of complex ready-made solutions such as ERP (Cunha, 2000), CRM – Customer Relationship Management or CMMS – Computerized Maintenance Management Systems. Moreover, there is a need to consider the shadow applications that populate the organizational IS, namely spreadsheets and desktop databases, sometimes developed by the end users and being determinant in the information they need for daily work (Handel & Poltrock, 2011). The enterprise model aligns the business needs with their supportive IS, interacting in a similar cycle of QMS continuous improvement (Cunha & Figueiredo, 2005). During this cycle there is a need to create enterprise models that document business processes (Šaša & Krisper, 2011), which is also required by ISO 9001 (Bernus, 2003; ISO, 2008b).

Simplicity and accessibility to be used by different stakeholders is an EA concern (Engelsman et al., 2010) that we share in our research. We also saw the importance of combining business and technological elements in the artifacts generated by EA (Klöckner & Birkmeier, 2010; Lucke et al., 2010; Robertson, 2010). Moreover we found that principles and goals (Lamsweerde, 2001; Lucke & Lechner, 2011) are important to represent in EA, not only the rules that a system must obey. According to Galliers and Leidner (2003) rules *"include guidelines and standards (or policies) which set a framework for decisions"*. Similarly, quality management is

not only about compliance to product or process specifications, it also involves the goals and principles defended by the organizational managers and process participants. Business processes are a key element in IS definitions (Buckingham et al., 1987; Hirschheim et al., 1995; Paul, 2007), in ISO 9001 (ISO, 2008b), and in enterprise architectures (von Rosing, Hove, Rao, & Preston, 2011), as we detail in the following paragraphs.

Business process management relies on cross-functional contributions. It includes the activities of analysis, design, execution, monitoring and measurement, as well as continuous improvement of business processes (Hammer, 2010; Zairi, 1997). It involves re-thinking process execution and not exclusively technology implementation or improving processes with IT, (Garimella, 2006; Hammer, 1990). Modeling processes is a common task of both quality and IT professionals (Gingele et al., 2002), that need to represent how the business operates and is aligned with IT (Hung, 2006). According to van der Aalst, ter Hofstede, and Weske (2003, p. 4) BPM is about "*supporting business processes using methods, techniques, and software to design, enact, control, and analyze operational processes involving humans, organizations, applications, documents and other sources of information*".

The technologies used by organizations in BPM are commonly called BPMS and sometimes referred to as BPM "suites" (Conger, 2010; Pacicco, Ravarini, & Pigni, 2010; SC-EAC, 2010). The review performed by Shaw, Holland, Kawalek, Snowdon, and Warboys (2007) identifies the main blocks that are common to the BPMS, including the subject being modeled (e.g., the organization); the software application; the modeling language and notation (e.g., BPMN – Business Process Modeling Notation); and the underlying technical infrastructure (e.g., Microsoft Windows). The BPMS main purpose is to assist the development of the core BPM factors that are generally identified as the strategic alignment, governance, methods, IT, people, and culture (Garimella, 2006; Hammer, 2010; Singer & Zinser, 2011).

The modeling of business processes can benefit from a facilitator, someone internal or external to the organization assuming the role of "*the caretaker of the collaborative modeling process in a workshop*" (Rosemann, Hjalmarsson, Lind, & Recker, 2011, p. 3). Modeling processes can create a formal representation of the work performed, assisting the creation of strategies, reasoning, insights and communication (Scozzi, Garavelli, & Crowston, 2005). Process models can have a didactic role, especially in organizations with lack of specialized resources to structure all the process information (Scozzi et al., 2005). There are several techniques for modeling processes, including Flowcharting, IDEF techniques, Role activity diagrams, Petri nets, Entity-relationship diagramming, and UML – Unified Modeling Language (Aguilar-Savén, 2004; Giaglis, 2001). One of the techniques is IDEF9000, that was developed for ISO 9001 (Gingele et al., 2002; Gingele, Childe, & Miles, 2003). The technique can include ISO 9001 documentation linked with the activities of each process. We can also find process-oriented approaches that suggest a holistic view of BPM, including dimensions such as the organizational strategy, people, IT, and process improvement (Willaert & Bergh, 2007). One example is the 8 Omega framework that suggests a sequence of activities to implement BPM, addressing four dimensions: strategy, people, process, and systems (Towers, Lyneham-Brown, Schurter, & McGregor, 2005). Another example emerging from the consulting practice is MLEARN, suggesting a comprehensive

approach to BPM that initiates with a top-down organizational strategy clarification (Coelho, 2005). Then, MLEARN proposes different stages for developing the enterprise business process architecture, achieving the strategic aligning of the IS, and the compliance with process-oriented standards such as the ISO 9001 (Coelho, 2010).

In the IS field, Curtis, Kellner, and Over (1992) suggest four perspectives that are commonly used in process models, namely the *functional*, *behavioral, organizational*, and *informational*. The *functional* perspective answers the question of "what" is performed in the process, namely the tasks and the information flows to accomplish those tasks. The *behavioral* perspective presents "when" the specific sequences occur, "how" they are performed, and their iterations. Moreover the IS must consider the social aspects and the context of the system that is being developed (Curtis et al., 1988). The *organizational* perspective represents "where" the process are executed and "who" participates. Finally, the *informational* perspective represents the information objects that are processed or a product of the system and their relationships. The questions of who, what, when, where, why, and how, are also tackled by Zachman (1987) to describe an enterprise architecture. The six questions are known as the 5W1H quality tool, having the potential to evaluate process transparency, namely in information objectivity, completeness, trustworthiness, ease of access, and understanding (Cappelli, Leite, & Oliveira, 2007).

Figure 2-8 presents the essential steps of the BPM lifecycle, although several variants can be found in the literature (Mathiesen, Watson, Bandara, & Rosemann, 2012).
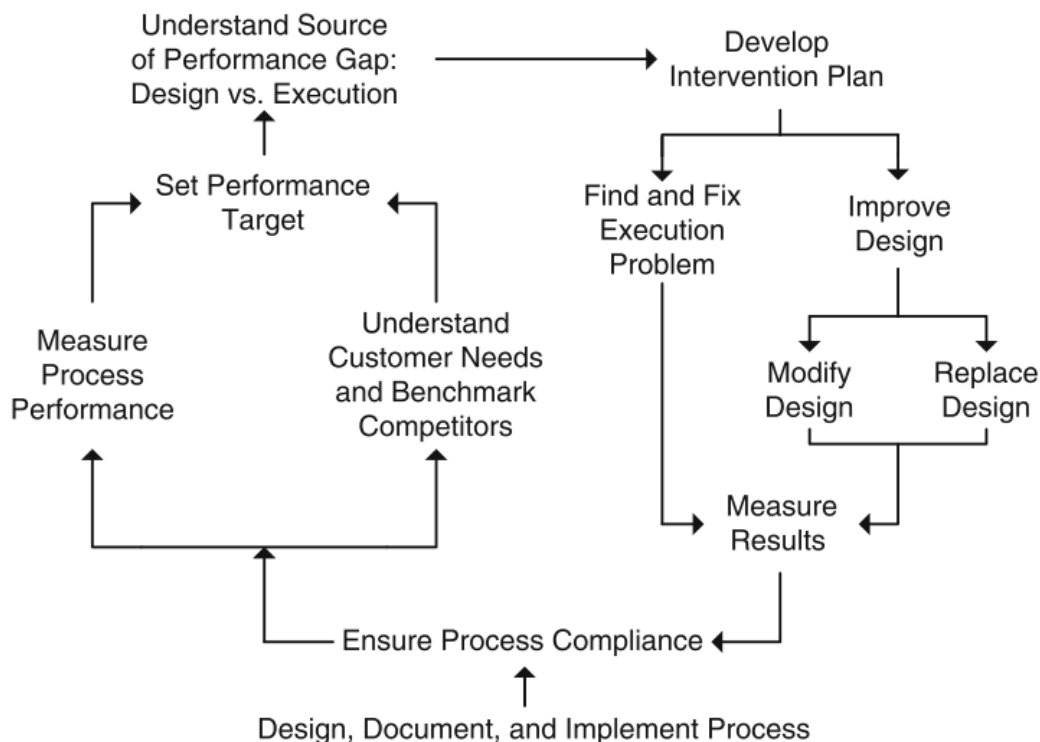
Figure 2-8. The essential process management cycle (Hammer, 2010)

The cycle shows an iterative sequence of process design and improvement, ensuring process compliance. It becomes clear that it is necessary to monitor process performance in relation to a

desirable output, coherent with customer, and competition needs. The lifecycle of BPM can also be represented in seven steps, starting with process identification and the sequent phases of modeling (as-is), analysis, improvement (to-be), implementation, execution (to-do), monitoring and control (Mathiesen et al., 2012). We can identify the design-time and run-time of business processes, as expressed in the iterative cycle presented by Hammer (2010). BPM can involve process redesign, as presented by Kettinger, Teng, and Guha (1997) that considers the following six stages the authors suggest according to the literature:

- Envision, an initial stage to gain management commitment and understand what needs to be changed;

- Initiation, to plan de project of change, the resources needed and goals to achieve;

- Diagnose, to document and analyze the existent processes;

- Redesign, consisting in the design of the new process and the new IS to support that process;

- Reconstruct, representing the implementation stage, involving training and new IT adoption;

- Evaluate, to monitor if the new process met the goals that the organization planned.

The work of Kettinger et al. (1997) reviews a vast range of techniques that can be used for each step of process reengineering, including project management techniques (e.g., Pert and Gantt), problem solving techniques, for example Pareto diagrams, process modeling flowcharts, business planning with critical success factors, and others. The authors then suggest an applicability guide of each technique according to the change characteristics. The proposal that was made by Kettinger et al. (1997) argues that a multidisciplinary team is needed to promote process changes, involving knowledge from different fields such as industrial engineering, creativity, organizational behavior, human resources management, and, especially, quality and IS. An example of the application of different quality techniques to an IT help desk process is presented by Conger (2010), concluding that they are complementary to BPM because while providing guidance in removing waste and errors in the processes, those techniques do not assist in recommendations for change and design of the new processes.

The critical factors identified for a fit of BPM and IS are the standardization of processes, informatization, automation, training, and empowerment of employees (Trkman, 2010), which are also shared by QMS principles. A book by Garimella (2006) describes the chronic problems between IT and QMS teams, arguing for BPM as a way of creating synergies for process design and run-time. The book also addresses Six Sigma and Lean approaches focusing the adoption of BPM tools to assist both approaches. However, not all companies plan to invest in BPM tools and there are difficulties when adopting a process approach in QMS contexts such as the ISO 9000 (Iden, 2012). Iden (2012) studied four process management dimensions in twenty-three ISO 9001-certified firms, namely: process awareness, process ownership, process measurement, and process

improvement. The author argues that the investment in ISO 9001-based quality management systems does not result in the adoption of process oriented approaches, with the risk of seeing the QMS as an imposed artifact rather than a valuable improvement tool.

Process models represent the present state and are the sources of improvement actions, but it is not easy to achieve process compliance as represented in Figure 2-8. In fact, this is a major challenge in BPM research in what refers to regulations (Abdullah et al., 2010a; Governatori & Sadiq, 2008; Sadiq & Governatori, 2010), one of the fundamental knowledge source of business processes (Hrastnik, Cardoso, & Kappe, 2007).

Several authors addressed the compliance of business processes and services, that include both legal and strategically imposed policies (Araujo, Schmitz, Correa, & Alencar, 2010; Sadiq & Governatori, 2010; Tran et al., 2012). Compliance should be a concern from the initial phases of IS design, as argued by Bonazzi et al. (2010) that suggest a multifaceted alignment between regulations and IT, by identifying IS requirements that are supported by regulations, and developing a set of artifacts that express both the processes and application level compliance requirements. This idea is held up by Julisch et al. (2011) who propose an approach for financial solutions that involve auditors in the lifecycle of IT development, namely in (1) plan, (2) build the solution, (3) deploy and operate, and (4) monitor the application to detect compliance violations. Several authors focused on the compliance of process models by adopting a language to represent obligations in business models, at the phases that the authors describe as design-time and run-time (Governatori, Hoffmann, Sadiq, & Weber, 2008; Sadiq et al., 2007; Sadiq & Governatori, 2010). The proposal of Breaux, Vail, and Anton (2006) balance both the rights and obligations in regulations. Other authors focused on languages for modeling regulations, for example PENELOPE (Goedertier & Vanthienen, 2006) or extensions to platforms such as ADOxx® (Karagiannis, 2008).

There are also contributions for evaluation of compliance, namely how to validate compliance to business rules (Araujo et al., 2010), audit compliance in BPMN models (Ghose & Koliadis, 2007), the OPAL compliance checking framework (Liu, Müller, & Xu, 2007), or approaches for the compliance of process fragments (Schumm, Leymann, & Streule, 2010). All these contributions are important for BPM compliance, complementing design approaches and providing a support for the entire process lifecycle. However, some of the approaches are too technical (Kharbili, 2012), others specific to languages such as BPEL, and others yet for specific platforms (Liu et al., 2007). We could not find an approach that could be simultaneously used by IS experts but also by the regulatory experts and regular users simultaneously, requiring minimum training and being platform or language independent.

The business processes and the organizational information system are major concerns of the quality managers (Addey, 2004). These professionals are daily searching for up to date, reliable, and timely data, not always easy to get. In fact, quality management is an information intensive activity (Khalil, 1995; Matta, Chen, & Tama, 1998), requiring a description of the business processes to ensure that the users always perform them consistently. However, the increase in bureaucracy caused by the quality documentation, and also a demanding measurement system, are

frequently reported problems for ISO 9001 certification (Kumar & Balakrishnan, 2011; Poksinska et al., 2006; Withers & Ebrahimpour, 2000). What emerges from the "*usage and adaptation of the IT and the formal and informal processes"* (Paul, 2007), in the context of quality management? The next section explores possible answers in the literature to this question.

2.2.4 *Quality information systems (QIS)*

The Quality information systems combines the quality management system and the IS, but there is no unanimous definition of QIS. In fact, there is some confusion regarding the QIS concept. Some authors use the expression to deal with the quality of the IS, such as Zahedi (1998), who defines a QIS as an IS in which TQM principles and techniques are applied. Other authors focus on the technological aspects of the QIS; for instance Ishizu (1996, p. 217) defines QIS as a system that aims "*to develop advanced TQM based on IT power*". According to Juran and Gryna (1993), a QIS is a separate IS that processes quality information to support decision making, and should be integrated with management information systems. This diversity of understandings means that each author needs to present their own definition of QIS depending on the purpose of the research (Gerber, Dietzsch, & Althaus, 2004). Additionally, there are important studies regarding distinct dimensions of the QIS but they are not integrated. For example, Forza (1995a) associated IT and information flows, while Naveh and Halevy (2000) addressed quality information. There is a need to interrelate all the dimensions of this important organizational system that may determine the success or failure of quality management approaches such as the ISO 9001 and TQM – Total Quality Management (Forza, 1995a, 1995b; Mathieson & Wharton, 1993; Sánchez-Rodríguez & Martínez-Lorente, 2011).The Table 2-4 presents some QIS definitions found in the literature, and the related QIS dimensions that we extracted using the same process we mentioned in section 2.2.2 regarding IS dimensions.

Table 2-4. Some QIS definitions and key dimensions

QIS definitions	QIS dimensions
"*sending the right quality information to the right point at the right time*" (Tang, Duan, & Chin, 2007)	Processes (information flows), Information/Data
"[is based on] *three levels of information creation and analysis: process control, process evaluation, and organizational assessment*" (Naveh & Halevy, 2000)	Context, (not only quality) Processes (information flows), Information/Data
"*capture quality information from both internal and external parties, and to facilitate the communication environment, in order to share quality information among enterprises, customers and suppliers*" (Tang & Lu, 2002)	Context (external parties, environment), Processes (information flows), IT
"*to support collaboration of member enterprises distributed in different regions to assure the efficiency and correctness of collaboration*" (Zhao, Xu, Yao, & Qin, 2008)	IT, Information/Data
"*information flows and information technologies which support managers and workers in their activities in order to improve quality performance.*	Processes (information flows), IT

QIS definitions	QIS dimensions
Information technologies are separated from information flows since information flows can take place even without information technologies and the presence of information technologies does not necessarily guarantee the achievement of information flows" (Forza, 1995a)	
"*applicability and superiority of the software in improving product quality and reducing production cost in a case study*" (He, 2006)	IT
"*necessary data to achieve and proof conformance with the specification of a product*"; "*logistics of QI*". "*[Present the development of a software tool]* to *build up quality control loops over and the complete production network*" (Gerber et al., 2004)	Processes (information flows), IT, Information/Data
"*[aims] to develop advanced TQM based on IT power (...) may also contribute to information technology*" (Ishizu, 1996)	IT, Information/Data (types of information)
"*be better able to manage their quality-related knowledge*" (Zeng, Lou, & Tam, 2007)	People (barriers in information flows), Processes (information flows), Information/Data
"*[sub-system of the Quality task system, associated with] designing and developing, operating, maintaining and auditing the quality system*". The IT component is a part of the "*quality technological subsystem*" (Jensen, 1991)	IT, Information/Data
"*help control manufacturing activities, analyze information, and support real-time policy making*"; "*requires gathering, processing, storage and the distribution of quality-related data*" (Mahdavi, Shirazi, Cho, Sahebjamnia, & Ghobadi, 2008)	Information/Data
"*it will be an effective work if QIS is developed by integrating it with ISO 9001:2000 quality system based-model. Hence, if a QIS compatible to ISO 9001:2000 standard is implemented in a company, it will leverage the performance of ISO 9001:2000 standard and offer very powerful solutions towards achieving continuous quality improvement.*" (Sakthivel, Devadasan, Vinodh, Raman, & Sriram, 2008)	IT
"*MIS department can take on this responsibility to link MIS with total quality management (TQM). The resulting quality information system (QIS) will focus less on technology and more on the business process*" (Keith, 1994)	People, Processes, IT

The technological aspects are most prevalent in the literature, focusing on IT and the required Information/Data for quality purposes. However, the mere adoption of IT may not be enough to develop a QIS (Morabito et al., 2010). The IS is a human activity system, involving socio-technical aspects (Davis, 2000), where IT requires a context, a purpose, and beneficiaries to make sense (Zhang et al., 2011). The positive impact of the IS on the QMS depends on information management, IT resources, and on the ability to make use of IT, thus making it a capability (Bharadwaj, 2000; Peppard & Ward, 2004; Zárraga-Rodríguez & Alvarez, 2013). Merging IS and quality theory, Mithas, Ramasubbu, and Sambamurthy (2011) found that information management has an important role in developing three quality capabilities: customer management, process management, and performance management. Moreover, IT needs to be complemented by well-designed information flows, accordingly with the organizational processes, change, flexibility, and training (Morabito et al., 2010). These studies show that IT is only one piece of the QIS puzzle.

The Context of QIS is predominantly confined to the requirements of the QMS, as an independent piece of the organizational IS. Although the dimensions of People and Processes can also be identified in Table 2-4, there is a lack of a holistic perspective of the QIS, from an organizational and managerial perspective. Moreover, the perspective put forward by Zahedi (1998) that a QIS is a IS that itself must have quality principles applied to it can be identified in the ideas of "*sending the right information*" (Tang et al., 2007), "*applicability and superiority of the software*" (He, 2006), "*necessary data*" (Gerber et al., 2004), and "*link MIS with total quality management*" (Keith, 1994). IS quality also emerges from the literature as a theme to include in our work, especially how the IT is interpreted in the context of ISO 9001 and how our joint development of the IS and the QMS can improve it in organizations. To address the concern of Zahedi (1998), in the next section we explore the concept of holistic IS quality (Stylianou & Kumar, 2000).

2.2.5 *Information systems quality from an enterprise perspective*

Quality is a multi-dimensional concept in IS, combining information, technology, social, and organizational aspects (DeLone & McLean, 1992; Nelson, 1996). Several authors addressed the topic of data and information quality, considering its multiple dimensions, intrinsic (e.g., accuracy), contextual (e.g., relevance, completeness), and representational (Lee, Strong, Kahn, & Wang, 2002; Nelson et al., 2005; Wang & Strong, 1996; Wang, 1998). Nowadays, the IT industry has many standards available for quality management, including ISO 9001 and other specific to this sector (Heston & Phifer, 2011). We can find advanced guidelines for software quality (Tian, 2005) and there are also contributions inspired in TQM for software development practices (Rothenberger, Kao, & Van Wassenhove, 2010), or software auditing (Chou, Yen, & Chen, 1998). Service quality is a concern for IS departments (Pitt, Watson, & Kavan, 1995), being essential to listen to the customer and to involve all the employees in service quality efforts (Berry & Parasuraman, 1997). Administrative quality address managerial aspects of IS (Stylianou & Kumar, 2000) and is one of the viewpoints previously identified by von Hellens (1997) to study IS quality. The different focus of interest to study IS quality is presented in Figure 2-9.
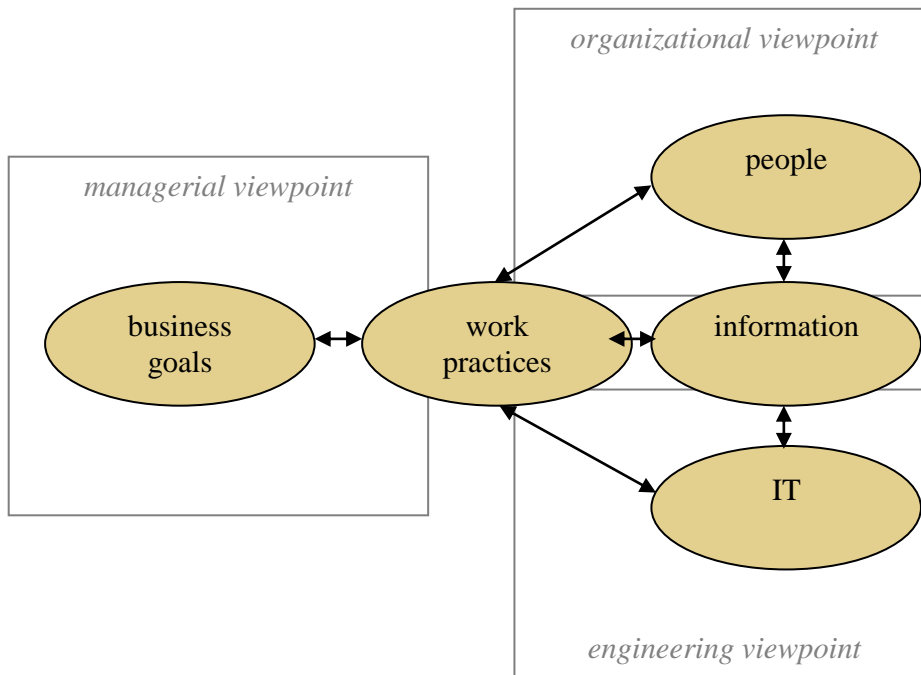
Figure 2-9. IS quality: The focus area of interest from a managerial, an organizational and an engineering viewpoint (adapted from von Hellens (1997))

According to von Hellens (1997), the managerial viewpoint is concerned in how the use and administration of IS can contribute to the firm's profitability, while engineers are more concerned with the quality of the development processes and the quality attributes of software as a product. In turn, the organizational viewpoint focuses on the impact that systems and IT have on the way organizations work. The organizational viewpoint is interested in the impact that systems and IT have on the way organizations work and compete. These perspectives, although not mutual exclusives, do emphasize different activities and the different methods available to control and improve IS quality. Von Hellens (1997) concludes for the need of more flexible and integrative methods.

Stylianou and Kumar (2000) frame "*enterprise quality*" as a holistic perception of IS and quality in the continuous improvement of the organization. They highlight that some of the viewpoints in IS quality overlap considerably, for instance, information with data; administrative quality and service quality; software quality and infrastructure quality, that, in turn, influences service quality. Figure 2-10 present the different dimensions of IS quality, according to Stylianou and Kumar (2000), and their relation with enterprise quality system.
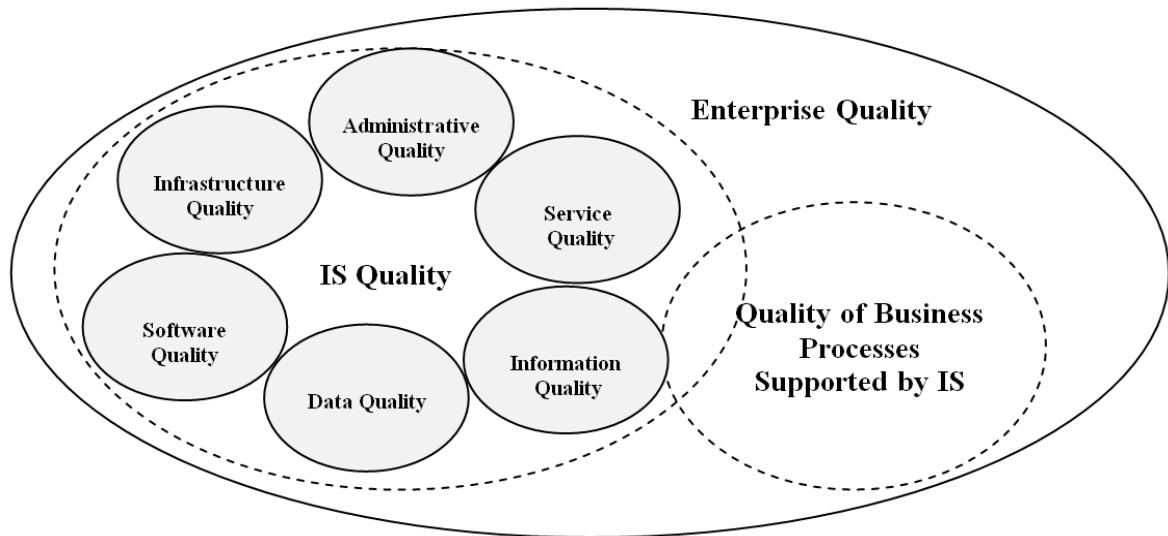
Figure 2-10. Distinct dimensions of IS quality (adapted from Stylianou and Kumar, (2000))

According to Stylianou and Kumar (2000), the dimensions of IS quality are described as:

- Infrastructure Quality: The quality of the infrastructure (hardware and enabling software) that is fielded and maintained by the IS function- includes, for example, the quality of the networks and systems software;

- Software Quality: The quality of the software applications built, maintained, or supported by IS;

- Data Quality: The quality of the data entering the various information systems (input);

- Information Quality: The quality of the output resulting from the IS. In many cases, the output of one system becomes the input of another. In that respect, information quality is related to data quality;

- Administrative Quality: The quality of the management of the IS function – includes the quality of budgeting, planning, and scheduling;

- Service Quality: The quality of the service component of the IS function – includes the quality of customer support processes such as those related to a helpdesk.

Each dimension is usually addressed separately, making it difficult to explore their connections (Ozkan, 2006; Salmela, 1997; Stylianou & Kumar, 2000; Wang, 1998). However, the IS quality dimensions reinforce and support each other. A study developed by Gorla, Somers, and Wong (2010) has shown that improving system quality can improve information quality. As proposed in the DeLone and McLean (2003)'s model, information, system, and service quality are dimensions that influence the IS success in organizations. In this thesis, we are not addressing each of these dimensions in particular. We address an holistic vision of IS quality as suggested by

Stylianou and Kumar (2000) that seems to have more potential to promote synergies for enterprise quality, in the context of ISO 9001.

IS quality has already proven its relevance for business quality. Salmela (1997, p. 819) defines business quality "*as the net value of an information system for the user organization. Thus, it is affected by both the cost of planning, developing, maintaining, and using the system and by the benefits achieved through systems use*". This conception of quality has no parallel in traditional QMS theory as proposed by Demming (1988), Juran (1974), or the ISO 8402 (ISO, 1994) standard. Salmela (1997) explores the value of information and articulates the notion of IS sustainability, acquired by flexibility to change both business and IS. Salmela (1997) corroborates that IS continuous improvement is a key element of business quality. Levis et al. (2007) conclude that high information quality is an enabler of TQM and serves as a key to quality success. In ISO 9001-certified organizations, the decisions must be based on data analysis and information.

There is a mutual influence between IS quality and ISO 9001. On one hand, ISO 9001 is an information demanding system that requires decisions based on facts, data analysis, and evidences of improvement (ISO, 2005b). It demands the development of documented procedures, evidences of quality conformity, and audits by internal and external entities. On the other hand, the IS research has been influenced by quality principles for decades (Lin, 2010; Ravichandran & Rai, 2000a), creating synergies between both fields. When combined, the IS and quality management domains contribute to business transformation, by promoting cultural changes (Philip & McKeown, 2004), improving quality and organizational performance (Hartman et al., 2002), and IT adoption (Lin, 2010). However, as Dahlberg and Jarvinen (1997) observe, an overall IS quality should be a result of systematic practices.

In the previous section we saw that the most predominant perspective for a QIS in the literature is that of an IS that supports quality. This section explores another perspective, that the IS must also be influenced by quality principles or its support to quality will be much less effective (Zahedi, 1998). The latter involves the creation of a quality culture, as we study in the next section.

2.3   Introducing cultural aspects

Culture is a key subject for quality management (Kanji & Yui, 1997) and IS (Leidner & Kayworth, 2006). Cultural studies are complex and diverse (Gallear & Ghobadian, 2004). They can address different perspectives, for example the national and the organizational. This section presents a review about organizational culture followed by the concept of quality culture. We then explore the relation between culture and IS.

2.3.1   *Organizational culture*

There is no unanimous definition for organizational culture. According to Gallear and Ghobadian (2004) some scholars describe culture as "*shared values*", another group as "*way of*

working", and others consider a combination of both. However, there is a general consensus that culture is a dynamic concept that can be learned (Schein, 1990).

> *"Culture can now be defined as (a) a pattern of basic assumptions, (b) invented, discovered, or developed by a given group, (c) as it learns to cope with its problems of external adaptation and internal integration, (d) that has worked well enough to be considered valid and, therefore (e) is to be taught to new members as the (f) correct way to perceive, think, and feel in relation to those problems"* (Schein, 1990, p. 111)

According to the definition presented by Schein (1990) culture is not static, it can be changed and learned by the group members. Barney (1991, p. 657) defines organizational culture as "*a complex set of values, beliefs, assumptions, and symbols that define the way in which a firm conducts its business*". Those values delineate the rules or context for the social interaction, having an impact on the behavior of firm members (Leidner & Kayworth, 2006). Therefore, culture is a socially negotiated and dynamic process, that can be studied at different interrelated levels, such as the national, organizational, and individual (Ali & Brooks, 2008; Hofstede, 1993). For each of these levels, culture manifests itself by artifacts, values, and underlying assumptions (Schein, 1990).

While writing this thesis, a debate emerged at the LinkedIn's HBR – Harvard Business Review group (HBR, 2014). The question "*What is CULTURE in one or two words?*" obtained 1674 commentaries in 6 days, from academics and practitioners that decided to participate. Although this comment thread provides opinions, we found it interesting to compare them to the literature. The pervasive combination of words was "*values*" preceded by "*shared*", "*lived*", or "*core*". Numerous opinions highlighted the "shared" perspective, for example "*collective memory*", "*common mindset*", "*collective mental map*", "*common laws*", "*organizational glue*", "*collaborative ownership*", and even "*our ways*". Some members proposed a single word, "*identity*", revealing a strong personal connection, while the relation with the group could be found by the expression of "*individuals' engagement*". An additional trend of statements pointed to dynamic aspects of action, such as "*feel and behavior*", "*behavior constitution*", "*beliefs and actions*", but also creating change: "*patterns asking to be altered*". The behavior may be revealed by "*formal and informal ways of operating*", which in turn may develop "*inner and outer frames which influence us*". These anecdotes found in the HBR group seem to emphasize the definitions proposed by Barney (1991) and Schein (1990).

Organizational culture can be created, considering the values of the group, but also the interaction with the external environment. Schein (1990) suggests that external adaptation involves the tasks of developing consensus regarding: (1) the core mission, functions, and primary tasks of the organization vis-à-vis its environments; (2) The specific goals to be pursued by the organization; (3) The basic means to be used in accomplishing the goals; (4) The criteria to be used for measuring results; and (5) The remedial or repair strategies if goals are not achieved. The dynamic of culture involves outside-in, within, and inside-out exchanges with the group

environment, with a strong influence of organizational management (Schein, 1990). Leaders influence the dynamics of culture by their own example when facing situations, but also by what Schein (1990) calls secondary articulation and reinforcement mechanisms, that are: "*(a) the organization's design and structure; (b) organizational systems and procedures; (c) the design of physical space, facades, and buildings; (d) stories, legends, myths, and symbols; and (e) formal statements of organizational philosophy, creeds, and charters*" (Schein, 1990, p. 115).

There are also problems when managing organizational culture, as presented by Ogbonna and Harris (1998). For example, cultural changes can be just a matter of compliance adaptation to the company values, and not a true change in behaviors. In this sense, how managers and employees see the organizational culture can differ. The authors suggest that while culture can be managed and specific values changed, the rationale for change influences the success of the change effort. It becomes critical that all the participants understand the principles to adopt, and participate in their implementation: "*the assessment of the success of a change programme depends on the perceptions of that which the change effort is designed to achieve*" (Ogbonna & Harris, 1998, p. 285). A previous work by Hofstede, Neuijen, Ohayv, and Sanders (1990) has shown that, besides values, the shared perception of daily practices is the core of organizational culture. Therefore, the organizational space provides the setting for learning and developing practices.

The development of the quality management system requires the integration of quality principles in daily practice. Therefore, those principles can influence organizational culture, becoming relevant for our research on synergies between the IS and the QMS. Several authors have studied the relation of quality principles with the organizational culture (Gallear & Ghobadian, 2004; Hildebrandt, Kristensen, Kanji, & Dahlgaard, 1991; Kanji & Yui, 1997; Kanji, 1998). Those authors suggest that quality culture aims at a dynamic of improvement in organizations (Detert, Schroeder, & Mauriel, 2000; Hildebrandt et al., 1991), as we address in the next section.

2.3.2 *Quality culture*

Quality management involves specific *"shared values"* and *"way of working"* (Gallear & Ghobadian, 2004; Kanji, 1998). It involves changing and learning practices that the organization decides to adopt. Therefore, quality culture is an essential aspect of the QMS lifecycle.

Quality culture requires a combination of the organizational culture, individual culture, and quality principles (Detert et al., 2000; Hildebrandt et al., 1991; Kanji & Yui, 1997). A strong quality culture involves customer orientation, continuous improvement, using data and analysis to support decisions, and the involvement of people in quality problems (Bahzad & Irani, 2008; Briscoe et al., 2005; Ishikawa, 1984). ISO 9001 defines a pattern of common quality principles that certified companies must learn and internalize in their daily practices. Those principles are similar in TQM and ISO 9001. Figure 2-11 illustrates the mutual influence of the quality principles in the organizational and quality culture.
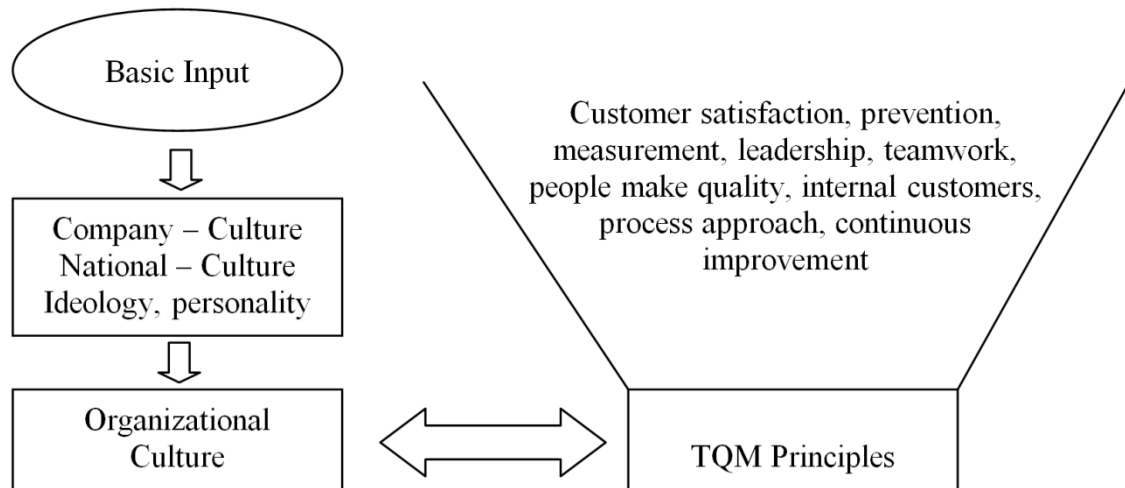
Figure 2-11. The creation of a quality culture (adapted from Kanji and Yui (1997))

Figure 2-11 suggests the creation of a quality culture based on the principles of TQM, representing a mutual influence with the organizational culture. A cultural change occurs when people internalize quality principles in organizational practices.

> *"The cultural stream of analysis leads to a different perspective on quality. The objective of introducing a quality management system is not necessarily the direct improvement of quality; the aim might be to change the culture in such a way that the introduction of a quality management system becomes culturally feasible"* (Vidgen, Wood-Harper, & Wood, 1993, p. 107)

TQM can provide a framework to build the organizational culture, promoting continuous learning and improvement (Detert et al., 2000; Gore, 1999). A study by Gore (1999) explores three elements of a culture that were found to support quality improvement: customer focus, employee involvement, and continuous improvement. We can find these three elements in the principles of a quality culture, consistent with the seminal work of Hildebrandt et al. (1991) that proposes a method to work with quality culture. The method is based on the assumption that TQM requires the creation of a quality consciousness in all employees (Hildebrandt et al., 1991, p. 10):

1. *"It is necessary to look at one's own quality situations through other people's observations, ideas, and thoughts. Quality development must take place in a group situation where insight, experience, and action can be created jointly"*;

2. *"Every individual must be involved and motivated in such a way that the framework acts as an incentive to quality development, and gives the courage to make decisions and instill confidence into others with whom initiatives are taken"*;

3. *"The ability to create quality can be developed by means of a method going beyond the traditional problem-solving tools. This requires a willingness to work with quality questions in a deeper way, relying also on one's own attitudes and values. As a rule,*

quality levels are for a given technology the result of the norms, culture, and expectations of individual employees";

4. *"There must be a readiness to set aside time and means to mobilize persons who have the possibility of deciding and implementing quality initiatives. It must be clear to the individual employee that a project is important to the company".*

ISO 9001 also involves cultural aspects (ISO, 2008b). By adopting the standard, organizations in different industries apply a set of principles that shape their organizational culture (Barney, 1986; Kanji & Yui, 1997). They promote a quality culture focused on the customer satisfaction, continuous improvement, and the involvement of people in quality efforts (Kanji & Yui, 1997). The study conducted by Gallear and Ghobadian (2004) identifies four ways in which quality management overlaps culture, namely the ways of working, values, a combination of the previous two, and collective learning. The authors found that several principles shared by TQM and ISO 9001 are important channels to create a quality culture; for example team work, top management involvement, involvement of all the employees, and continuous improvement.

> *"Working with a company's quality policies is one of the ways in which we can work with quality culture in practice"* (Hildebrandt et al., 1991, p. 10)

Hildebrandt et al. (1991) propose a method to work with quality culture, according to the culture circle presented in Figure 2-12.
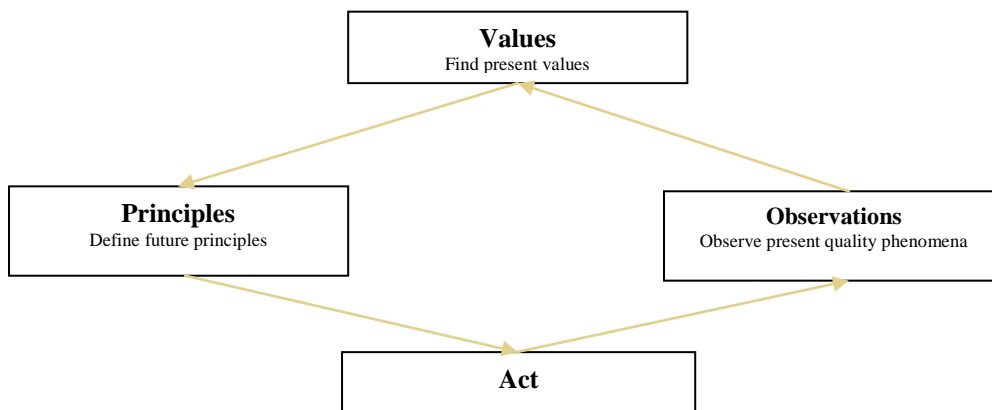
Figure 2-12. The O-V-P-A culture circle (adapted from Hildebrandt et al. (1991))

The starting point of the O-V-P-A cycle is observation. First step, O, suggests raising questions relating to quality, leading to observations of the present quality situation. Next step, V, aims at identifying quality policies, based on the organizational values. The result of working with the O and V is a number of statements or sentences characterizing the quality principles; for example the ones suggested by TQM and ISO 9001. Step V will be followed by the desire for change, representing the future quality behavior in the company (P). The last part of the method

suggested by Hildebrandt et al. (1991) is the decision on the requirements of new quality policies and of actions to implement changes. The result is a participatory method to identify and improve the quality culture.

The complexity of cultural studies requires taking into account several warnings, as stated by Harvey and Stensaker (2008), namely that a quality culture is not mechanistic and pre-determined, but rather a "*way of life*". It is an iterative process of evolution "*that does not just focus on internal processes but relates them to a wider appreciation of social and political forces and locates them historically*" (Harvey & Stensaker, 2008, p.439). The authors argue that a quality culture is context-bound and, while constructed, it generates knowledge. The next section presents possibilities to address cultural aspects in IS research.

2.3.3 *Culture, IS, and business processes*

Information systems also possess a deep relation to organizational culture. The interest of this type of studies is presented as follows:

> "*To specialists in User Studies and Information Systems Design* [organizational culture] *provides a further means of gaining insight into the working of organizational information systems, both formal and informal. To practicing managers seeking to implement and maintain information systems it offers explanations for their ineffective use, misuse and non-use*" (Brown & Starkey, 1994, p. 824)

People values, principles, and behavioral norms have been a major concern since the initial studies of IT adoption and use, sometimes called by socio-technical aspects (Bostrom & Heinen, 1977). Gallivan and Srite (2005, p. 320) identify four stages in the history of researching IT and culture:

1. "*Technological determinism: IT ''impacts'' organizations and their cultures*", assuming that IT can change culture, focusing the IT impact in the organization. This view is rejected by a majority of researchers and assumes "*that IT will have a pre-determined effect on the people and organizations adopting it, largely independent of the context in which it is adopted, how it is used or the specific intentions and actions of its users*" (Gallivan & Srite, 2005, p. 320);

2. "*The organizational imperative to change organizations and their cultures*", assuming that managers and IS designers can achieve whatever outcomes they desire for the organizational, practices, strategy, and performance. In this perspective, managers can "*manipulate*" organizational culture. This perspective is rejected by many scholars (Ciborra, 1996, 1997; Orlikowski, 1992) because does it not consider the motives and users agency, chance events, or even the possibility in which IT usage in practice will change over time;

3. *"The interactionist view of IT and culture"*, arguing that IT and organizational culture can interact producing different outcomes such as acceptance and use of IT. Several studies defend the need of a cultural analysis when implementing IT. This perspective understands culture as a "*fixed*" concept, very difficult to change so the challenge is to fit IT with "*immutable*" culture. However, quality management suggests the creation of a culture toward quality (Ross, 1995) and there are studies showing the benefits of introducing cultural changes with IS (Philip & McKeown, 2004);

4. *"IT-culture fit as an emergent process"*, sustaining that the outcomes of IT adoption are non-deterministic, "*will depend on the symbolic meanings that a given form of IT has for a given user (...) and may change over time*" (Gallivan & Srite, 2005, p. 324). We agree with this perspective that understands the combination of culture and IT as a dynamic process, contested, temporal, socially constructed by developing values and organizational practices (Hofstede et al., 1990; Myers & Tan, 2002).

A comprehensive review of culture in IS research is presented by Leidner and Kayworth (2006). The authors start by discussing the divergent definitions of culture, including the aspects of basic assumptions, values, and artifacts. A total of 82 articles are studied in the themes of culture and IT, at national and organizational level. There are also studies that point to the mutual influence between the IS and cultural quality principles. For instance, quality and improvement of information leads to changes in the customer orientation, flexibility, quality focus, and empowerment and integration (Doherty & Doig, 2003; Doherty & Perry, 2001). However, most of the studies address the impact of cultural aspects in IS development, and IT adoption and management (Leidner & Kayworth, 2006). Later, Silva and Hirschheim (2007) argue that the implementation of strategic information systems should incorporate the social dynamics of the organizations, including their core values, which may lead to restructuring and rearranging their practices.

The vision of a dynamic and socially constructed quality culture has a parallel with the IS definition by Paul (2007), presenting it as emergent from IT use and business processes development. Moreover, IT use will only be successful if embedded in the organizational practices of its users, supporting the introduction of the intended strategic changes (Arvidsson, Holmström, & Lyytinen, 2014; Silva & Hirschheim, 2007). Recent research points to the importance of combining culture and process management (Schmiedel et al., 2014). However, the literature does not provide approaches that organizations can be used to intertwine quality culture with their processes, information, people, and IT. Moreover, there is evidence that both organizational culture and environmental factors such as regulatory pressure, can influence the success of IT projects (Gu, Hoffman, Cao, & Schniederjans, 2014).

According to Brown and Starkey (1994) while organizational culture is not a paradigm for integrating all the IS research, it can assist IS design and management. Nevertheless, there is a gap in the literature regarding synergies between quality culture and IS. We could not find any definition for a multidimensional IS quality culture. The ones available are mainly focused on

data quality perspectives. They consider that IS quality culture exists when all organizational processes take into account data quality issues in order to improve it (Caballero, Gómez, & Piattini, 2004). Although we agree with the definition by Caballero et al. (2004), we argue that it is not sufficient to address an holistic perspective of the IS as we presented earlier in this chapter. The IS includes information/data, but also the IT, the business processes, and the users participation in improvement (Paul, 2007).

2.4 IS and QMS synergies

For over thirty-five years, researchers have been interested in how quality management systems and information systems can support each other. One of the first papers addressing the subject was published in 1979 (Wolfe & Tassé, 1979), however, the possibility of leveraging synergies between IS and QMS lifecycles remains a fragmented and fuzzy topic in the literature. In particular, there is a lack of advice on how to actually entwine these two systems, both at design-time and at run-time. With an holistic perspective, quality and information systems managers, consultants, auditors, and, ultimately, all the users of these systems may effectively collaborate in their lifecycles, from the design to the run-time phase. But first, there is a need to connect the pieces of the literature puzzle.

The QMS requirements are usually supported by the underlying IS (Khalil, 1995; Matta et al., 1998). In ISO 9001 these requirements include describing the business processes, usually in written documents, and to ensure that users always perform them consistently. One of the major difficulties in quality management is, precisely, in managing information. The increase of bureaucracy caused by the QMS documentation, such as procedures, work instructions, quality specifications, record templates, and also a more demanding measurement system to support data analysis requirements, are frequently reported as problems in ISO 9000 adoption (Kumar & Balakrishnan, 2011; Poksinska et al., 2006; Withers & Ebrahimpour, 2000).

There are evidences that the IS can influence the effectiveness of the QMS (Forza, 1995b) with potential synergies (Cunha & Figueiredo, 2005; Sánchez-Rodríguez & Martínez-Lorente, 2011). According to Rademacher and Clark (1993, p.769) "*the* IT [information technology] *quality mission is likely to remain an issue for some time*". In their survey among IS managers, the majority of them (80%) are in a position of merely reacting to the QMS rather than taking a proactive position (20%). However, according to Rademacher and Clark (1993, p.775), there is strong potential for synergies: "*the ISO 9000 standard offers an excellent opportunity for IT to have a wide-reaching impact on parent organizations as well as an impact on organizations competing for world markets. It would be refreshing, indeed, if this new quality initiative is viewed as a challenge and opportunity rather than simply a problem of compliance*".

Despite their distinct goals and functions, the IS and the QMS are mutually dependent, and capable of significant positive organizational impact when combined (Sánchez-Rodríguez & Martínez-Lorente, 2011). There is a significant overlap in concerns and actions when deploying any of these systems, such as, for example, designing business processes and their supporting

documents, attending to people's information requirements, training staff on daily operations. Paradoxically, the current practice for designing the two systems is unconnected (Cunha & Figueiredo, 2005). But without integrating their design, redundancies, inconsistencies, and inefficiencies emerge. The daily operation of those systems also calls for coordination, especially for managing organizational change and improvement (Spencer & Duclos, 1998).

There are several similarities and complementarities between the IS and the QMS. The QMS requires documents, on paper or digital form, that need to be designed and continuously adapted to business processes. Similarly, the IS can involve the design and adaptation of IT to those same processes. In the QMS, there are high-level principles to achieve in daily practice, involving all the process stakeholders, while the IS studies address people participation in the use and adaptation of IT and the organizational processes (Alter, 2008; Paul, 2007). Business processes and *"ways of working"* are common concerns to both the IS and the QMS. When we address each system independently, in a narrow perspective, the IS can provide tools and assist information flows, while the QMS provides principles and practices that can improve IS quality. However, both the IS and QMS managers needs to operate in every aspects of the business (Addey, 2004; Luftman & Ben-Zvi, 2010). Both systems require a holistic identification of the context in which the organization does business. Both the IS and the QMS have different dimensions that must be considered for their joint design-time and run-time.

Without specific resolve, however, the adoption of one system does not automatically improve the other (Prajogo & Sohal, 2006). On one hand, Casadesús and Castro (2005) have shown that, in spite of implementing ISO 9000, companies did not adopt practices to enable and integrate IT. On the other hand, Perez-Arostegui et al. (2012) have shown that IT competence by itself does not improve quality performance. They conclude for the need to explore in greater depth the relationship between IT and QMS. In fact, each of these two fields traditionally sees the other as a mere way to solve their own needs: the IS in providing tools and information for quality management (a simple supplier); the QMS in providing normative guidance with principles and practices that apply to the IS (a difficult regulator). A deeper synergistic approach to the design of the two systems in tandem is not common. Since this concern is at the core of this doctoral work, we have conducted a systematic review of the existing literature with the following objectives: (1) to identify the mutual support of the IS and the QMS, (2) to explore how these two different types of systems can be jointly designed, and (3) how they should be articulately managed when in operation.

A systematic literature review must follow an explicit methodological approach, with inclusion and exclusion criteria for the publications (Kitchenham, 2004). The review follows an iterative sequence of steps that produce *"context-sensitive research"* (Tranfield et al., 2003), and are suggested to be concept-centric rather than author-centric (Webster & Watson, 2002). According to Tranfield et al. (2003, p.220), *"for academics, the reviewing process increases methodological rigor. For practitioners/managers, systematic review helps develop a reliable knowledge base by accumulating knowledge from a range of studies"*.

Our systematic literature review was conducted for documents that explore QMS and IS integration in EBSCO, Science Direct, Google Scholar, and Mendeley. The search space included journals and conferences. Backward and forward searches for references and authors were performed for each relevant article (Levy & Ellis, 2006). Given the generic nature of the terms "information system" and "quality management", the search keywords were refined to include "ISO 9000" or "ISO 9001" (the terms are used interchangeably), combined by boolean operators (e.g., "information system" + ("9000" or "9001")). Our searches also included the terms "information technology", "TQM" and "quality information system". Additional iterations of search refinement included convergent terms uncovered in relevant literature previously found, such as "document management" or "top management support". Specific books were considered, for example, Juran (1974), Woodall, Rebuck, and Voehl (1997), and Garimella (2006), although not included in the literature coding process, due to the variety of topics addressed by the authors. According to the limits established for this thesis, care has been taken to exclude papers that address the distinct area of IS quality standards and practices from an engineering viewpoint (von Hellens, 1997).

As a next step, an overall analysis of top IS, operations, and quality journals was carried out, considering the period from January 2010 to December 2014. The publications included MIS Quarterly, Journal of Management Information Systems, Information Systems Research, Information Systems Journal, European Journal of Information Systems, Management Science, Manufacturing and Service Operations Management, Production and Operations Management, Total Quality Management and Business Excellence, Journal of Operations Management, and Operations Research. Each publication was tagged and annotated using the Mendeley free reference manager tool. The pertinent papers were grouped by similar concepts into categories, using an iterative coding approach. The abbreviations, IS and IT, will be used interchangeably, accordingly to the original use of the cited author.

In our classification of the papers we used the most prevalent categories and concepts they addressed, as described in the top and bottom rows of in Figure 2-13, respectively.
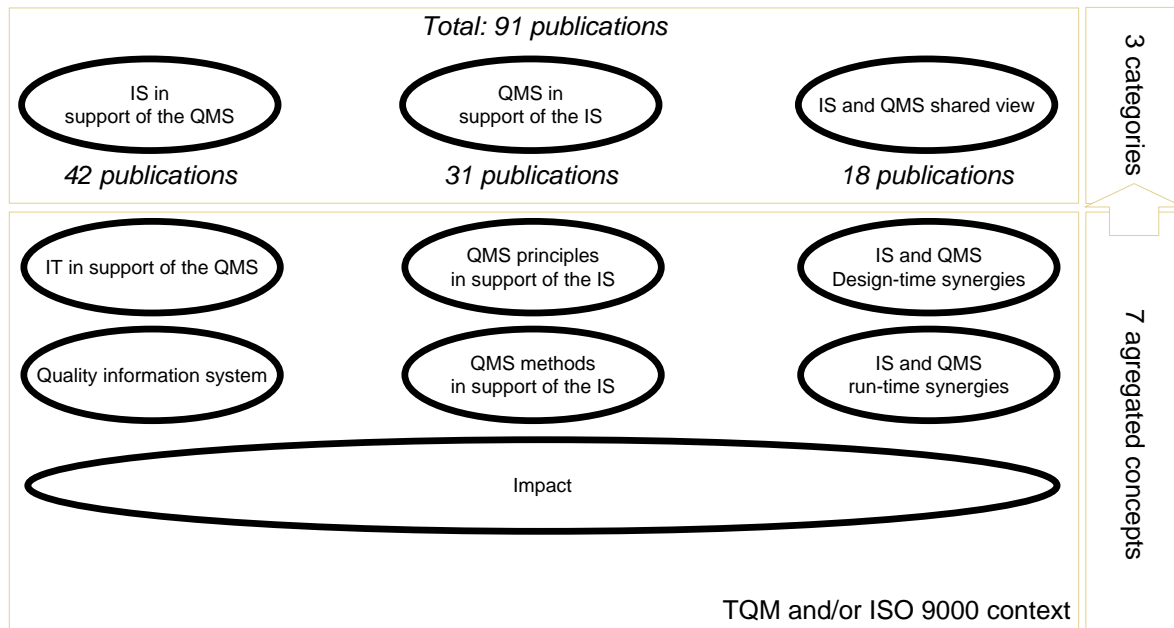
Figure 2-13. Major categories and concepts in the IS-QMS literature

The categories (1) "*IS in support of the QMS*" and (2) "*QMS in support of the IS*", are unidirectional perspectives of one type of system backing the needs of the other. Category (3) "*IS and QMS shared view*" represents a synergistic relation, where both systems build on each other, thus enabling wider organizational gains. The expression *"shared view"* comes from the work of Chen, Mocker, Preston, and Teubner (2010), who identify the *"shared view"* of the IS role within the organization as one of the conceptions of IS strategy.

Regarding category (1), two main concepts emerge from the supporting role of the IS, namely IT solutions and quality information systems that also includes information flows (Forza, 1995a). Another perspective – (2) – explores the *"QMS in support of the IS"*, addressing the adoption of quality principles (e.g., continuous improvement) and methods (e.g., audits) for the design and management of the IS. The shared view addresses the potential benefits of the joint design and management of the IS and the QMS. The papers that deal with evidences of organizational impact can be found across the three categories. Figure 2-14 shows the distribution of the collected papers by (a) research type, (b) approach to quality management, (c) lifecycle phase, and (d) major categories.

a) Research type
Theoretical 33%
Empirical 67%

b) Approach to quality management
TQM and ISO9000 15%
ISO9000 20%
TQM 65%

c) Lifecycle phase
Run-time 59%
Design-time 41%

d) Major categories
IS and QMS shared view 20%
IS in support of the QMS 46%
QMS in support of the IS 34%
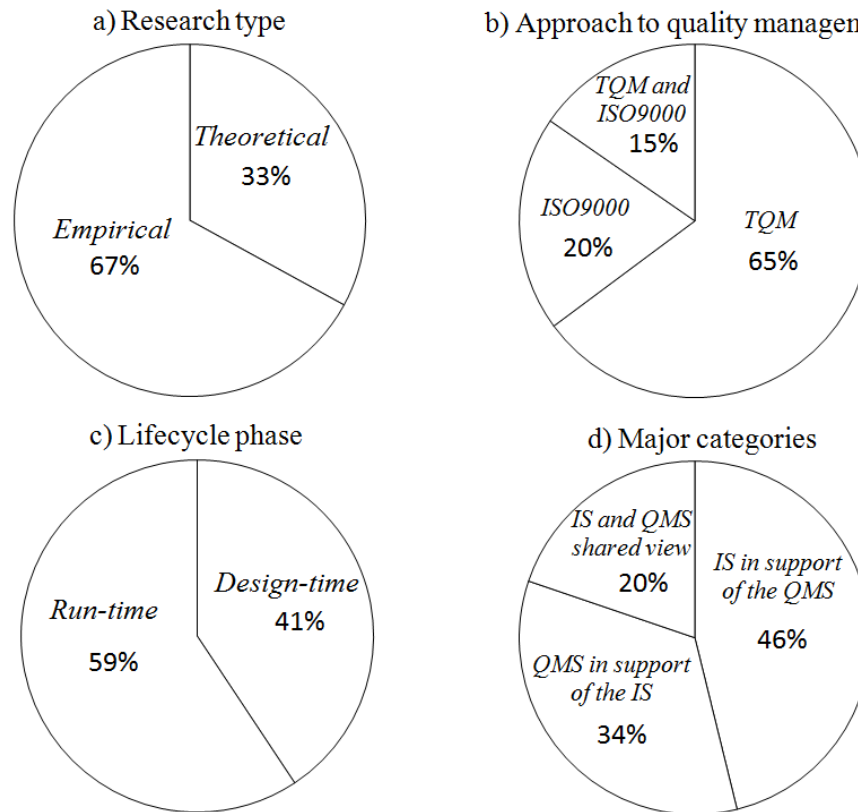
Figure 2-14. Paper distribution

Empirical studies are frequently found (67%), when comparing with theoretical (33%). TQM is the most referenced approach to quality management when discussing its relation with the IS (65%), more than tripling the 20% figure for ISO 9000. There is more balance in the focus of the discussion in what regards the lifecycle. Papers addressing the design (e.g., development of IT, creating documentation) represent 41%, while the run-time (e.g., operation and management practices for controlling or improving the systems, measurement, and audit) concerns 59%. At 46%, the area "*IS in support of the QMS*" represents the most significant share of the studies, followed by 34% that look into how the QMS can be used to support the IS. Only 20% of the papers deal with synergies. In the following sections we address these three categories of papers.

2.4.1 IS in support of the QMS

The IS may determine the success or failure of the QMS (Mathieson & Wharton, 1993; Matta et al., 1998; Wai et al., 2011) and that impact is well documented. A stream of the literature addresses quality dimensions, concluding that the IS can benefit information and analysis, compliance, human resource utilization, leadership (Ang, Davies, & Finlay, 2000, 2001; Keramati & Albadvi, 2009; Wu & Gu, 2009), as well as quality awareness, measuring, and reduction of quality costs (Mjema, Victor, & Mwinuka, 2005; Pursglove & Dale, 1996; Taylor & Wright, 2006).

There are several IT solutions to support quality efforts. For example, electronic data interchange (EDI), ERP, and computer-aided design / computer-aided manufacturing

(CAD/CAM) have a direct impact on related quality management capabilities: customer and supplier relations, product and process management, and workforce management (Sánchez-Rodríguez, Dewhurst, & Martínez-Lorente, 2006; Sánchez-Rodríguez & Martínez-Lorente, 2011). The use of groupware tools in process improvement groups, such as the workflow and decision support systems is suggested by Kock and McQueen (1997, 1998). The study presented by Lobo and Ramanathan (2005) includes a comprehensive list of IT for each QMS principle.

The positive effects cross the boundaries of the organization, extending to customer and supplier relationship (Anh & Matsui, 2011; Daghfous & Barkhi, 2009; Dewhurst et al., 2003; Kuei, Madu, & Lin, 2011; Ray, Muhanna, & Barney, 2005; Xu, 2011). The use of Internet technologies is popular in this area, with Tang and Lu (2002) specifying a QIS for the entire supply chain, while Shao, Wu, Deng, Li, and Feng (2006) present a web platform for collaboration with the suppliers, customers, and other partners. In the domain of organizational networks, Gerber, Dietzsch, and Althaus (2004) specify a QIS for non-hierarchic regional production, and Mahdavi, Shirazi, Cho, Sahebjamnia, and Ghobadi (2008) model and implement a QIS for distributed manufacturing shops. The web technologies can also assist quality inside the organization, by means of intranets (Hussain, Barber, & Hussain, 2009) and e-commerce (Tan, Lin, & Hung, 2003).

Other authors have studied IS support in the context of economic sectors; for example in construction (Love & Irani, 2003; Zeng et al., 2007), agro-food (Schiefer, 1999), laboratorial (Schmitz & Boukhari, 2007), and manufacturing (Bandyopadhyay, 2003; Jiao, Pokharel, Kumar, & Zhang, 2007; Zhao et al., 2008). Transversal studies can be found in the work of Ulbrich and Woll (1993) and Li (2007), describing quality information modeling for product development. Other authors like Tang, Duan, and Chin (2007) have designed an integrated QIS, in a manner similar to software quality packages available in the market today. In the scope of ISO 9000, Sakthivel, Devadasan, Vinodh, Ramesh, and Shyamsundar (2007) describe the development of an IS and Lari (2002) points out areas where decision support systems could be used, for example, for corrective and preventive actions.

Khalil (1994) has proposed a pioneer IS-TQM framework, identifying information management as a key constituent of QMS implementations. Figure 2-15 represents the macro view of the framework.
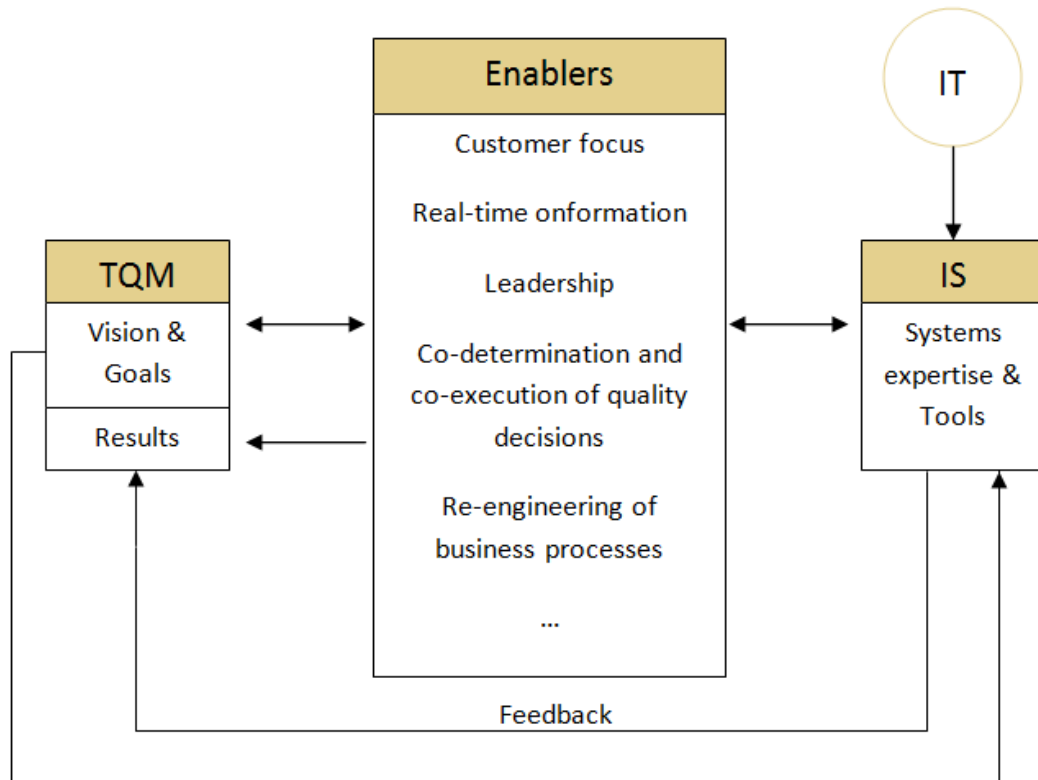
Figure 2-15. IS–TQM framework (Khalil, 1994)

Khalil (1994) starts with an introduction about quality principles, emphasizing their interest to organizational management and to the IS. The author observes that successful QMS initiatives are directly dependent on the IS, a fact that has not received proper attention. Poor and inconsistent data and incompatible support systems can sidetrack QMS efforts by focusing on problems on the quality of the data or the information system, rather than on the quality of the organization's outcomes. According to the author, the IS and the QMS are entirely compatible and capable of being combined into a composite model of action, for an organization seeking to maximize its competitive position (Khalil, 1994). We may identify a linkage of the IS and TQM through the enablers (quality principles). Even if the author does not detail the contribution of QMS to the IS and does not present how it can be put into practice, significant contributions prevail: the identification of problems and needs to integration; the establishment of a tentative high-level link (more significant for IS role in TQM); and call for future research.

However, IT is only one part of the equation. A seminal model for studying the role of IS within quality management was developed by Forza (1995a), and is presented in Figure 2-16.
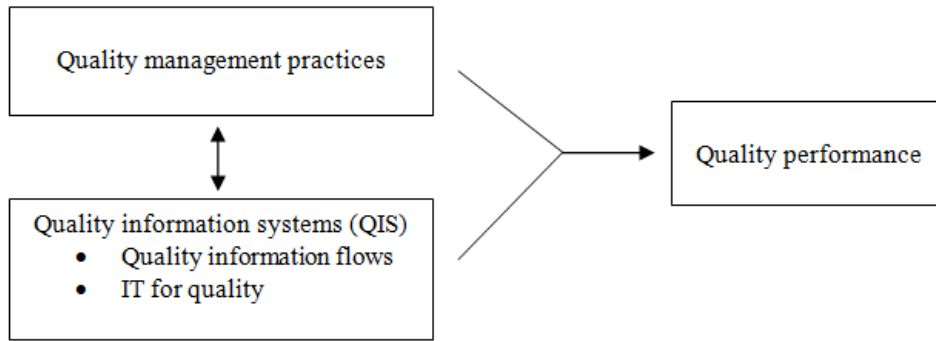
Figure 2-16. Framework for studying the role of IS in supporting QMS (Forza, 1995b)

The model of Figure 2-16 suggests the study of QIS by its information flows and IT in support of quality management practices. A subsequent publication by Forza (1995b) found that information flows contribute to high quality performances, while the IT contribution requires further investigation. Although the model by Forza (1995b) suggests a mutual influence between the IS and the QMS (as denoted by the vertical bidirectional arrow), the author's findings mostly address the role of the *"IS in support of the QMS"*. This influential framework was selected by Sadeh, Arumugam, and Malarvizhi (2013) to show the supportive effect of QIS in TQM. Later, other frameworks were developed: Valmohammadi (2011)'s, about the relation of IT with seven TQM principles; Ahmed and Ravichandran (2002)'s, that presents an IS design framework for TQM implementation and a case study; Kostagiolas (2006)'s, for supporting ISO 9000 in healthcare; and Naveh and Halevy (2000)'s on using QIS as a basis for improvement programs.

Au and Choi (1999, p. 296) present a singular study of QIS design (the author named it TQMIS) were they received training by the QMS experts. This helped them to understand the users' needs and why the information was needed. The authors argue that keeping systems aligned with continuous improvement strategies will be the challenge, and share lessons learned during their research:

- *"Early involvement with IT professionals is essential"*;

- *"IT avoid delays and errors during data input"* (supports the idea of data analysis requirement with valid data – improve data quality);

- *"Information must reach the management in an effective manner"*, with a positive effect on user acceptance of the program;

- *"Synchronization between results generated by the TQMIS and management's continuous improvement actions"* (in general terms, since the impact of IT change or the QMS change would need further investigation);

- *"Outputs from the TQMIS must be thoroughly tested and validated"* (software issue);

- *"Listen to employees' feedback and initiate positive changes"* (a question that is aligned with synchronization and continuous improvement).

The IS also plays an important role in QMS internalization. Drawing from IS and QMS theory, Mithas, Ramasubbu, and Sambamurthy (2011) found that information management capability can enhance the quality-related capabilities of customer and process management. The positive impact on the QMS depends on the information management, IT resources, and on the ability to make use of IT, thus building it into a capability (Zárraga-Rodríguez & Alvarez, 2013).

In summary, several studies addressed the impact of the IS on the QMS, in multiple contexts and with different IT solutions. However, there is a lack of methodologies to assist practitioners in the collaborative design and elicitation of the information requirements and IT support of business processes, according to QMS principles and requirements. As for run-time, guidance is missing on how to make sure that the information system is audit-friendly and prepared to evolve according to the principles that the QMS encloses. A plethora of IT solutions is already available as building blocks, leaving the organizational, social, and cultural issues involved in the synergistic design and evolution of the IS and the QMS as one of the major challenges to tackle.

2.4.2 QMS in support of the IS

We have seen why and how the IS becomes an important element in support of the QMS, but the reciprocal is also true (Delić et al., 2014). Quality is a multi dimensional concept in IS. Stylianou and Kumar (2000) advocate the idea of "*enterprise quality*" as an holistic perception of IS and QMS in continuously improving of the organization. Nevertheless, each view of IS quality is usually researched individually. For example, software engineers centre their attention in the quality attributes of the software, while the management is concerned with the way the use of IS contributes to the profitability of the firm, and the impact on the performed work (von Hellens, 1997).

TQM and ISO 9000 can be adopted for use in the entire IS lifecycle. Starting with the design, Wang (1998) proposes the Total Data Quality Management methodology, inspired by the Plan-Do-Check-Act cycle used for continuous improvement, while Worthington (2000) presents the techniques to build an IS, starting by the selection of a quality system model such as ISO 9000. For the auditing phase, Chou et al. (1998) propose an integrated process designed with TQM and ISO 9000 requirements. Some authors explored technological aspects to improve with quality, for example, Stylianou, Kumar, and Khouja (1997) adopted quality function deployment for IS development; Rothenberger, Kao, and Van Wassenhove (2010) demonstrated that quality is the key to cost-effective software production. Mandke and Nayar (2004) introduced the concept of information integrity. A positive impact of TQM in ERP projects can be explained by the emphasis on customer satisfaction, top management support, and life-long learning (Li et al., 2008; Lin, 2010; Schniederjans & Kim, 2003). A field survey conducted by Prybutok, Zhang, and Ryan (2008) found that other principles, namely leadership, strategic planning, and customer focus, had a positive impact on the IS dimensions of information, system, and service quality. Moreover, CRM has been shown to be positively influenced by ISO 9000 principles, such as customer focus (Ku, 2010; Su, Tsai, & Hsu, 2010). These examples illustrate how a purely

technical perspective is insufficient and how quality models should be linked to IS practice (Dahlberg & Jarvinen, 1997).

Other authors addressed social issues to bridge the user expectations gap in the IS lifecycle. By adopting TQM, the IS design is guided to satisfy potential expectations, uniting behavioral and technical aspects (Aggarwal & Rezaee, 1996; Bartel, 1995; Chou, 2001; Zahedi, 1998). Hartman et al. (2002) reinforce this viewpoint, showing that, as the QMS maturity increases, the adoption of IS will be more user-centered and participative. The QMS is an opportunity for clarifying processes and for documenting know-how, therefore promoting knowledge transferability (Molina, Montes, & Fuentes, 2004). Furthermore, the lifecycle stage of assessing the IS may benefit with the QMS support, as presented by the socio-technical approach of Palvia, Sharma, and Conrath (2001).

Both, technological and social aspects of IS, can improve with TQM and ISO 9000, but are organizations exploiting all the potential? According to Ravichandran and Rai (2000a), the IS departments should adopt a strategy that integrates all the dimensions of TQM. Top management support, stakeholder participation, product/service design, service quality and quality information, are examples of dimensions with a direct and positive impact on their performance (Chow & Lui, 2003; DeJarnett, 1991; Siddiqui & Rahman, 2006). A pioneer study of TQM use in the IS function was developed by Pearson et al. (1995), revealing the benefits of improved customer satisfaction, enhanced quality of products and services, and flexibility in meeting customer demands. Afterwards, Paper and Rogder (1996) present three case studies of TQM adoption, encouraging the involvement of the IS function with business process improvement. However, continuous improvement typical in quality poses challenges to the IS function in the organization, namely the constant changes required to systems, thus increasing IS pressure. On the other hand, failure to meet those demands may cause users to bypass the IT staff in the quality journey (Khalil, 1995).

The literature reveals several benefits in adopting quality principles and methods in IS design and management. As presented by Morabito, Themistocleous, and Serrano (2010), to improve the business value, the organization must combine IT with complementary resources such as training, process orientation, change, and flexibility orientation. Delić, Radlovački, Kamberović, Vulanović, and Hadžistević (2014) found out that the use of IT might be determined by quality practices, reinforcing IT organizational impact. The authors also suggest the adoption of quality practices to improve IT quality, namely *leadership, quality planning, employee management, supplier management, customer focus, process management, continuous improvements, and learning* (Delić et al., 2014). However, the major challenge seems to be how to apply the values of a quality culture (Hildebrandt et al., 1991) to all the dimensions of the IS; for example, how to deal with continuous improvement as an opportunity for the IS, rather than a threat.

2.4.3 Summing up the IS and QMS mutual support

A number of scholars have researched the mutual support provided by IS and quality principles. For example, Lin (2010) found that the combination of IS quality and management commitment, as proposed by ISO 9001, affects ERP system usage through user perceptions of usefulness and satisfaction. Leadership is another example of a quality principle that influences both quality and IS (Quaadgras, Weill, & Ross, 2011). Ang et al. (2001) suggest that the information system benefits the dimensions of important innovations, information and analysis, output quality assurance, and human resource utilization. Dong (2010) found out that IT could enable quality initiatives such as process design and innovation with the supply chain partners. Other examples include the support for administrative and service viewpoints of the IS (Paper & Rogder, 1996; Pearson et al., 1995).

Table 2-5 summarizes the contributions that we found in the literature addressing QMS principles and the support relation with the IS. The first column identifies the quality principle selected from ISO 9001 (ISO, 2005b). Column 2 describes the principle according to the standard (ISO, 2005b) and column 3 a list of related terms in the literature. For each principle we searched for the support provided by the IS, presented in column 4. Then we have searched for the benefit of that principle in IS theory. The literature coding did not include the principle of system approach, because the concept is intrinsic to both the IS and ISO 9001.

Table 2-5. QMS principles and the support relation with the IS

QMS principle	Description	Related terms in the literature	IS in support of the QMS principle	QMS principle in support of the IS
Customer focus	Organizations depend on their customers and therefore must understand the present and future customer needs, satisfy the requirements of the customers and make an effort to exceed customer expectations.	Customer service; Service quality; Customer relation; feedback	(Ray et al., 2005); (Daghfous & Barkhi, 2009); (Dong, 2010); (Banker, Bardhan, Chang, & Lin, 2006); (Sánchez-Rodríguez et al., 2006); (Sánchez-Rodríguez & Martínez-Lorente, 2011); (Dewhurst et al., 2003); (Anh & Matsui, 2011); (Wu & Gu, 2009); (Mithas et al., 2011); (Forza, 1995b); (Lobo & Ramanathan, 2005)	(Baroudi, Olson, & Ives, 1986); (Prybutok et al., 2008); (DeJarnett, 1991); (Pearson et al., 1995); (Paper & Rogder, 1996); (Stylianou & Kumar, 2000); (Kanungo & Bhatnagar, 2002); (Molina et al., 2004); (von Hellens, 1997); (Hartman et al., 2002); (Aggarwal & Rezaee, 1996); (Ravichandran & Rai, 2000b); (Ravichandran & Rai, 2000a); (Li et al., 2008); (Ku, 2010); (Morabito et al., 2010); (Fok et al., 2001)

QMS principle	Description	Related terms in the literature	IS in support of the QMS principle	QMS principle in support of the IS
Leadership	Leaders establish the unity of purpose and orientation of the organization. They must create and maintain an internal atmosphere in which the people can become fully involved in the achievement of the organization objectives.	Top management support; supervision; coordination; planning	(Sánchez-Rodríguez et al., 2006); (Anh & Matsui, 2011); (Keramati & Albadvi, 2009); (Lobo & Ramanathan, 2005)	(Lin, 2010); (Quaadgras et al., 2011); (Prybutok et al., 2008); (Pearson et al., 1995); (Paper & Rogder, 1996); (Stylianou & Kumar, 2000); (Kanungo & Bhatnagar, 2002); (Siddiqui & Rahman, 2006); (von Hellens, 1997); (Chow & Lui, 2003); (Ravichandran & Rai, 2000b); (Ravichandran & Rai, 2000a); (Li et al., 2008); (Schniederjans & Kim, 2003)
Involvement of people	People, at all levels, are the essence of the organization and their total commitment enables their skills to be used for the benefit of the organization.	human resource utilization; workforce management; teamwork; employee development and training; inter-departmental information flow; cross-functional communication; Employee suggestion	(Ang et al., 2001); (Sánchez-Rodríguez et al., 2006); (Sánchez-Rodríguez & Martínez-Lorente, 2011); (Dewhurst et al., 2003); (Anh & Matsui, 2011); (Wu & Gu, 2009); (Keramati & Albadvi, 2009); (Lobo & Ramanathan, 2005); (Kock & McQueen, 1997, 1998)	See customer focus (in the revised IS literature, involvement of people is concerned with user – customer involvement)
Process approach	A result is achieved more effectively when the related activities and resources are managed as a process	process design, process management, process control	(Dong, 2010); (Sánchez-Rodríguez & Martínez-Lorente, 2011); (Dewhurst et al., 2003); (Anh & Matsui, 2011); (Mithas et al., 2011); (Wu & Gu, 2009); (Lobo & Ramanathan, 2005)	(Stylianou & Kumar, 2000); (Pearson et al., 1995); (Kanungo & Bhatnagar, 2002); (von Hellens, 1997); Walgenbach (2001); (Aggarwal & Rezaee, 1996); (Ravichandran & Rai, 2000b); (Ravichandran & Rai, 2000a); (Schniederjans & Kim, 2003); (Morabito et al., 2010);
System approach to management	Identifying, understanding and managing interrelated processes as a system, contributes to the effectiveness and		N/A	N/A

QMS principle	Description	Related terms in the literature	IS in support of the QMS principle	QMS principle in support of the IS
	efficiency of an organization in the achievement of its objectives.			
Continual improvement	Continual improvement of the organization's overall performance must be a permanent objective.		This principle appears in the literature as an achievement of other principles adoption, such as the involvement of people (Ang et al., 2001), the process approach (Casadesús & Castro, 2005), feedback from the customers (Forza, 1995a; Taylor & Wright, 2006) or from the quality indicators (Sánchez-Rodríguez & Martínez-Lorente, 2011), as a consequence of leadership (Aggarwal & Rezaee, 1996; Dewhurst et al., 2003), in process improvement groups (Kock & McQueen, 1997, 1998)	This principle appears in the literature as an achievement of other principles adoption. A number of authors specifically address this principle, namely, (Wang, 1998); (Stylianou & Kumar, 2000); (Pearson et al., 1995); (Aggarwal & Rezaee, 1996); (Bartel, 1995)
Factual approach to decision-making	Effective decisions are based on data analysis and information.	Information and data analysis; quality data and reporting; quality cost; decision process; benchmarking; quality tracing and control; timely and correct decisions; process metrics	(Taylor & Wright, 2006); (Ang et al., 2001); (Sánchez-Rodríguez et al., 2006); (Sánchez-Rodríguez & Martínez-Lorente, 2011); (Dewhurst et al., 2003); (Wu & Gu, 2009); (Mithas et al., 2011); (Anh & Matsui, 2011); (Jiao et al., 2007); (Lobo & Ramanathan, 2005); (Mjema et al., 2005); (Zhao et al., 2008)	(Stylianou & Kumar, 2000); (Pearson et al., 1995); (Kanungo & Bhatnagar, 2002); (Chow & Lui, 2003); (Mandke & Nayar, 2004); (Ku, 2010); (Bartel, 1995)
Mutually beneficial supplier relationships	An organization and its suppliers are interdependent and a mutually beneficial relationship increases the capability of both for creating value.	Vendor participation	(Dong, 2010); (Banker et al., 2006); (Sánchez-Rodríguez et al., 2006); (Sánchez-Rodríguez & Martínez-Lorente, 2011); (Dewhurst et al., 2003); (Anh & Matsui, 2011); (Forza, 1995b); (Lobo & Ramanathan, 2005)	(Ravichandran & Rai, 2000a); (Ravichandran & Rai, 2000b)

Table 2-6 summarizes a review of studies that address the mutual impact of some well known IT applications and quality management. This table does not include specific tools for quality management such as statistic process control or solutions for vertical sectors of activity.

Table 2-6. IT and quality management synergies

IT	IT support to the QMS	QMS support to IT
ERP – Enterprise Resource Planning (Foster, Wallin, & Ogden, 2011; Li et al., 2008; Lin, 2010; Lobo & Ramanathan, 2005; Sánchez-Rodríguez & Martínez-Lorente, 2011)	customer and supplier relations, product and process management, quality data, workforce management	user involvement, IS quality, top management support, process approach. QMS as a predecessor of Enterprise Resource Planning
EDI – Electronic Data Interchange, Groupware (Kock & McQueen, 1997; Lobo & Ramanathan, 2005; Sánchez-Rodríguez & Martínez-Lorente, 2011)	customer and supplier relations, product and process management, quality data and workforce management, employee and stakeholders communication, system development, audit, training	
CAD/CAM – Computer-aided Design / Computer-aided Manufacturing (Foster et al., 2011; Hammer, 1990; Lobo & Ramanathan, 2005; Sánchez-Rodríguez & Martínez-Lorente, 2011)	customer and supplier relations, product and process management, quality data and workforce management, product development	
Intranet, Extranet, and Internet (Cunha & Figueiredo, 2005; Hussain, Barber, & Hussain, 2009; Lobo & Ramanathan, 2005; Silveira, Rodríguez, Casati, Daniel, D'Andrea, Worledge, & Taheri, 2009; Tang & Lu, 2002)	feedback for strategic planning, market research e-commerce	requirements evaluation
CRM- Customer Relationship Management (Bandyopadhyay, 2003; Daghfous & Barkhi, 2009; Ku, 2010; Lobo & Ramanathan, 2005; Su et al., 2010)	customer focus, customer service	QMS as a predecessor of the CRM, QMS principles to improve CRM systems
Document Management Systems (Bandyopadhyay, 2003; Cunha & Figueiredo, 2005; Kasim, 2011; Rezaei, Çelik, & Baalousha, 2011; Yao, Trappey, & Ho, 2003)	process documentation, documenting the QMS, communication	strategic record management

2.4.4 *Leveraging synergies across IS and QMS lifecycles*

The third (minority) research strand that we have identified in the literature addresses synergies between the information system and the quality management system, instead of merely putting one at the service of the other. A need for deeper integration between the IS and the QMS is concluded by D'Souza and Sequeira (2011) in the context of the Malcolm Bridge National Quality Award, while Zárraga-Rodríguez and Alvarez (2013) found a link between information management capability and the European Foundation for Quality Management model. Pérez-Aróstegui, Bustinza-Sánchez, and Barrales-Molina (2015) conducted a survey of 230 firms to analyze possible complementarities between IT competence and quality management practices. Other authors go further; for example, Jabnoun and Sahraoui (2004) advocate that QMS and IT plans should be developed simultaneously.

Although the QMS and the IS are different in nature, they may require similar organizational cultures (Fok et al., 2001). Philip and McKeown (2004) describe an example of business transformation and cultural changes developing managerial and organizational competencies, IS, and QMS. Increasing the TQM maturity also increases the users perception of organizational performance and service quality (Hartman et al., 2002). Lin, Chuang, and Shih (2012) present a correspondence between the development stages of TQM and IS. These studies acknowledge the potential of mutual impact, but once again their focus is unbalanced; the primary being the impact of quality principles on IS development, but missing emphasis on the role of the IS in fostering a quality culture.

Business process management is a common area of discussion in the IS and QMS research (Davenport & Short, 1990; Hammer, 1990, 2010; Zairi, 1997). There are studies supporting the existence of a mutual benefit of the IS and the QMS in the performance of specific processes; for example in purchasing, as shown by Hemsworth, Sánchez-Rodríguez, and Bidgood (2008). Nevertheless, Iden (2012) argues that process goals are insufficiently detailed in ISO 9000-based quality management systems and don't lead to consistent process improvement practices. There are also critical factors for a fit of BPM and IS, namely the standardization of processes, IT, training, and empowerment of employees (Trkman, 2010). These findings suggest that, when working separately, QMS and IS practitioners may have difficulties in implementing effective BPM systems, so teams should be multidisciplinary (Keith, 1994; Spencer & Duclos, 1998).

In conclusion, a shared organizational view of the IS and the QMS is appealing and considered desirable in the literature (Cunha & Figueiredo, 2005; Delić et al., 2014; Ferreira et al., 2012), but there is a lack of practical guidance on how to do it. For example, how to synergistically: (1) plan, establishing the requirements and goals for the joint development, in a way that is accessible and useful to both QMS/IS teams; (2) do, putting the systems in action, ensuring compliance and adherence to daily practice; (3) check, the development outputs; and (4) act, improving both systems and continuously refining the plan. The endeavor is complex, since the synergistic design of the IS and the QMS must consider organizational, social, and technological aspects that interact and support each other (Jensen, 1991). Studies illustrate this

interaction, such as Gunasekaran, Arunachalam, and Devadasan (2006), which proposes a TQM approach enhanced by IT. Conversely, maintaining both systems as separate entities increases a risk of overlaying a new bureaucratic system on top of an already existing one (Rivers & Bae, 1999). To achieve the desired synergies, Cunha and Figueiredo (2005) suggest that efforts should be made to integrate the IS and QMS at design-time. In our analysis of the literature, we found evidence that the synergies should also be sought for run-time of the IS and QMS.

2.5 Conclusions

This chapter synthesized our contribution for "RO1. Compile relevant literature about IS and QMS synergies by means of a systematic literature review". Given the scarce actionable advice in the literature on how to create and deploy highly synergistic information and quality management systems, we set out to extend the seminal framework of Forza (1995a, 1995b). Our goal was to identify research guidelines for design-time and for run-time of the IS/QMS development. We adopt the designation of design-time (when both systems are being prepared, diagnosed, sourced) and run-time (the moment when both systems are operating, requiring evaluation and improvement) to represent two main phases that iteratively occur in the development lifecycle. Figure 2-17 presents a map for our research.
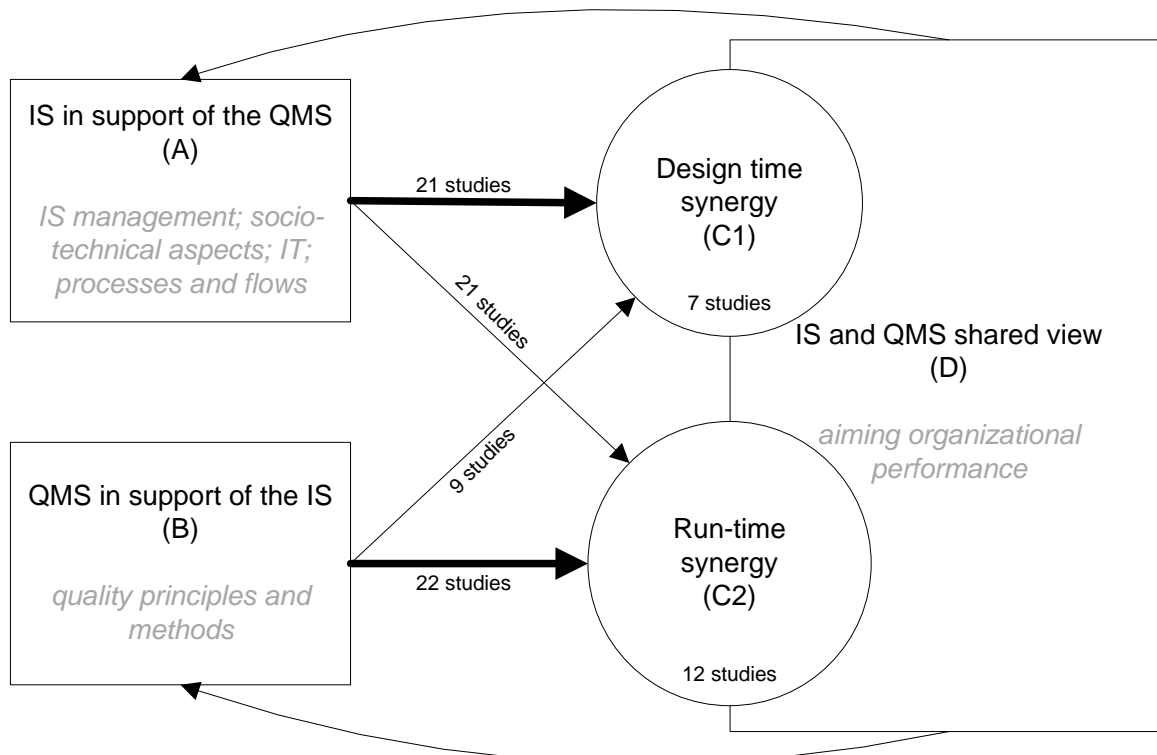
Figure 2-17. A map for researching design-time and run-time synergies

The factor (A) *"IS in support of the QMS"*, holistically considers the organizational IS. Our review suggests the need to add other IS dimensions besides the QIS dimension of the original framework. For instance, the IS management practices, business processes, and the socio-technical aspects of the IS (Bostrom & Heinen, 1977; Laudon & Laudon, 2007; Zárraga-Rodríguez & Alvarez, 2013). Factor (B) proposes the study of the QMS not only as a source of requirements for the IS but also as a source of value, with the potential for dynamically contributing to IS design and management. Factors (C1) and (C2) assert that design-time and run-time have distinct challenges and are sources of potential synergies. The design-time is the stage of the "to-be" and "should be" models for the creation of artifacts and tools, currently addressed disjointedly by IS and QMS teams. The run-time considers the phase when IS and QMS are already implemented and continuous improvement becomes a central concern. Nowadays, at this stage, IS and QMS teams continue to work separately, in spite of the success in the improvement of both systems being closely interrelated. The two moments are dependent of each other: the run-time is the result of the actions of design-time, and also the basis for new iterations of design, as recommended by the PDCA cycle (Shewhart, 1939).

Nowadays, virtually all organizations have management information systems in place, to support their business processes and data requirements of the various stakeholders. An increasing number is also setting up quality management systems (e.g., based on TQM or ISO 9000 standards) to ensure that their products or services consistently meet defined quality criteria and that improvement opportunities are sought.

The risk to ignore QMS needs may lead to problematic IS projects, with incomplete requirements, a higher risk of nonconformities, and not supporting organizational needs. Worse, ignoring the QMS context may convert it in to a source of problems for the IS, incapable of participating in organizational improvement. In addition, the quality principles and requirements may be compromised if the IS is not properly developed. In that case, the IS may become an obstacle for change, decreasing the potential of IS to realize organizational strategy.

What we have found out in our extensive literature review is that those organizations are not realizing the full potential of designing and having both systems in operation. Furthermore, we have found out that this is not merely caused by lagging practice, but that it stems from limitations in the extant body of knowledge. In fact, although it is known that the articulation of the IS and the QMS can deliver significant organizational benefits (Cunha & Figueiredo, 2005; Delić et al., 2014; Ferreira et al., 2012; Sánchez-Rodríguez & Martínez-Lorente, 2011), only 20% of the studies address a shared view of these two systems. Moreover, even fewer of these provide concrete guidance on how to design and operate both systems, so that synergies are leveraged and the result is more than the sum of the two parts.

We argue that a new approach should be developed, that include practical artifacts to assist its users (Lee et al., 2015; Pentland & Feldman, 2008; Zhang et al., 2011). Examples of artifacts can be architectural documentation of both systems and patterns of action that IS and QMS practitioners can adopt. Compliance to regulations (Abdullah et al., 2010a; Julisch et al., 2011; Sadiq, 2011) and the creation of a holistic enterprise quality (Stylianou & Kumar, 2000) must be a concern from the early stages of IS/QMS design. At run-time, there is a need to foster the emergence of a shared quality culture (Gallear & Ghobadian, 2004; Hildebrandt et al., 1991), guided by the principles of the QMS (ISO, 2008b). A shared view will be less effective if the integration stops at the design phase.

Chapter 3

Research strategy

3.1 Introduction

In the previous chapter, we started with a review of quality management and ISO 9001. Then, we identified the five main dimensions of an holistic IS and supporting theory that inspired our work. Finally we presented a critical analysis of the literature about design-time and run-time synergies of IS and QMS. Our approach to address their combined lifecycle must ensure support to different phases, while the development teams are planning and building both systems, but also when they are in daily use. The latter involves ways of working, the adoption of high-level principles in improvement actions (Gallear & Ghobadian, 2004; Philip & McKeown, 2004), emerging the cultural aspects of IS quality and business processes (Caballero et al., 2004; Fok et al., 2001; Schmiedel et al., 2014).

From the preliminary study and literature review, we argue that a new joint development approach is desirable to explore the synergies of IS and QMS development. At design-time, IS and QMS teams could combine their efforts while designing and documenting business processes. There is an opportunity to integrate IT with QMS procedures and instructions, at the same time improving compliance management. At run-time, the designed processes, the QMS and the IS can be jointly audited and continuously improved, aiming the flourishing of a quality culture in daily practice. Therefore, our research has the overall research purpose:

> *"Propose a synergistic approach for the joint development of the Information System and the Quality Management System, in the context of ISO 9001"*

We identified specific research objectives to guide the path to the research aim, listed below. RO1, RO2, RO3, and RO4 were identified when our work started, while RO5, RO6, and RO7 emerged during our fieldwork.

RO1. Compile relevant literature about IS and QMS synergies by means of a systematic literature review

There is an inherent complexity in holistically combining two systems as important and vast as the IS and the QMS. There is a vast array of literature about either one, even if we narrow the latter to the context of ISO 9001. This is our first challenge, accomplished through a systematic review of the literature (Webster & Watson, 2002). The systematic literature review about the synergies of the IS and QMS and its discussion can be found in chapter 2.

RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors.

We have interviewed ISO 9001 quality auditors for two reasons: the first is their expertise in the standard and its application in different organizations. The second is their consulting experience in QMS design. The interviewed auditors belong to a Portuguese certification association and three of them are from organizations that participated in our studies. This research question addresses a professional group and not specific organizations. The perspective of quality auditors is presented in chapter 4, section 4.2.

RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations.

It is essential to understand the point of view of IS and QMS managers for three reasons: first, to avoid incurring in the same mistakes that they already identified through their experience; second, to incorporate in our approach their suggestions and best practices; and third, to maximize our confidence that the approach will be usable in practice. We selected organizations where we had contacts or where we had developed past projects. The results allowed us to create a frame of reference (Shrivastava & Mitroff, 1984) for the design-time and run-time phases, which complemented the theoretical insights provided by RO1. The perspective of IS and QMS managers is offered in chapter 4, section 4.3.

RO4. Outline the main steps of the synergistic approach for the phases of design-time and run-time in the joint development of the IS and the QMS.

The approach should consider the lifecycle phase of design, when the IS and the QMS teams develop tools and artifacts to describe both systems. Moreover, the approach should focus the lifecycle phase of run-time, when both systems are in daily operation by their users, with a necessity to audit and improve them. The context of both the IS and the QMS is defined by the ISO 9001 principles and requirements (ISO, 2008b). Additionally, ISO 9001 requires managing a number of regulations that affect the business context. The main steps of our approach and the initial set of artifacts to support them in practice are explained in chapter 5, section 5.2. In section 5.3 we address regulatory aspects.

The following research objectives emerged while executing our fieldwork:

RO5. Clarify the concept of quality information system in the selected organizations and propose a definition for our work.

A common definition for quality information system was absent in the literature (Gerber et al., 2004). We even found contradictions about the concept because some authors consider the QIS as the quality of the IS (Zahedi, 1998), while other authors consider that a QIS is a combination of IT and information flows in support of quality management (Forza, 1995a, 1995b). Our aim was to understand how both IS and Quality managers see the QIS from the lens of five critical dimensions, namely Context, People, Processes, IT, and Information/Data. The holistic concept of QIS and its analysis according to the perspective of IS and QMS managers is included in chapter 4, section 4.3.2.

> **RO6.** Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles.

The principles of ISO 9001 contribute to a quality culture (Hildebrandt et al., 1991; Kanji & Yui, 1997) and were found to be a central aspect to the IS and QMS synergies. The opportunity to develop a quality culture initially emerged from the literature review in the QMS area. We found that a quality culture is created by the adoption of quality principles. Then we identified that cultural aspects have been addressed by IS scholars (Leidner & Kayworth, 2006) and are a current topic under research, for example at the business process level (Schmiedel et al., 2014; vom Brocke & Schmiedel, 2011). However, an holistic quality culture perspective that combines quality principles and IS was not found in the literature. We could confirm the interest of including quality principles in our approach with the auditors we selected to interview in RO2, and with the organizations that we selected to study in RO3. We explored this line of research from the angle of IS quality and business process management. We found that a quality culture could foster synergies at both the design phase, namely for process design, and at the run-time phase, for IS quality auditing and for business processes auditing and continuous improvement, as suggested by ISO 9001. Our contribution for the development of an IS quality culture can be found in chapter 5, section 5.4.

> **RO7.** Contribute to the development of a business process quality culture in the selected organizations, in the context of organizational policies and ISO 9001 principles.

This question emerged in the final phase of our research. In the light of the five dimensions of an IS that we identified, quality culture shapes the *Context* for the space in which we aim to create synergies. Moreover, it is developed by *People*. We also suggest that quality culture can be studied from the perspective of *Information/Data* and *IT*. We found that Culture and Business Processes is a recent research topic (Schmiedel et al., 2014) and we could contribute to this debate in the perspective of business process quality culture, extending the findings for RO6. This work is presented in Chapter 5.

The remainder of this chapter presents the underlying nature of knowledge claims (Walsham, 1995a) and the research approach that we selected to address each research objective. At the end of the chapter, the reader should be able to:

1. Identify the adopted research strategy;

2. Understand the reasons for the selection of the various methods and their relation with the research objectives.

3.2 Epistemology and research methods

Epistemology concerns *the nature of knowledge claims* (Walsham, 1995a). In her study in the accounting literature, Chua (1986) classifies three main research epistemologies into positivist, interpretive, and critical. Several IS researchers adopted this classification in their studies, concluding that the two initial paradigms dominated IS research (Lee & Baskerville, 2003; Mingers, 2001; Orlikowski & Baroudi, 1991), as described below.

The positivist tradition has dominated research in distinct areas of knowledge, for example in natural sciences, with stable laws that are "waiting" to be discovered (Cunha & Figueiredo, 2002). However, positivism has been criticized in its capacity to give an answer to complex problems that organizational contexts present: the prediction and control of the object of study is difficult when they are humans; the role of history is important in organizational studies; it has deficiencies to represent an holistic social system; and the knowledge of the inquirer cannot be excluded to knowledge creation in an organizational setting (Susman & Evered, 1978).

Interpretivism adopts the position that our knowledge is socially constructed by people, therefore, the researchers use their own preconceptions while doing research and interacting with the research contexts (Walsham, 1995b). Facts and values are intertwined, both contributing to knowledge creation (Walsham, 1995a). Positivism contrasts with this perspective stating that knowledge only consists on facts, directly observable by independent observers (Susman & Evered, 1978; Walsham, 1995a). In a positivist stance, the reality must be divided into as many parts as possible and necessary to resolve the problem (Figueiredo & Cunha, 2007). An example study that compares positivist and interpretive approaches is presented by Trauth and Jessup (2000), suggesting that both visions of the world are not incompatible; they can provide different lens to the same phenomena. Therefore, a plurality of perspectives can benefit the information systems research (Orlikowski & Baroudi, 1991).

> *"If a human's consciousness, worldviews, language, etc., are a product of the history of ideas as well as of social and economic development, then a social science model that ignores this product will ratify the past rather than help to create a better future"* (Susman & Evered, 1978, p. 586)

Interpretivism asserts that reality can be constructed by recognizing the world as complex and constantly changing. Therefore, the world can be known by the research interaction (Figueiredo & Cunha, 2007). It is built upon the need of a strategy to differentiate people and

objects of natural sciences, requiring that the researcher grasp the subjective meaning of human action (Bryman, 2012). This view is appealing for social studies (Checkland & Holwell, 1998a; Susman & Evered, 1978) but is also a subject of criticism, for example: due to the personal involvement of the researcher, that can lead to biased results; for its challenges regarding generalizations; and for the low control of the environment (Kock, McQueen, & Scott, 1997). Researchers must be aware of the benefits and potential obstacles of each research tradition, selecting the one that best fits the research purpose (Orlikowski & Baroudi, 1991).

Our research addresses the synergies between two important organizational systems. We are dealing with a dynamic context that is built by humans, involving social and technical issues. Therefore, interpretivism is best suited for our research purposes. Klein and Myers (1999) suggest seven interrelated principles to be adopted as a whole for conducting interpretive research. The principles and how we address them is presented as follows:

1. *"The Fundamental Principle of Hermeneutic Cycle".* This is an essential principle suggesting that understanding is obtained by iterating between the whole that we want to know and its interdependent parts. The whole is obtained by the "*shared meanings*" (Klein & Myers, 1999, p. 71) that emerge from these iterations involving both researchers and practitioners.

In our research, we studied distinct parts of the IS and the QMS, promoted a shared understanding about those parts, and about the outcomes that we wanted to achieve with a joint development approach. The iterations proceeded during our entire research, at both design-time and run-time phases of the joint development.

2. *"The Principle of Contextualization".* The principle requires a complete presentation of the situation that we are investigating. It includes social and historical context about the setting and the problems involved.

In our work, we present the research subject in its social and historical context, allowing the reader to understand how the problem emerged and how the situation evolved. Our case studies provided an overview about IS and QMS development in multiple organizations. Then each setting of our action research cycles is explained, including the relations between them.

3. *"The Principle of Interaction Between the Researcher(s) and the Subjects".* Both the researcher and the participants are analysts of the situation, contributing for changes in the context.

In our research, we present the researcher participation in each project, the participants, and the interactions that occurred.

4. *"The Principle of Abstraction and Generalization".* Interpretive studies can produce relevant theory from cases. Nevertheless, as pointed by Gregor (2006), that theory is not likely to have the characteristics of the laws of nature, because there are a large number of variables in the setting.

To address this principle, we were guided by the suggestion given by Figueiredo and Cunha (2007): to have in mind Karl Popper's critical rationalism. According to Popper (1982), a theory is valid if it is falsifiable but not yet falsified and scientific progress is made by rejecting theories that are not satisfactory and replacing them for better ones.

5. *"The Principle of Dialogical Reasoning"*. The researcher needs to confront the findings with his/her preconceptions that guided the research design. This iterative process leads the researcher to defy preconceptions and do not become jammed in the initial plan of action. It is important to know the researcher philosophical direction and beliefs.

Our research presents the researchers motivation, the researcher background, and the original lenses for our research design. During our case studies and action research we gathered evidence from different organizations, influencing the course of our research.

6. *"The Principle of Multiple Interpretations"*. The researcher must gather evidences from different viewpoints and seek for the influences of the social context in the actions under study.

Our work combines multiple viewpoints of the context, seeking different sources of information such as documents, interviews, and observation. According to Avison, Lau, Myers, and Nielsen (1999, p. 96) "the emphasis is more on what practitioners do than on what they say they do", requiring a permanent effort from the researcher to evaluate evidences to produce better results.

7. *"The Principle of Suspicion"*. The researcher must be sensitive to potential biases in the statements collected from the participants.

Our research adopts suggested practices for data collection and analysis, aiming to reduce biases introduced by the researcher's activities. Because reality is constructed and knowledge created by interaction, we present how they occurred and the different aspects that present risks of distortions in the interpretations drawn.

Ontology is an important concept for a research project that concerns with "*the nature of reality*" (Walsham, 1995a, p. 75). There are two main positions that Bryman (2012) describes: objectivism and constructionism. The former asserts that reality is independent from us and driven by immutable laws (Figueiredo & Cunha, 2007; Walsham, 1995a). On the contrary, constructionism asserts that reality can be build and we know the world by interacting with it, thus changing it in the process – this is the usual ontological stance for interpretivism (Orlikowski & Baroudi, 1991; Walsham, 1995a). In this case, culture simultaneously shapes people's behavior and is an emergent reality in a continuous state of construction. According to Bryman (2012, p. 19), "*if the researcher formulates a research problem so that the tenuousness of the organization and culture as objective categories is stressed, it is likely that an emphasis will be placed on the active involvement of people in reality construction*".

The relation between theory and research can be referred to as deductive, when the theory is deduced from existing knowledge, and inductive if the theory is obtained by observation, in this case, theory is an outcome of data (Bryman, 2012; Gregor, 2006). However, as noted by Bryman (2012), this duality should be regarded as a tendency of the research and not as a clear differentiation. For example, inductive theory building is typically associated with action research and case studies (Eden & Huxham, 1996; Eisenhardt, 1989), but theory is commonly used to provide the background that guides that type of research (Bryman, 2012).

A differentiation between methodology and method is presented by Marrais and Lapan (2004) in the introduction of their book. According to these authors, methodology includes the researcher position concerning the nature of knowledge and reality, describing how inquiry should proceed. The worldview according to knowledge and reality then leads to the selection of a research method that appears preferable for the problem in hand. A research method is the strategy of inquiry that the researcher selects based on the underlying philosophical foundations to guide the research design and data collection, providing the logic that links the data collected and the contribution to the purpose of the study (Myers, 1997; Rowley, 2002). The recommendation provided by Schutz, Chambless, and DeCuir (2004, p. 274), is that inquiry should be seen as "*a problem-solving activity, or as ways of investigating and working to solve problems within a socio historical context rather than attempting to predict or discover universal principles*". It is a particular way to gather evidence about specific phenomena (Marrais & Lapan, 2004). We can find a broader perspective of "method" in the literature, proposed by Johnson, Onwuegbuzie, and Turner (2007), in which the term may refer to methods of data collection (e.g., interviews, observation), research methods (e.g., case study, ethnography), and philosophical issues such as epistemology and ontology.

Different research methods can be adopted following different epistemological foundations, as exemplified by Klein and Myers (1999) regarding case studies and action research. For example, a case study can be done with an interpretive or positivist stance, just as action research can be interpretive or positivist (Klein & Myers, 1999). Moreover, research methods can be combined to achieve better results (Chiasson, Germonprez, & Mathiassen, 2009). Some authors, for example Mingers (2001), argue for a pluralist approach in IS research, pointing to the possibilities of using different research methods, sequentially or in parallel. Johnson, Onwuegbuzie, and Turner, (2007) consider the combination of qualitative and quantitative research "*for the broad purposes of breadth and depth of understanding and corroboration*" (Johnson et al., 2007, p. 123).

When using distinct methods, it is important to differentiate the mixed-method design and multi-method design. According to Morse and Niehaus (2006) mixed-method design is a plan for a research project with a qualitative or quantitative core and a qualitative or quantitative supplementary component. A quantitative part means the use methods such as statistical analysis, linear programming, and simulation (Gallagher & Watson, 1980), while the qualitative part includes the use of interviews, documents, and observation (Myers, 1997). In this design, the methods can be used sequentially (e.g., qualitative -> quantitative) or simultaneously (e.g., qualitative + quantitative), fitting together to improve description, understanding, and explanation

(Morse & Niehaus, 2006). Morse and Niehaus (2006) present multi-method as a different design. They define multi-method as a research program conducted by a series of quantitative and/or qualitative research projects over time (Morse & Niehaus, 2006). In multi-method the different studies performed are related with a broader topic, but each one has a specific purpose addressed by a specific qualitative and/or quantitative method (Morse & Niehaus, 2006).

In the field of collaborative research and systems development, Mathiassen (2002) propose the combination of action research, case studies, and experiments. The author argues that the proposed combination can support a variety of research goals and balance rigor and relevance. A systematic review conducted by Chiasson et al. (2009) presents several examples where action research is adopted after the insights obtained through other methods. An example of a research program with two sequential research projects of case study and action research is presented by Momme and Hvolby (2002). In our research program, we also combined a sequence of case studies and action research. The next two sections describe these approaches.

3.3 Case studies

As a research method, Yin (1994) defines it as an empirical enquiry that investigates a phenomenon within its real-life context, especially when the borders between phenomenon and context are not clear. This makes case studies well suited for IS research because its focus evolved to include socio-organizational aspects and not only technical issues (Benbasat, Goldstein, & Mead, 1987; Myers & Avison, 2002). According to Myers and Avison (2002), and Orlikowski and Baroudi (1991), case study is a popular qualitative method in IS research. Additionally, there are studies that specifically address the use of case study in IS research, either adopting the positivist lens (Benbasat et al., 1987; Lee, 1989) or the interpretive lens (Klein & Myers, 1999; Walsham, 1995a). In their study of 210 IS case study articles, Dubé and Paré (2003) found that the positivist paradigm dominates 87% of their sample. There are formal research hypothesis and propositions; evidences of measuring variables or constructs; the clear purpose of testing or building theory; and concerns of validity and reliability similar to the natural sciences (Dubé & Paré, 2003).

In the interpretive paradigm, the researcher tries to understand the phenomena "*through accessing the meanings that participants assign to them*" (Orlikowski & Baroudi, 1991, p. 5). According to Orlikowski and Baroudi (1991), interpretive studies improve the understanding of the situation within its cultural and contextual aspects, from the perspective of the participants, and not imposing an a priori understanding on the situation. An evaluation of conducting case study research according to different philosophical paradigms is presented by Darke, Shanks, and Broadbent (1998), concluding that successful case studies require the selection of areas that are relevant for industry and practitioners.

When using case studies, the researcher can resort to different techniques for data collection such as interviews and document analysis. In interpretive case studies, interviews are central sources of data, with a special interest in the "how" and "why" questions, that can be used for

exploratory, descriptive, or explanatory research (Rowley, 2002; Yin, 1994). The researcher does not have experimental control or manipulation in the field (Benbasat et al., 1987). Case studies can adopt a single case or a multiple case design (Yin, 1994). Single cases can provide a detailed description and understanding of a situation, usually very specific or unique to that case, or with a revelatory purpose (Walsham, 1995a; Yin, 1994). Multiple case studies can provide a more robust theory (Yin, 1994), allowing the comparison of the same phenomena in distinct settings, thus improving generalizability (Eisenhardt & Graebner, 2007; Eisenhardt, 1989). Multiple cases allow a broader exploration of the problem, with the advantages of finding differences and similarities among the cases (Eisenhardt, 1991), but sampling is more difficult. The cases can be selected by extremes (e.g., high and low performance), for similarity reasons such as replication, or others including the extension of theory, and elimination of alternative explanations (Eisenhardt & Graebner, 2007; Yin, 1994).

There are different types of events that can be analyzed in a case study. It is possible to research real-time events, but it is also possible to investigate past events, in retrospective (Leonard-Barton, 1990). Retrospective cases are based on interviews and archival data, being more accurate when the events are recent (Eisenhardt & Graebner, 2007). The main criticism concerning retrospective studies is the memory loss regarding specific details of the situation and the bias that can occur. However, Miller, Cardinal, and Glick (1997) argue that retrospective reports are not less reliable than non-retrospective ones. They also point to the option of free reporting to increase the validity of the results, which avoid forced questions and allows the interviewees to address the aspects that they remember. The authors also give additional suggestions, for example, to use simple questions, to ensure confidentiality of the results, and to provide a complete explanation of the usefulness of the project to the participants in the study.

Case studies can be used to evaluate cultural aspects (Schein, 1990), and some authors such as Philip and McKeown (2004) have used retrospective case studies for that purpose. The authors have gathered different types of data to understand "how" business transformation occurred, including interviews, archival data, and strategy documents. Additionally, the authors found benefits in the fact that one of the authors had previously worked with the selected organization, allowing them to compare the data interpretation with the author experience (Philip & McKeown, 2004). Another example can be found in the study that Trauth and Jessup (2000) performed in computer mediated discussions, as the second author was a member of the selected institution for their case. According to Trauth and Jessup (2000), that experience was a "barometer" to compare and challenge the interpretations. In interpretive studies there is an expected interaction between researcher's experiences and the context of the study. Therefore, authenticity emerges by "*the way in which we deliberately shared the process of developing our interpretation openly with the readers, rather than simply presenting it as a finished product to them*" (Trauth & Jessup, 2000, p. 69).

Case studies can produce context-dependent knowledge which, as argued by Flyvbjerg (2006), is central for social studies and for human learning. Moreover, this type of knowledge is "*at the heart of expert activity*" (Flyvbjerg, 2006, p. 222), provides details that rule-based knowledge misses, and is "*much more valuable for learning human affairs than predictive*

theories" (Flyvbjerg, 2006, p. 224). Nevertheless, the dependence of the context also creates generalizability problems to distinct contexts (Flyvbjerg, 2006; Lee, 1989). Generalization requires a rigorous evaluation by the researcher, the questions raised, and the method used, however, this is a common issue to distinct paradigms, not exclusive to interpretive studies (Lee & Baskerville, 2003). Researchers should seek generalizability, that is possible by one or multiple case studies (Walsham, 2006). For example, a single case study can be used to test if a theory is false in a specific setting (Popper, 1982). Flyvbjerg (2006) argue that case studies can be central to scientific development, and that generalization is only one form of knowledge creation. In this perspective, according to Flyvbjerg (2006), even a descriptive case study without attempt to generalize can be of value in knowledge accumulation and can contribute for scientific improvements. Multiple case studies can describe patterns in a larger scale, employing the logic of replication (Eisenhardt, 1991; Yin, 1981).

> *"The researcher needs to be entirely focused before beginning to collect data at the case study site, but at the same time flexible enough to see answers to research questions when they were not expected"* (Hays, 2004, p. 226)

The article published by Eisenhardt (1989) offers a set of iterative steps to produce theory from cases. The author presents a complete roadmap and guidelines for each phase. The activities of defining research objectives and possibly a priori constructs are the initial ones. Regarding the selection of cases, it is suggested that they should be theoretically useful and not randomly selected, to focus the efforts in those cases that are more likely to extend theory. A set of instruments or protocol can guide the researcher when entering the field, trying to understand each case with the required detail and cross-case analysis to find similar or contrasting data. The process may conclude when improvement of results becomes negligible (Eisenhardt, 1989). As stated by Eisenhardt (1989), it is likely that the process involves backward and forward iteration between the steps described. For example, the researcher can find evidences when analyzing the data that requires defining new questions and additional fieldwork. However, it is essential that the process converges to specific constructs and a theoretical framework for structuring the findings (Eisenhardt, 1989).

Validity and reliability must be a permanent concern for any measurement approach (Miller et al., 1997). There are specific suggestion for quantitative IS case studies presented by Boudreau, Gefen, and Straub (2001), including instruments of content/construct validity and reliability. Nevertheless, there are different ways to classify validity and reliability in case studies, for example Guba and Lincoln (1989) present an alternative definition when they are qualitative, by considering *credibility*, *transferability*, *dependability*, and *confirmability*. A synthesis of different recommendations (Christie, Rowe, Perry, & Chamard, 2000; Guba & Lincoln, 1989; Rowley, 2002; Yin, 1994) is presented as follows:

- Construct Validity/Confirmability: establishing appropriate measures, reducing subjectivity. The researcher may use triangulation of different types of data, ensuring that the investigation is according to the research questions. The constructs must be developed trough a literature review, establishing a chain of evidence. There are advantages in the external informants' review of the case study reports;

- Internal Validity/Credibility: establishing a causal relation when the case study is causal or explanatory. This aspect does not apply to exploratory or descriptive case studies because interpretive research does not usually deal with cause and effect problems of specific variables. There is a suggestion of prolonged engagement with the cases, cross case analysis, peer review, pilot cases, and creating a connection with prior literature;

- External Validity/Transferability: generalization based on replication logic and ensuring the definition of the domain that it applies. Multiple case studies and a case study protocol are recommended;

- Reliability/Dependability: ensuring that others may follow the discovery process, allowing repeatability. It is advised to develop a protocol and a case study database with case notes, documents, interviews, and analysis of the evidence. The researcher must demonstrate any changes in how the inquiry was conducted to ensure the stability of data over time.

To guarantee the proper adoption of the recommendations for validity and reliability in our research, we have used a comprehensive researcher checklist for case studies proposed by Runeson and Höst (2008), addressing case study design, data collection, data analysis, and reporting. An assessment for the 38 items of the checklist for our cases is included in chapter 4.

3.4 Action research

According to Baskerville (1999), creating or changing a systems development approach is impossible from a socio-organizational viewpoint without intervening in the real world to test it. Moreover, a responsive and flexible conduct is vital during such interventions to ensure that the knowledge built through practice shapes the approach (Baskerville, 1999). Cunha and Figueiredo (2005, p. 2246) argue that "*few research approaches can fit in such a context, since the principles on which most of them base their rigor and validity – problem decomposition, standardization of procedures and collection of rigorous quantitative measures under the control of independent researchers – become unfeasible*".

Action research is a cyclic combination of planning, acting and reflecting (Lewin, 1946). Whereas case study research examines phenomena in their natural setting with the researcher as an outsider, in action research the researcher is also a participant in action (Avison & Wood-harper, 2003; Rowley, 2002). In some cases the research project can start with a fuzzy question and also fuzzy results because of the nature of social problems and then, after each cycle, the

researcher eventually converges towards precision (Dick, 1993). Action research "*aims for an understanding of a complex human process*" (Baskerville, 1999, p. 11). According to Baskerville (1999), the ideal domain of action research is characterized by a social setting where (1) the researcher is actively involved, with expected benefit for both researcher and organization; (2) the knowledge obtained can be immediately applied; and (3) the research is a (typically cyclical) process linking theory and practice.

Action research is an approach that simultaneously aims to improve a problem situation in the target organization, and contribute to scientific knowledge (Davison et al., 2004; Hult & Lennung, 1980; Rapoport, 1970). This approach is suitable for complex problems, involving multiple variables, where a solution is reached by collaboration between researchers and practitioners (Avison, Baskerville, & Myers, 2010). The approach encourages the interaction between the researcher and external clients, consequently contributing to the current informing challenge of IS research (Gill & Bhattacherjee, 2009). Moreover, rigorous action research is seen as one of the solutions to improve the relevance of IS, by solving real world problems (Vries, 2007). In Hult and Lennung (1980) we find the following definition:

> "*Action research simultaneously assists in practical problem-solving and expands scientific knowledge, as well as enhances the competencies of the respective actors, being performed collaboratively in an immediate situation using data feedback in a cyclical process aiming at an increased understanding of a given social situation, primarily applicable for the understanding of change processes in social systems and undertaken within a mutually acceptable ethical framework*" (Hult & Lennung, 1980, p. 247)

There are multiple forms of action research, as presented by Baskerville and Wood-Harper (1998), usually represented in a cyclic combination of phases (McKay & Marshall, 2001). We followed one of the most used and well documented forms that is the Canonical Action Research, characterized by five phases of *Diagnosing, Action planning, Action taking, Evaluating, and Specifying learning* (Susman & Evered, 1978), as illustrated in Figure 3-1.
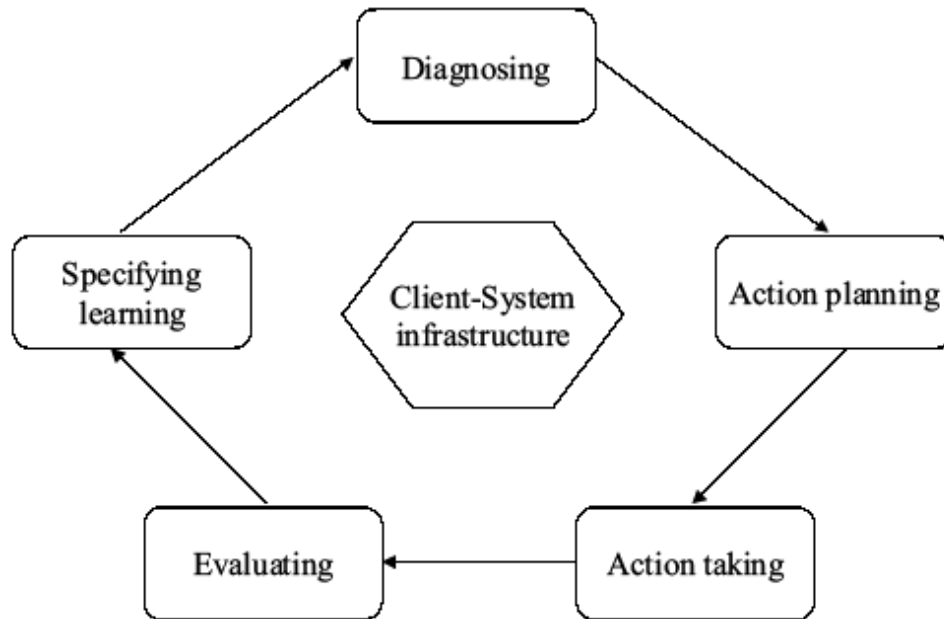
Figure 3-1. Action research process (Susman & Evered, 1978)

The five phases consist of (Lindgren et al., 2004; Susman & Evered, 1978):

1. "*Diagnosing*", identifying, or defining the problematic situation, as a shared task by the researcher and practitioner. The actors holistically interpret the phenomenon and formulate working hypothesis to be used in the sub-sequent phases of the cycle;

2. "*Action planning*", specifying possible courses of action to improve the problematic situation;

3. "*Action taking*", referring to the implementation of the course of action, causing change to occur and trying to create improvements to the situation;

4. "*Evaluating*", assessing the consequences of the actions, involving a critical analysis of the results;

5. "*Specifying learning*", identifying the findings, documenting and defining the outcomes that will add to the body of knowledge. As mentioned by several authors (Baskerville & Wood-Harper, 1996; Cunha & Figueiredo, 2002) although appearing last, this phase is a permanent activity.

Embarking in action research requires that the client setting be clearly defined (Susman & Evered, 1978). While planning the action, both the researchers and practitioners create a theoretical frame of reference that will guide the development of a system (Baskerville, 1999; Davison, Martinsons, & Ou, 2012; Lau, 1999; Shrivastava & Mitroff, 1984). The objective is to improve the problematic situation, not necessarily to solve the problem due to the possible complexity involved. Therefore, it is difficult to establish a detailed intervention plan because of the developments during the research (Davison et al., 2004). Moreover, the cycles described

above may not have a perfect sequence, as mentioned for step 5, and it is possible to have action research projects with less than five phases (Susman & Evered, 1978). An action research project may have multiple cycles in the same setting or in different settings (Braa, Monteiro, & Sahay, 2004; Chiasson et al., 2009; Holwell, 2004; Sahay, Sæbø, & Braa, 2013). They can be sequential in time, as illustrated by the two CAR cycles presented by Lindgren, Henfridsson, and Schultze (2004), or they can be simultaneous, as illustrated by the two parallel cycles described in Cunha and Figueiredo (2005). Moreover, we can identify from these examples that the cycles may proceed with or without interaction between them, and new cycles can be initiated while previous cycles are still under development.

There are other aspects that action researchers must be aware while developing their work; for example, the risk that the scientific community perceives an AR project as relevant but not rigorous, which may be due to the potential loss of impartiality by the researcher or confusing AR with consultancy (Avison et al., 2010). Moreover, the personal over involvement with the research, the need to contribute to both science and to the subject of action, and the pressures from practice that may bias the results were earlier identified in the "*Three dilemmas*" of Rapoport (1970). Finally, there is a need to ensure the quality of the data collected and the correctness of the interpretation (Dick, 1993). While recognizing that these threats may be stronger in AR than in other methods (Baskerville & Wood-Harper, 1996), we argue that AR provides guidance for theory to be interpreted and refined by others in different contexts, requiring scientific discipline in the adoption of its principles (Avison & Wood-harper, 1991; Davison et al., 2004; Susman & Evered, 1978).

According to Baskerville and Wood-Harper (1996, p. 242), "*One of the most important differences between the diagnosis stage of an action research project and the advice stage of a consulting project is the careful theoretical foundation of diagnoses*". Other authors, such as Davison et al. (2012) give guidance for the role of theory in all the five stages of CAR. There are also risks after the project initiation, requiring control procedures for authority and formalization within the project, as proposed by Avison et al. (2010). There are five main differences regarding consulting activities and action research, as presented by Baskerville (1999, p. 12):

1. "*Motivation. Action research is motivated by its scientific prospects, perhaps epitomized in scientific publications. Consulting is motivated by commercial benefits, including profits and additional stocks of proprietary knowledge about solutions to organizational problems*".

Our research was motivated by a problem that multiple organizations face, recognized by both academics and practitioners (Cunha & Figueiredo, 2005). There was a mutual interest and both goals suggested by Avison et al. (2010) in the initiation of the action research project were accomplished, namely: (1) researchers found prospects for knowledge discovery in the problem setting; and (2) practitioners found prospects for improving a problematic situation.

2. "*Commitment. Action research makes a commitment to the research community for the production of scientific knowledge, as well as to the client. In a consulting situation, the commitment is to the client alone*".

Our research is part of a doctoral work, and involves publications to be scrutinized by the scientific community, thus contributing to the body of knowledge and opening new avenues for future research. Simultaneously, we also committed to the client organizations in improving their problematic situation.

3. *"Approach. Collaboration is essential in action research because of its idiographic assumptions. Consulting typically values its "outsider's," unbiased viewpoint, providing an objective perspective on the organizational problems"*.

Collaboration occurred along our entire research. In the case of the organizations selected, the collaboration was effective to understand the complex context of IS and QMS development, at the diagnosis stage. Moreover, that collaboration was determinant for the agreement of action planning, to take the necessary actions in each organization, and for the joint evaluation of the findings in our action research cycles. The importance of collaboration between researcher and practitioners can be found in all stages of CAR presented by Lindgren et al. (2004). For example, regarding the evaluation phase of the first cycle, the authors state that "in this analysis, practitioners offered comments on and corrections to our interpretations" (Lindgren et al., 2004, p. 445).

4. *"Foundation for recommendations. In action research, this foundation is a theoretical framework. Consultants are expected to suggest solutions that, in their experience, proved successful in similar situations"*.

We started our research with a comprehensive literature review. Moreover, we performed case studies and interviews with quality auditors in early stages of our research. The experience of the researcher in the field of quality management and IS is an additional element to take into consideration to our research. There was a permanent effort to direct that experience benefits for the reflection and learning in collaboration with the practitioners, guided by a solid theoretical background.

5. *"Essence of the organizational understanding. In action research, organizational understanding is founded on practical success from iterative experimental changes in the organization. Typical consultation teams develop an understanding through their independent critical analysis of the problem situation"*.

Our research focused on experimental changes in the design and run-time phases of IS and QMS development. We based our decisions on the literature, the insights from interviews, case studies, and finally, iterative cycles of action research. The use of cycles is one of the tactics systematized by Cunha and Figueiredo (2002) to ensure rigor and validity. Additional tactics include the use of different sources of information (Lee & Hubona, 2009) and a theoretical framework that "*must be set at the beginning of the process. It is in light of this framework that new knowledge arising from the research will be identified*" (Cunha & Figueiredo, 2002, p. 23).

There are also difficulties, misunderstandings, and criticisms of action research that we must be aware of. We summarize how we addressed eight of those problems identified by DeLuca, Gallivan, and Kock (2008, pp. 50-51), namely:

1. *"(…) it is not yet recognized by some as 'mainstream' research."*

On one hand, there are researchers that discouraged new researchers from conducting action research (DeLuca et al., 2008). On the other hand, there is a strong IS community that accepts it as an important research approach. The approach is now accepted in top IS publications (Avison et al., 2001; Mathiassen, Chiasson, & Germonprez, 2012) and its selection expected to be justified by the specificities of the problem that we need to solve (Robey, 1996).

2. *"(…) it is not valid research because it is not conducted 'behind the glass'."*

We agree with DeLuca et al. (2008) that being conducted in a natural setting, with the practitioners, is in fact one of the strengths of action research to assist in the solution of complex problems. Nevertheless, we also recognize that the interpretations are influenced by the subjectivity of the researcher and of the people who are being researched (Walsham, 1995a). To minimize such risk, we followed scientific guidance to ensure the validity of the action research (Davison et al., 2004), presenting the justification for the choices that we made and the combination of multiple cycles of research, in distinct settings. Moreover, we have followed the guidance of different scholars to ensure rigor and validity in action research (Cunha & Figueiredo, 2002; Davison et al., 2004; Lindgren et al., 2004).

3. *"Lack of consistent research paradigm vocabulary"*

We follow the perspective that action research is an approach that "*can be conducted from a variety of epistemological perspectives using a variety of methods*" (DeLuca et al., 2008, p. 50). We found inspiration in publications that specifically addressed CAR (Davison et al., 2004; Lindgren et al., 2004), adopting the vocabulary that is used within our area of research.

4. *"(…) authors are criticized for failing to mention the form of AR they are using"*

Considering the purpose of researching synergies between two important organizational systems, we selected the Canonical Action Research (Susman & Evered, 1978). This is one of the most used and reported forms of action research in the IS literature (Davison et al., 2004). Moreover, we found the appropriate criteria for evaluating that form of action research (Davison et al., 2004), informing the reader about the role of the researcher in each scenario (Avison et al., 1999).

5. *"(…) often the theoretical basis is not evident"*

A theoretical basis from the IS and QMS areas is at the forefront of our research, as presented in chapter 2. We have performed a systematic literature review (Webster & Watson, 2002) and developed specific frameworks to guide our research, as present in chapter 2 and chapter 3. New theoretical development was disseminated in the scientific community, describing the rationale that we used.

6. *"they are not rigorous enough"*

We believe that the iterative nature of action research and the contributions of several scholars can provide a solid foundation for rigor (Cunha & Figueiredo, 2002; Davison et al., 2004, 2012; Klein & Myers, 1999). Action research is suggested for IS challenges that need to combine technological, managerial, and organizational issues (Myers, 1997). To address these challenges, action research can be rigorous and relevant (Avison et al., 2010; Baskerville & Wood-Harper, 1996; Cunha & Figueiredo, 2006; Davison et al., 2004; Vries, 2007).

7. *"(…) tend to amass large amounts of primarily qualitative data, multiplied for each cycle, ushering articles to unwieldy lengths"*

Action research collects different types of data that may be qualitative such as interview text, documents collected or developed in the research, diagrams, or even comments recorded by the researcher (Bryman, 1984; McLellan, MacQueen, & Neidig, 2003; Myers, 1997). This is not an exclusive problem to action research and may occur when the approach requires detailed presentations or involves multiple sources of data, for example in multiple case studies. To avoid the difficulty presented above, the writing of this thesis and the related publications considered that "*what to include should always be driven by the research question that an analysis attempts to answer*" (McLellan et al., 2003, p. 67). In this perspective, we tried to select information that was simultaneously relevant and "*a coherent and interesting story for the reader (…) rather than making the quote 'do the work'*" (Walsham, 2006, p. 327).

8. *"effective dissemination"*

The dissemination was achieved by scientific publications and by the effective use of our approach in different organizations. To write this thesis we sought inspiration in guidelines of publishing action research work, combining the researchers and practitioners criteria for perceiving the findings (Gill & Bhattacherjee, 2009), the possible structures for action research thesis (Dick, 1993), and the recommendations of concise presentation formats and graphical conceptual frameworks (DeLuca et al., 2008). Among the different possibilities to present action research studies (Mathiassen et al., 2012), we selected the structure of the article written by Lindgren et al. (2004). Their study concerns an action research project involving different CAR cycles. They followed a presentation according to the different steps of CAR (Susman & Evered, 1978), ending their paper with a detailed evaluation according to the five principles and 31 criteria proposed by Davison et al. (2004). Lindgren et al. (2004)' paper is one exceptional example "*that engaged intellectually with these key components* [of CAR]" (Davison et al., 2012, p. 765).

There are different views regarding the degree on which generalization is required (Gregor, 2006). The perception of AR as "*context-bound*" creates problems to generalization of the findings (Avison & Wood-harper, 2003), however, the action researcher should look for transferable results. For example, Eden and Huxham (1996) assert that (1) there must be implications beyond those required for action in the specific project context, allowing it to inform other contexts; (2) there is a need to produce theory that is significant to others; (3) in the case of designing tools, techniques, models, and methods, its basis must be clear and linked to theory; (4) theory emerges from action and previous knowledge; and (5) theory building is incremental in

action research, moving gradually from the particular to the universal. Several authors discuss how generalization can occur in action research. For example, CAR and its cyclic characteristics allows generalization at group level and regarding commonalities found across cycles (DeLuca & Kock, 2007; Kock et al., 1997). Walsham (1995a) presents four examples of generalization in interpretive studies that are the development of concepts, theory, drawing of specific implications, and contribution of rich insights. To justify generalization and transferability of results, Checkland and Holwell (1998) stress the importance of recoverability of the research process, allowing others develop a critical scrutiny, since, by its nature, each action research project cannot be repeated as happens in natural sciences. Lee and Baskerville (2003) argue that for a theory to be generalized to a new setting, it must pass an empirical test in that setting, as it happens in action research cycles.

We are warned by Baskerville and Wood-Harper (1996) that the main problem in AR may be in the poor understanding of the approach by those who practice it, requiring a continuous effort to improve our research. To ensure rigor and validity, there are five principles that we must consider in CAR (Davison et al., 2004, p. 69):

1. *"Principle of the Researcher–Client Agreement"*: obtain an explicit client agreement with the research approach, and understanding about what will be developed, and how it is going to be evaluated. There is a need to identify the risks of the context, because failure may be a part of an action research path of discovery (Figueiredo & Cunha, 2007);

2. *"Principle of the Cyclical Process Model"*: ensure that the project follows the steps of the method or justify any deviation. At each research cycle the results are expanded to different settings, which would lead to a generalization of the findings (Kock et al., 1997);

3. *"Principle of Theory"*: ensure there is an initial frame of reference for the action research to be executed and that a theoretical model is used to evaluate the outcomes. Davison et al. (2012) present a detailed application of this principle for each CAR phase and an illustration with two AR cycles;

4. *"Principle of Change through Action"*: ensure that the intervention aims to create change, properly documented. According to Checkland and Holwell (1998), this is a major principle in AR that requires a proper description of the area of interest, the methodology to produce change, and the framework of ideas;

5. *"Principle of Learning through Reflection"*: reflect about the results involving both the client and the researchers, producing new theory or providing valuable knowledge for future cycles. This is a permanent activity in action research (Figueiredo & Cunha, 2007; Lindgren et al., 2004).A possible way to learn about an organization is to promote change, raising new factors that was not present in a stable environment (Eden & Huxham, 1996).

The application of the CAR principles and associated criteria to ensure rigor (Davison et al., 2004) are presented in Chapter 5, for each of our three action research projects.

3.5   Data gathering techniques

Data gathering can resort to observation, documents, records, and interviews, that are one of the most important types of data to be collected (Hays, 2004). The qualitative interview can be used in distinct scientific approaches such as case studies and action research, being one of the most important data gathering tools for qualitative research (Myers & Newman, 2007). According to Polkinghorne (2005), the interview is not simply a mirror of the experiences of the participant, sometimes it is an opportunity to reflect about past events, collaboratively with the researcher engaged in the data collection (Schultze & Avital, 2011). According to DeMarrais (2004, p. 54) "*An interview is a process in which researcher and participant engage in a conversation (...)* [where] *the interviewer and participants engage in a process where both are working toward shared meanings*". The selection of the participants depends on the purpose of the research and it is more likely that the researcher adopts a "*network selection strategy*", using personal contacts to locate the potential participants for the study that fit that purpose (DeMarrais, 2004). Therefore, the experience and skills of the researcher can also contribute to improve the qualitative data gathering and analysis (Polkinghorne, 2005).

There are different formats for the qualitative interview design, starting with the less structured informal conversation, the general interview guide, and the more structured standardized open-ended interview (Turner, 2010). The first two formats are more flexible (Turner, 2010): in the informal conversation the questions appear as the interview evolves; in the general interview guide there is space for new questions to appear as the interview evolves; and the standardized open-ended interview allows the participants to express their experience and viewpoint answering identical questions. The interviews are labeled as semi-structured when there is a set of clear pre-defined questions but there is a room for improvisation because the script is not entirely closed, being the most used in IS research (Myers & Newman, 2007). A later study developed by Schultze and Avital (2011) reinforces the conclusions of Myers and Newman (2007), verifying that interviewing has tripled in six IS top journals during the period of 2004-2008.

> "[interviews involve] *engaging participants directly in a conversation with the researcher in order to generate deeply contextual, nuanced and authentic accounts of participants' outer and inner worlds, that is, their experiences and how they interpret them*" (Schultze & Avital, 2011, p. 1)

The researcher must decide if the data analysis is best supported by transcriptions or by the researchers notes that were taken during the interview of after reviewing the interviewee

statements (McLellan et al., 2003). The use of audio taped data was increasingly used by researchers after the cassette appearance in the 1960's, and can supplement or even be useful to refine the researchers notes, nevertheless they are not sufficient in an interpretive process (Fasick, 1977). While analyzing the data there is a need to interpret and reduce the data, selecting sentences, passages or stories that must be put into the context of the interview, and that can contribute to enlighten the specific purpose of the research, accordingly to the research questions (Crawford, Leybourne, & Arnott, 2000; McLellan et al., 2003). When used in an interpretive epistemology, the interview contrasts with the positivist notion that interviewees are "*truth tellers*", capable of presenting facts that are interesting for the phenomena (Schultze & Avital, 2011). The interpretive researcher takes the human interaction during the interview as natural, in an attempt to construct meaning rather than merely reporting the facts (Schultze & Avital, 2011). The advantage of the interpretive perspective is to improve the mutual understanding about the phenomena, by both the researcher and the interviewee; however, there is a risk of influencing the data collection process, requiring transparency on how the data was obtained. Moreover, there is a need to ensure confidentiality of sensitive data because it represents the perspective of the participants (Polkinghorne, 2005).

Walsham (2006) summarizes the main advantages and disadvantages of recording interviews: on one hand, audio recording allows the comparison of field notes with what was really said, for direct quotes, freeing the researcher to engage in the interview; on the other hand, it is time consuming to do transcription of the text, and it may make the interviewee less open or less truthful. Finally, audio recording does not capture the tacit and nonverbal elements of the interview that are essential for interpretation. Due to the potential disadvantages, some authors such as Puhakainen and Siponen (2010) decide to rely only on field notes. In our research we experimented with both the advantages and disadvantages presented by Walsham (2006) and, in our opinion, field notes should be the core technique to support the interpretive process. Field notes allow the recording of specific aspects about the context of the interview, including information about the interviewee that can clarify their statements. Field notes can also capture the researcher's perception about the event at the moment it is confronted with it; for example recording ideas that the interview raised (even if not relevant to the interviewee), or related thoughts inspired by the facts revealed. That said, we found benefits in supplementing that technique with audio recording using a smart pen device (Livescribe, 2013), when possible. Our experience of the benefits and pitfalls of using the smart pen is presented in the chapter 4. Nevertheless, we agree with Silverman (1998) that the open-ended interview method may have limited capacity to capture people interactions. The method can benefit from *in situ* examinations, for example trough observation and document analysis, the two other common data gathering techniques of case studies and action research.

3.6 Research design

According to Rowley (2002), the research design involves defining the components of the investigation, providing the logic that links the data and the conclusions of the study. It can be seen as an action plan with the following components: the study's questions; the study's propositions; the study's units of analysis; the logic linking the data to the propositions; the criteria for interpreting findings (Rowley, 2002).

Our research combines sequential qualitative research projects, each one with specific research objectives, yet contributing to a broader purpose of a synergistic approach for the joint development of IS and QMS. At each phase, we selected different research approaches, with several data gathering techniques. When distinct data gathering techniques were available in one project we have used them for triangulation, searching for convergent, inconsistent, and contradictory evidence (Mathison, 1988). Figure 3-2 recap the overall research strategy, which was previously presented in section 1.4, reproduced here for the convenience of the reader.
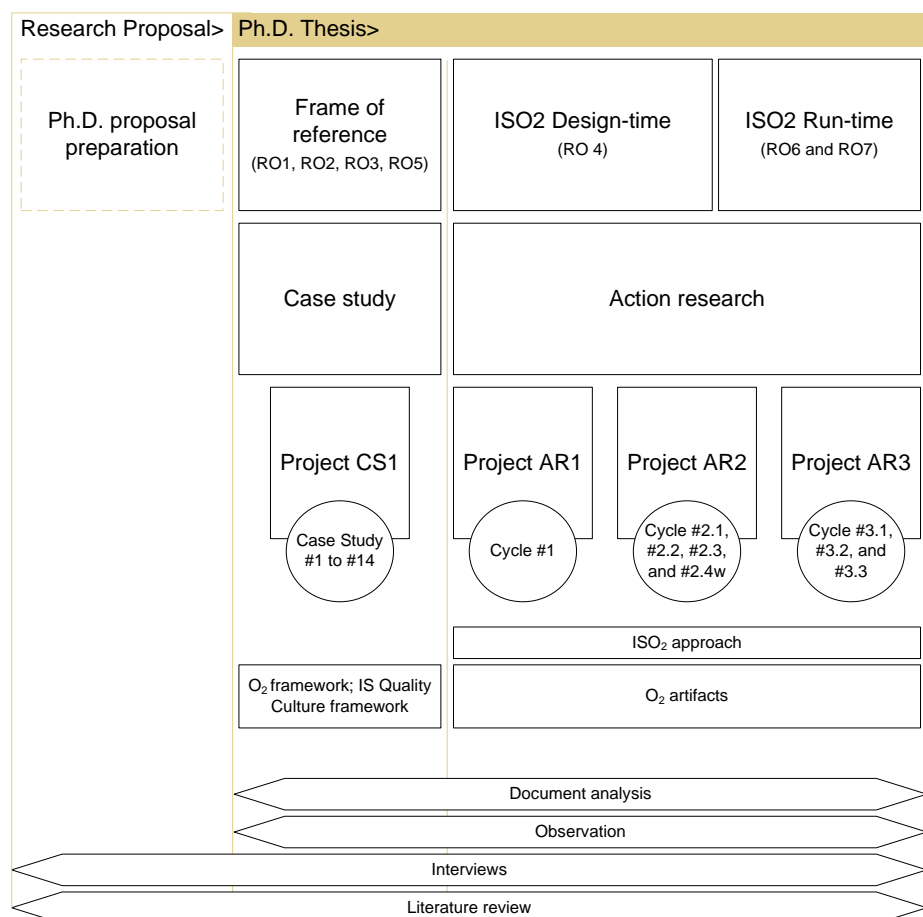
Figure 3-2. Overall research strategy

Figure 3-2 presents the distinct phases of our research program, starting at the initial insights that we collected during the research proposal, the exploratory phase that we addressed

through a literature review, and interviews. The research proposal was defended in the second year of the doctoral program. Although represented as a sequence for simplification of the figure, the outcomes of one research project were used as inputs for the next. The same interaction occurred between the AR cycles and, more often, between the cycles of each action research project.

Research consisted of three main phases, namely (1) the creation of a frame of reference for the beginning of action research, according to theory and practice (Baskerville, 1999; Davison et al., 2012; Lau, 1999; Shrivastava & Mitroff, 1984) of IS and QMS synergies, represented by the research objectives RO1, RO2, RO3, and RO5. Our first research objective was "RO1. Compile relevant literature about IS and QMS synergies by means of a systematic literature review". Case studies have provided the insights from practice that addressed "RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors", "RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations", and "RO5. Clarify the concept of quality information system in the selected organizations and propose a definition for our work". Having gathered a solid foundation about synergies, we started our action research approach with the drafting of ISO_2. Then (AR2) we focused on the construction of the IS and the QMS, how to represent them as integrated models, how people could collaborate in their design. The sequent action research project (AR3) was guided by our purpose to research the run-time phase. We developed several artifacts during our research, as a support of the ISO_2 approach.

There were two main research questions addressed with the case studies: "RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations", and "RO5. Clarify the concept of quality information system in the selected organizations and propose a definition for our work". Moreover, case studies were useful to initiate our incursion in the cultural aspects of quality and IS, namely for "RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles". Pérez-Aróstegui et al., (2014) studied complementarities between IT and quality management practices but their data comes from one participant per company, stating that "*would have preferred to have two key informants, one specializing in each of the two disciplines examined in this study, IT and QM*". Since our main purpose was to create an approach that quality and IS managers could use, we decided to focus on their level of analysis. The multiple case studies involved fourteen organizations that recently implemented ISO 9001. The selection was made from a set of organizations where we knew that their QMS development also included some type of IS development. The details of each case and the findings from these organizations are presented in Section 4.3.

After case study, we organized our work as a series of action research cycles, in diversified client settings (Susman & Evered, 1978), to refine the initial set of ideas and practices into a coherent body. Before entering the first action research cycle we created a theoretical proposal of ISO_2 composed by its main steps. Only with the first action research case we could draft ISO_2 with insights from practice, later refined in several cycles.

It is not easy to define the beginning of an action research cycle and the end of another (Braa et al., 2004). Moreover, each project can involve multiple cycles and distinct sites, for example Fuller-Rowell (2009) explores the option of multiple cycles with a similar focus, each one in a single organization, while Lindgren et al. (2004) present a CAR project with two cycles, addressing multiple organizations in each one. We identify three major projects of action research within our research program, represented in Figure 3-3.
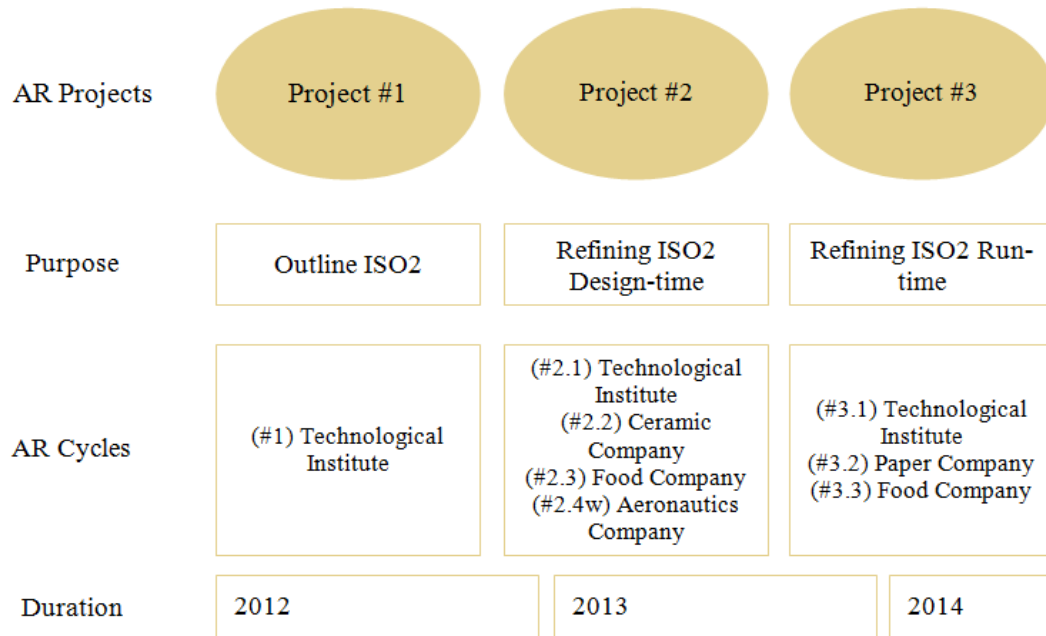
Figure 3-3. ISO$_2$ action research projects

The first action research project occurred in a technological institute, with the purpose of developing the initial version of the ISO$_2$ approach with CAR. Next, we carried out a multi-site action research project. The research was simultaneously started in the technological institute of cycle #1, in a company operating in the food industry, and in a company operating in the ceramics industry. Finally, a third project aimed at refining and extending ISO$_2$, especially focusing the run-time phase of ISO$_2$. This time we included a company from the paper industry and proceeded with the technological institute and food company of the previous project. The last project is a sequence of three independent cycles. It was initiated at the technological institute and then at a paper industry. The findings of the first cycle were used as inputs for the second. A third and final cycle included the site from the food industry.

Action research was the main approach in our program; therefore, it was our reference for "RO4. Outline the main steps of the synergistic approach for the phases of design-time and run-time in the joint development of the IS and the QMS". The action research phase was carried on with the inputs from the literature review, auditor's interviews, and the case studies. Action research also addressed "RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles" and "RO7. Contribute to the development of a business process quality culture in the selected organizations, in the context of organizational policies and ISO 9001 principles".

We used interviews in different stages of our research program. First, interviews were used to understand the auditors perspective of IS and QMS synergies. Therefore, the use of interviews addressed our exploratory "RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors". The selected auditors do not develop their activity in a single site; they audit multiple organizations, from distinct sectors of activity, sometimes providing consulting activities, but with the same ISO 9001 referential as a guide. In the case study phase, interviews were one of the data gathering techniques we used, combined with observation and document analysis (e.g., procedures, process maps, software specifications, and manuals). The interviews were also used with a different type of participants, the IS and QMS managers. Next, in the action research, interviews were important to the CAR phases of diagnosing and evaluating. We performed a second round of interviews with quality auditors during our third action research project. Our purpose at this stage was "RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles". We also used interviews in the client settings, particularly at the diagnosis phase of CAR and during project meetings.

3.7   Conclusions

In this chapter we outlined our research strategy, stating our research purpose and research objectives. Our work adopted an interpretive stand, more suited for complex problems in organizational settings. Case studies and action research are applied to address our overall purpose and related objectives, four of them that emerged during our fieldwork. Then we presented the data collection techniques that we used in different phases of this research. The systematic literature review and the findings from our case studies allowed us to create a frame of reference for action research. We also created a theoretical proposal for our synergistic approach, sequently developed and refined in our action research cycles. Rigor and validity are crucial to every research, so we presented the principles and criteria that we followed to ensure these aspects in our results. We selected canonical action research, one of the most used forms of action research that has specific principles and criteria to follow.

Following Gregor (2006)'s classification of the nature of theory in IS, we would position our contribution in the *Type V – Theory for design and action*, with a synergistic approach for the joint development of the IS and the QMS, in the context of ISO 9001. We pursue an emergent and interactive process with target organizations, well-matched to the "*designerly way of knowing*" with action research proposed by Figueiredo and Cunha (2007).

Chapter 4 presents our contributions for the development of a frame of reference (Baskerville, 1999; Davison et al., 2012; Lau, 1999; Shrivastava & Mitroff, 1984). It aims to "*explore the problem, learn about stakeholder goals, and seek to discover drivers and constraints in the problem environment*" (Briggs, Nunamaker, & Sprague, 2011, p.14), setting the foundations for a solution to evolve in the sequent action research phase.

Chapter 4

Theory building: a frame of reference for action research

4.1 Introduction

The review of the literature in Chapter 2 allowed us to understand the IS and the QMS foundations, while identifying potential synergies to explore in the design-time and run-time of their lifecycle. This chapter explores the perspective of experts, namely quality auditors (Barata, Cunha, & Costa, 2013a, 2013b) and IS/QMS managers in ISO 9001-certified organizations (Barata & Cunha, 2013a, 2014a). Based on insights from the field that complemented our literature review, we created a frame of reference for action research, constructed from both theory and practice (Lau, 1999; Shrivastava & Mitroff, 1984). The auditors and the organizational IS/QMS experts are key stakeholders of a joint development approach that we aim to propose. Auditors have expert knowledge about the standard, which allowed them to be qualified for conducting ISO 9001 audits. IS/QMS experts are potentially aware about the difficulties in the synergistic development of the systems in attendance and may provide improvement suggestions.

> *"The last research mile is where academia creates value for society (…). Begins when a research team finds real people with a real problem in a real organization. They explore the problem, learn about stakeholder goals, and seek to discover drivers and constraints in the problem environment. They propose possible solutions to stakeholders and listen carefully to their responses"* (Briggs, Nunamaker, & Sprague, 2011, p. 14)

The next section presents the viewpoints of the auditors in different stages of our research. Section 4.3 describes the perspectives of the IS and QMS managers that we elicited while conducting the case studies. At the end of the chapter, the reader should be able to:

1. Understand the point of view of the auditors regarding IS and QMS synergies, which we used to guide our research and balance our previous knowledge about the problem;

2. Comprehend the problems ensuing from the lack of integration between the IS and the QMS, that are common in organizational practice;

3. Discover the concept of quality information system according to the IS and QMS managers in the selected organizations;

4. Realize how we developed a first draft of a synergistic approach for the joint development of the IS and the QMS to use and refine with action research, in a sequent phase of our investigation.

4.2 Interviews: insights from quality auditors

This section compiles the three moments in which we interviewed quality auditors. The first one occurred in 2008, while we were preparing the research proposal. It consisted of informal interviews with five auditors. The initial round was interesting to identify research opportunities, but it required additional detail in specific questions. Later, in 2009, there was a second round of semi-structured interviews with those five auditors, developed during an internship of an IS student. Our purpose was to get deeper into the results of the initial round. Finally, a third round, in 2012, involved three additional auditors to assess their perception of IS quality culture. Round one and round two were developed before we started the case studies and much earlier than our action research phase. Round three was conducted more recently, after our second action research project, when we were refining the run-time phase of ISO_2.

The auditors' interviews were our source of data for "RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors". Initially, the aim was to write the research proposal and identify possible lines of future research. Then, our purpose was to identify potential synergies from this group that we could explore later in the case studies and action research, by increasing the auditor sample and refining our questions as needed to create a frame of reference. Regarding "RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles", the auditors' interviews provided insights to prepare action research projects. The auditors' insights provided an important guidance for the initial steps of our research. Later on, the auditors were asked to help with our efforts to understand the run-time phase of the joint development of the IS and the QMS.

4.2.1 Round 1: the first insights about synergies in IS and QMS

The first round occurred with informal interviews with five ISO 9001 qualified auditors, conducted after a meeting with the administrator of a Portuguese certification association. Based on his opinion we were able to confirm the relevance of our study to quality certification. Additionally, the association stated their interest in collaborating with us, reinforcing our idea to explore the auditors expertise. The main reasons that justified our interviews with ISO 9001 auditors were:

- Their experience and technical skills in the QMS context;

- Their global field knowledge about the ISO 9001 reality (not restricted to a company or economic sector);

- Their input on successful and challenges cases in IS or QMS;

- Their insights on auditing practices;

- Their feedback about previous studies among this group of quality experts.

The five auditors agreed that the knowledge they gathered while conducting ISO 9001 audits could assist in the discovery process of an approach to joint develop the IS and the QMS. They stated the following consensual aspects about the potential contribution that auditors could bring into our work:

- Sharing of best practices in quality audits: a unified methodology may facilitate the audit process;

- Identification of common non-conformity patterns;

- Assessment of the impact of IT in modern quality management: as presented in chapter 2, IT is one dimension of the IS that we address in our research;

- Suggestion of potential opportunities of improving the ISO standard;

- Evaluation of common problems in the practice of QMS implementation: four of the auditors are, simultaneously, quality consultants, and use distinct methodologies to implement the QMS;

- Easiness of using the new approach by organizational workers: according to the auditors, external consultant activity only represents a maximum of 20% of the time spent in developing the QMS. Most of the work is done internally by managers and process participants, on a daily basis;

- Suggestion of concrete solutions to joint develop the IS and the QMS.

Our ideas about the details of the approach were not yet firm at this stage of the research. Nevertheless, we captured interesting aspects to include in our future work during these early stage interviews. The answers of the auditor highlighted the following aspects:

- They have agreed with the importance of IT in quality management, but, above all, claimed that information management is a central aspect for QMS success. In this case, the IT usage and social aspects of IS come forward;

- They have declared the lack of coordination in the pathway of the IS and the QMS implementation. Furthermore, the creation of quality documents may represent 75% of the QMS team efforts in the project;

- They stressed the need for more coherence between the language of the IS and the language of the auditor, and that evidences should play a key role in the discourse, because, in these auditors' point of view:

  o The evidences should be attestable by the information system, which is, presently, a difficult task;

  o IS quality is not a priority for ISO 9001-certified organizations – when exists, it is assessed by comparing some software result with a manual calculation. We recorded two sentences regarding IS quality issues:

    "We [auditors in general] *intuitively believe in software outputs, assuming rigor and validity is present as a fact"*

    "We should be able to validate information and software as we validate other tools or equipments, but the documentation and even the quality of the IT itself does not allow us to prove IT usage as adequate and trustful." This observation appears to be related with software quality.

- Processes based in electronic tools are documented in separate formats such as procedures, spreadsheets, and flowchart diagrams, duplicating both the process description and the system construction. Worse, it becomes a problem to the system evolution (continuous improvement) and maintenance (increase costs).

The interviews with the auditors have provided useful insights to take in consideration: (1) the auditors' commitment to collaborate with the research and their potential contributions; (2) the need to consider social aspects, for example to promote the participation of users in the joint development; (3) the role to play in improving the audits, for example in IS quality issues. We decided to follow up with a deeper inquiry with the auditors, in order to explore additional aspects detailed in Table 4-1.

Table 4-1. The topics for follow up work with auditors

Topics	Potential interest for our research program
IS and QMS synergies	Elaboration of the thesis proposal
"Document" interpretation	Incorporation of ISO 9001 information artifacts
IS nonconformity pattern	Identification of problems and priorities to address in future case studies
IS audit procedures	Integration of audits in unified design and operation; Viability and requirements for internal auditors role in IS design process (Chou, Yen, & Chen, 1998)

Topics	Potential interest for our research program
Auditors relation with IS	Understanding the context of this group of QMS actors and possible restrictions to attend in the methodology
IS cases	Determination of key processes supported by IT, best practices, and potential applications

In summary, the results of the first round of interviews provided general clues for subsequent work; nevertheless, they were important for our research progress. They gave us a perspective from the persons that assess ISO 9001-based quality management systems, who are struggling to get proper evidences of compliance. Later, in 2009, we met these auditors again, to ask them additional questions, using semi-structured interview. Next section presents the findings.

4.2.2 Round 2: detailing the auditors perspective through semi-structured interviews

The initial interviews were informal in its nature, requiring a deeper investigation of some ideas that the auditors provided. In this sense, the auditors provided a different source of information to triangulate with the organizations point of view, the literature review, and with our interpretation of the data.

From February to June 2009, the thesis author supervised an internship in business informatics regarding the theme of "Information Systems in ISO 9001: An audit perspective". This project occurred after the Ph.D. research proposal, yet in an exploratory phase that was prior to the case studies. The first phase of the internship included a literature review of key documents regarding quality, IS, and interviews. In the field of quality management the focus was on the standards: ISO 9001 and ISO 19011 – Guidelines for auditing management systems (ISO, 2011).

We organized the study using the guidelines of Ghiglione and Matalon (1993): we prepared a set of propositions that emerged from the literature review, and the previous round of interviews, as follows:

1. The IS can contribute to quality management support;

2. The IS audit practices can be improved in the scope of ISO 9001;

3. The ISO 9001 auditors consider that they are prepared to audit any ISO 9001-certified organization, independently of the process maturity and IT adoption;

4. A new standard is desirable to complement ISO 9001 regarding the IS.

In this follow up study we enquired the same five qualified auditors that we already interviewed in the research proposal phase. We used semi-structured interviews (Myers & Newman, 2007) allowing the interviewees to answer freely, with their own vocabulary, providing

the details and comments that they prefer (Ghiglione & Matalon, 1993). In fact, although we had established ideas about what the issues to explore with the auditors, these were not so delimited that we could use just closed questions. According to Ghiglione and Matalon (1993), semi-structured interviews are appropriate to deepen a specific topic of interest or understand the evolution of a selected domain of knowledge. The open-ended questions were justified by the complexity of the topic under analysis.

There are several suggestions regarding the way question should be formulated to ensure clarity to the interviewee and unity of analysis that are compatible with the purpose of the research (Ghiglione & Matalon, 1993), namely:

- Avoiding confusion about the purpose of each question. Negative sentences, especially in interrogatives, can be a source of ambiguity, incomprehension, and mistake;

- Avoiding interpretation problems. We proposed questions with minimal interpretation regarding the QMS experts' knowledge;

- Avoiding the introduction of multiple ideas in the same question;

- Avoiding expressions that involve emotional aspects and different connotations that could bias the answer interpretation.

The decision was to prepare a set of direct questions to ensure that all the propositions were addressed in the interview, further allowing the interviewee to develop the answer freely. The questions are presented in Table 4-2.

Table 4-2. Interview questions

Propositions	Questions
1. The IS can contribute to quality management support	1. Is the IS essential for the ISO 9001 certification? 2. How can the IS support quality management? 3. Which IT solutions do you know for quality management? a. Sub-question: Which are the advantages and disadvantages?
2. The IS audit practices can be improved in the scope of ISO 9001	4. What are the most usual nonconformities that you find in a ISO 9001 audit, regarding IS issues? a. Sub-question: and the most common strong points? 5. The audit team could benefit from including an IS expert? (please explain)

Propositions	Questions
3. The ISO 9001 auditors consider that they are prepared to audit any ISO 9001-certified organization, independently of the process maturity and IT adoption	6. Which are the IS knowledge requirements of ISO 9001 auditors? a. Sub-question: Their knowledge is sufficient for auditing IS issues in the context of ISO 9001?
4. A new standard is desirable to complement ISO 9001 regarding the IS	7. Imagine the following scenario: "*To exclude IS aspects from the most relevant ISO management systems standards (e.g., ISO 9001, ISO 14001), creating a separate standard that unites all the IS requirements for ISO certifications*". Which are the advantages and disadvantages?

We used this script to guide the interviews, but we allowed additional topics to be included. These questions were first used in a pilot interview to test if the interpretation was correct; which lead to some adjustments. For example, the second question of proposition 4 was initially: "Do you think that there should be created an ISO standard only for IS issues?". However, the pilot interviewee stated that already existed that standard, misinterpreting our intention to ask about the separation of IS aspects that are now included in top level ISO standards. Another aspect that we included beforehand was a brief explanation about the differences between IT and the IS, to ensure that our questions was interpreted as desired: "Please consider IT as the technological tools such as networks, hardware, and software, similar to the documents of the QMS. Consider the IS at the same level of the quality management system. People use tools such as software and paper to develop such systems".

The answers of the interviewed auditors to the questions attached to each proposition are presented bellow. We assigned a number to each auditor: [AUD1] – [AUD5].

1. The IS can contribute to quality management support: *agreed*

All the interviewees recognize the IS as an essential pillar of quality management and certification audits. For example [AUD1] stated that "*the IS use may facilitate the records management, which are key evidences to analyze* [for quality purposes]", while [AUD2] focused the "*importance in document management, an essential requirement of quality (...) ensuring that information is accessible to everyone that requires it*". [AUD3] pointed to the importance of the processes being formalized "*in this perspective, the IS can reduce the occurrence of errors in the process, guiding the users in their activities*". More important than reducing the amount of paper used, according to [AUD4] is to "*improve information search and retrieval*". As expected, the auditors considered an IT-based QMS. When we asked about the importance of information in ISO 9001, the answer was unanimously in favor that information (evidences) is what makes quality management and audit possible. "*Sometimes organizations exaggerate with information quantity and we see that they do not do anything with it, they think that having huge amounts of spreadsheets and pdf instructions is a measure of their quality performance or the performance of*

their quality manager" [AUD5]. Taking into account information for ISO 9001, the answers did not vary when it refers to the need to find the right information for each process, for each person, in each context. One of the auditors stated that "*otherwise we* [auditors] *and the standards principles were not needed (...) the requirements must be interpreted for each case*" [AUD1]. Regarding the importance of supporting the QMS with IT solutions, the more representative answers are that "*it helps, but is not an obligation*" [AUD3].

2. The IS audit practices can be improved in the scope of ISO 9001: *agreed*

The five auditors told us that their knowledge of IS is at the "*user level*". In that perspective they recognize that audits could be improved because "*we do not know how some solutions could be better used, which additional solutions could be adopted, how to help the organization in improving the IS*" [AUD5]. However [AUD2] stated that "*but we do not need to know all the possible IT* [solutions] *available in the market, we only need to confirm if what the organization says that they use, is in fact being used*". According to the answers, their difficulties are not in the IT knowledge; the problem is to obtain guidance about what to audit that can impact process quality and IS quality.

3. The ISO 9001 auditors consider that they are prepared to audit any ISO 9001-certified organization, independently of the process maturity and IT adoption: *inconclusive*

The auditors think that having training in IT solutions and process management is important for their profession, but it is not a requirement. According to [AUD4], "*ISO 9001 can be used by all types of organization, with different structures and sizes, we must follow the standard and it will work in any case*". However, according to [AUD1] "*some organizations use their IS as a drawing of their activities, not a photo. This means that they can draw whatever they want and we are looking at fabricated evidences to influence our perception. The auditor must know how to lead the audit, not allowing the company to lead us in that process. In that perspective, I think that we could be more prepared in IS knowledge to avoid that difficulties or quality will be judge by wrong evidences*". An interesting statement was given by [AUD2], when she told us "*we audit the systems in good faith (...) it is more important for the organization that they implement their processes and IS in daily practice than for us (...) they could trick us in the audit day, but if quality is not a daily concern what they are really damaging is their investment in the QMS*". According to the interviewee perception, they do not think that their training in IS is critical for auditing, but the findings also suggest that the audit does not assess the organizational IS in depth. The standard suggests continuous improvement and decisions based on facts, but does not seem to have the tools to audit that continuous improvement in IS, nor in the quality of the information. Worse, while the audit certifies requirement *compliance*, lack of guidance is provided for *conformity* with the quality principles.

4. A new standard is desirable to complement ISO 9001 regarding the IS: *disagreed*

Although two of the auditors agree that it could be possible (although not convinced about the benefit), the others disagree. In favor we could found [AUD1] stating that "*the IS is transversal to the different standards so we could compile all the IS requirements in one*

independent standard. Another option would be to include a specific section in all the standards”. Contrarily, [AUD5] stated that “*each standard addresses a viewpoint of the organization, if we follow that idea we would create standards for everything*”, [AUD2] mentioned “*more costs for the organizations with more standards and auditors*”, and [AUD3] focusing on the IT aspects “*many organizations only use paper, a standards would be excessive for small organizations that ISO 9001 needs to attend to*”. However, four out of the five auditors agreed that a guide for auditing would be necessary to improve the assessment of IS aspects in ISO 9001 audits.

The interviews allowed us to gather additional evidences to guide our research, but we also confirmed that our work was only at the beginning. For example, additional questions emerged after we analyzed the data (e.g., how to audit the IS in practical terms – what is asked, how they select the questions?). In some cases we found that the auditors were more open to changes and improvements, for example recognizing limitations in the standard regarding IS issues or when recognizing limited knowledge about IS issues. In other cases they were more formal and supportive about the actual standards configuration (e.g., another standard would require specific IS auditors and more costs to the organizations). Nevertheless, the perspective of the auditors provided a valuable guide and an opinion to consider in sequent phases of our research. The next section presents the results of a final round of interviews with auditors. Round three occurred a few years after the interviews we present in this section. We decided to present it as a sequence because their purpose was in the creation of our frame of reference for action research and addressed the same professional group in which we are concentrating our attention.

4.2.3 Round 3: understanding the IS quality culture

This time we have conducted semi structured interviews (Myers & Newman, 2007) with eight ISO 9001 auditors. We aimed at understanding which IS quality aspects (Stylianou & Kumar, 2000) were covered in ISO 9001 audits. The interviews were interpreted (Walsham, 2006) in the light of the literature to identify gaps in audit practice and propose improvements. The first five are lead auditors with expertise in coordinating ISO 9001 audit teams, while the remaining are technical auditors. All of them have over eight years of experience, with [AUD1, AUD2, and AUD4] holding 14 years of auditing experience. The fields of expertise include mechanical engineering [AUD1], chemical engineering [AUD2 and AUD3], materials [AUD4], environmental engineering [AUD5], industrial management [AUD6], food safety [AUD7], and occupational health and safety [AUD8]. The interviews were personal, in two rounds, averaging 30 minutes per auditor. Five of the auditors are the same that we already interviewed, as presented in the previous section, but we addressed them with different questions.

First, we wanted to know what happens in the practice of auditing IS quality, in the scope of ISO 9001: as it is. Second, we wanted the auditors’ opinion about which additional aspects to consider: as it should be. We prepared two questions beforehand, namely: (1) “How do you audit IS quality in ISO 9001 audits?” and (2) “Which additional aspects of IS quality do you consider that should be audited?”. This time we used a smart pen to tape the answers, ensuring the capture

of complete and accurate information. Simultaneously, we took notes to facilitate the transcription and the comparison of results (McLellan et al., 2003). These interviews aimed to clarify aspects of IS quality that could be included in our research, not to define each organizational setting individually.

1. Auditing IS quality with ISO 9001: as it is

Mostly data and administrative dimensions of IS quality (Stylianou & Kumar, 2000) were mentioned by the eight auditors. The words that came up more often were "backup" and "access". For instance, "*we ask for backups, backup routines, data access protection*" [AUD1]; and "*document control and file access protection in specific spreadsheets for critical calculation*" [AUD5]. It was also noticeable that auditors aim at the effectiveness of the IS, "*documentation must suit organization needs and be available to everyone that needs it*" [AUD3].

We found some inconsistencies between the ISO 9001 and the insights from the interviews. On the one hand, the auditors stress the *effectiveness* of the IS and the contextual notion of IS quality, similarly to the "*fitness for use*" (Juran, 1974). On the other hand, the audit seems to ask for specific technical issues (*efficiency*) such as backups, file protections, document management, and distribution. Curiously, the need to continuously improve the different dimensions of IS quality (Stylianou & Kumar, 2000) was not mentioned. Although the eight auditors acknowledged IS quality relevance, the practice does not confirm it as a priority of ISO 9001 audits. According to the auditors that we interviewed, the audit does not address the organizational "*ways of working*" (Schein, 1990) to ensure and improve IS quality, which is crucial for a cultural approach.

2. Auditing IS quality with ISO 9001: as it should be

The auditors do not consider one needs to be an IS expert to audit an ISO 9001-based QMS. According to [AUD3] "*I audit the systems in good faith, auditors are not IS experts, we do not know all the possible technologies and technical details*". However, seven of the eight auditors answered that the existing guidelines need improvement. One of the reported difficulties is the unfamiliarity of the auditors with the IS problems and opportunities, which makes it difficult to formulate questions. According to [AUD2], "*auditors have different backgrounds and some of them try to escape from IS issues. The majority only scratch the surface of information quality indirectly, checking contradictions in data and procedures: a checklist made by experts could help*". We knew that something should be done to improve the auditors' work. The auditors do not feel that they need to be IS experts, but they feel they would benefit from a guide. Additionally, there is a discrepancy between the IS quality audit and the "*fitness of use*". For instance, we did not find auditing practices of information quality for business processes, which one of the dimensions of IS quality identified by Stylianou and Kumar (2000), in a comprehensive enterprise quality. Furthermore, there is a lack of practices to identify user satisfaction concerning information quality and software quality. To clarify this problem, we present the excerpt of an interview transcript, concerning clause 7.6, control of monitoring and measuring equipment (ISO, 2008b).

[AUD7] *"Quality requires rigor in measured data; if an equipment does not provide correct values, we can't have quality. Therefore, the equipment calibration is a major concern"*

[Question] *"Is it a critical requirement in ISO 9001 audits?"*

[AUD7] *"Yes, the organization can't use equipments that are not suitable to the process. It is a common cause of nonconformity, if the equipments are not properly identified, the calibration plan is not complete, and the data is not evaluated to ensure that the acceptance criteria are met for that process"*

[Question] *"Can we compare the impact on quality of software and measurement equipment, in the scope of ISO 9001?"*

[AUD7] *"Yes, they are similar tools to provide trust to quality"*

[Questions] *"And have they received similar attention in ISO 9001 audit? For example, do you need to track software changes as you do with measuring equipment? Do you need to ensure that people have proper training in using software? Is it relevant to identify which software is used in which process?"*

[AUD7] *"Care has to be taken to ensure validity of the* [formulas] *results if the software is used for monitoring and measuring. However, it is possible that the importance that clause 7.6 gives to measurement equipments is not so developed for software (...) it is easier to audit 7.6 for equipments. We have laboratorial reports and training in metrological calculations. To audit software we mainly have the organization -limited- records and our experience as software users. For instance, equipment manufacturers provide declarations of equipment conformity, while the software providers do not"*

[Question] *"And what about information quality? For instance, how do you audit to ensure that the information provided the organization product is correct and reliable?"*

[AUD7] *"We need to cross information sources to find discrepancies. Although it is not easy to audit information quality, or other aspects besides calculations, backups, and access permissions. The depth of the audit depends on the background and experience of the auditor"*

The interviews with the auditors have highlighted the contextual dimension of IS quality (Nelson et al., 2005), similar with the "*fitness for use*" (Juran, 1974), and the organizational perspective of IS quality (von Hellens, 1997). Sample statements about the concept of IS quality are:

> *"aims to reduce the duration of the daily tasks; ensure information accessibility to the entire organization, with proper permissions, intuitively, and answering all the organization needs, without data duplication"* [AUD6]

> *"the IS ability of being useful, reliable and timely updated, for the desired purpose"* [AUD5]

When compared with the contextual dimension, the auditors paid less attention to the intrinsic view of IS quality, such as the information quality attributes, and software quality (except for clause 7.6 of ISO 9001, about the control of monitoring and measuring equipment). The interviewees also did not emphasize the managerial perspective of IS quality, for example: the measurement of IS service performance; how infrastructure is managed to ensure that a proper support to each process exists; and how information quality is monitored and improved in daily practice.

> *"without IS quality, the ISO 9001 certification fails, because quality must be based in facts (...) we must ensure: reliability, that data must reflect reality, without errors or omissions; protection against intrusions, manipulation or failures; and availability, ensuring that data can be recovered in case of problems"* [AUD1]

A similar perception was mentioned by [AUD2] [AUD3], [AUD4], and [AUD7]. IS quality has impact in the process approach of ISO 9001, because it:

> *"allows the process documentation, accurate standardization, and consequent predictability"* [AUD2]

> *"because quality fails if it is not seen systemically and it does not involve other entities such as the suppliers. For instance, we need proper documentation of our safety equipment and dangerous chemicals, or we can have accidents for that reason"* [AUD8]

The eight auditors view the IS quality importance at a level that is not exclusively technological. However, their definitions point to the purpose and relevance of IS quality, lacking a multidimensional perspective (Stylianou & Kumar, 2000). Curiously, the need to continuously improve the IS quality was not mentioned. We also could not find other principles reflected in the auditors comments, such as the customer focus (IS users), involvement of people (e.g., IS quality surveys), leadership (e.g., procedures or practices directly aiming IS quality), and a process approach to IS quality (e.g., actions to improve the quality of process indicators). Not surprisingly, the auditors reinforced the idea of the IS as a support of ISO 9001. The interviewed

ISO 9001 auditors do not show awareness of the potential benefits in using quality principles to improve IS quality, but we suggest that they could be key players for the organizational IS quality culture. The next section discuss potential limitations of the auditors interviews.

4.2.4 Potential limitations of the auditors interviews

We considered carefully the potential limitations of our study. First, the auditors already knew the researcher, his professional activities, and research interests. Therefore, the auditors could feel tempted to see potential opportunities for synergies between the IS and the QMS, rather than evaluating what happens in the present. Second, because interviews involves both researcher and interviewees working into a shared meaning, both the researcher and the interviewees past experience have an influence on the interpretations made (DeMarrais, 2004). Third, we only interviewed auditors and there are other professional groups that could provide additional information, for example the members of ISO technical committees or the members of certification organizations. Forth, the Hawthorne effects that may occur because the qualitative interview is intrusive and can potentially change the situation under study (Myers & Newman, 2007). Fifth, the ambiguity of the language and time pressures to provide the answers can also influence the interview results.

Regarding the limitation of previously knowing the auditors, we have followed the suggestions presented by DeMarrais (2004) and Turner (2010), selecting participants with the knowledge, credibility, and willingness to talk openly about the selected topics. ISO 9001 auditors have distinct expertise, background, and experience. Therefore, when interviewing the auditors we must be aware of their auditing experience, consulting activity, and others. Moreover, not being complete strangers, we reduced the potential lack of trust (Myers & Newman, 2007). Second, we allowed the reader to follow our conclusions made according to the findings, grounded in a comprehensive literature review that we performed earlier. We have interviewed persons with experience in auditing and developing ISO 9001-based quality management systems. Finally, regarding the potential Hawthorne effects, language interpretation problems, and time pressure, we have adopted the guidance of the literature in performing qualitative interviews (DeMarrais, 2004; McLellan et al., 2003; Myers & Newman, 2007; Walsham, 2006), providing transparency of the auditors' answers, how we created our interview guide, and supporting the findings in the comparison of the answers we found. The literature review was key in our interpretation and continuous confrontation between our own experience and the feedback from the interviewees. Next, we present the framework for developing and auditing IS quality culture.

4.2.5 Discussion of the results: a framework for IS quality culture

The interviews have strengthened our idea that cultural aspects of IS quality could be improved in the scope of ISO 9001 audits. We also saw in our literature review that an holistic IS quality includes several dimensions besides data quality (Nelson, 1996; Nelson et al., 2005; Wang, 1998), for example service quality and administrative quality (Stylianou & Kumar, 2000). Additionally, there is a need to include technical, managerial, and organizational viewpoints in its

development (von Hellens, 1997). Therefore, the creation of a holistic IS quality culture requires one to learn, adopt, and develop quality principles in daily practice (Fok et al., 2001; Hartman et al., 2002; Hildebrandt et al., 1991; Irani et al., 2004; Kanji & Yui, 1997). However, a definition for IS quality culture was not provided by the auditors and cannot be found in the literature. For example, according to Caballero et al. (2004), the IS quality culture exists when all organizational processes take into account data quality issues in order to improve it. To propose an IS quality culture definition, in the context of ISO 9001, we must take in consideration the distinct IS quality dimensions (Stylianou & Kumar, 2000), and the ISO 9001 principles for a quality culture (ISO, 2008b), as illustrated in Figure 4-1.
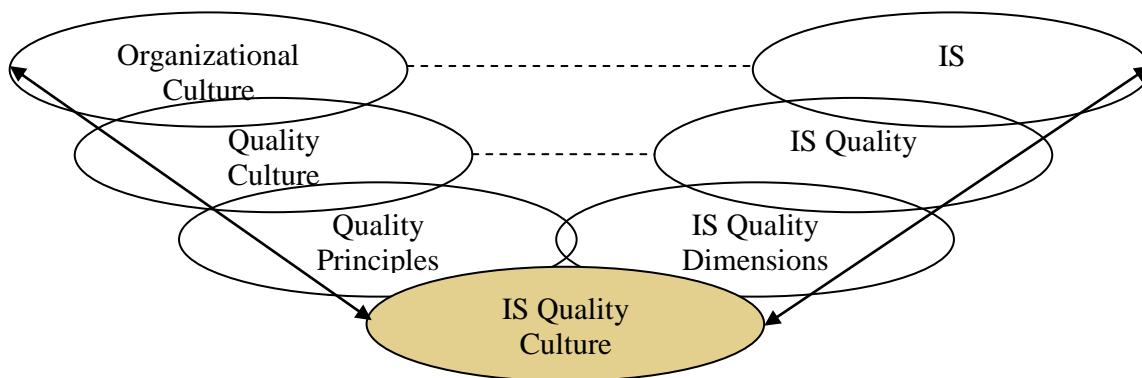
Figure 4-1. IS quality culture (Barata et al., 2013b)

The development and auditing of an IS quality culture must have an holistic perspective, combining social, technical, and organizational dimensions (Nelson, 1996). There are distinct dimensions to consider: administrative, information/data, software, service, and infrastructure (Stylianou & Kumar, 2000). The development and audit of the distinct IS quality dimensions can be done by each quality principle: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships (ISO, 2005b). For our study, we propose an integrated definition of IS quality culture:

> *"Set of values, beliefs, assumptions, and symbols that an organization develops in order to improve the distinct IS quality dimensions and quality principles"* (Barata et al., 2013b)

An IS quality culture is not a set of rules to ensure the quality of the IS; it must be learned and developed by the organizational users (Schein, 1990). The benefits of IS quality must be understood by the entire organization, and then be used to aid in creating the most suitable practices. Each element of the organization must be aware that IS quality is critical for the decisions made, for the image that a customer has of the organization, and for a truthful measurement of process results. IS quality affects the individual work, the organization, and the

outside environment, and thus cannot be the single responsibility of the IS department. A framework for IS quality culture is represented in Figure 4-2.
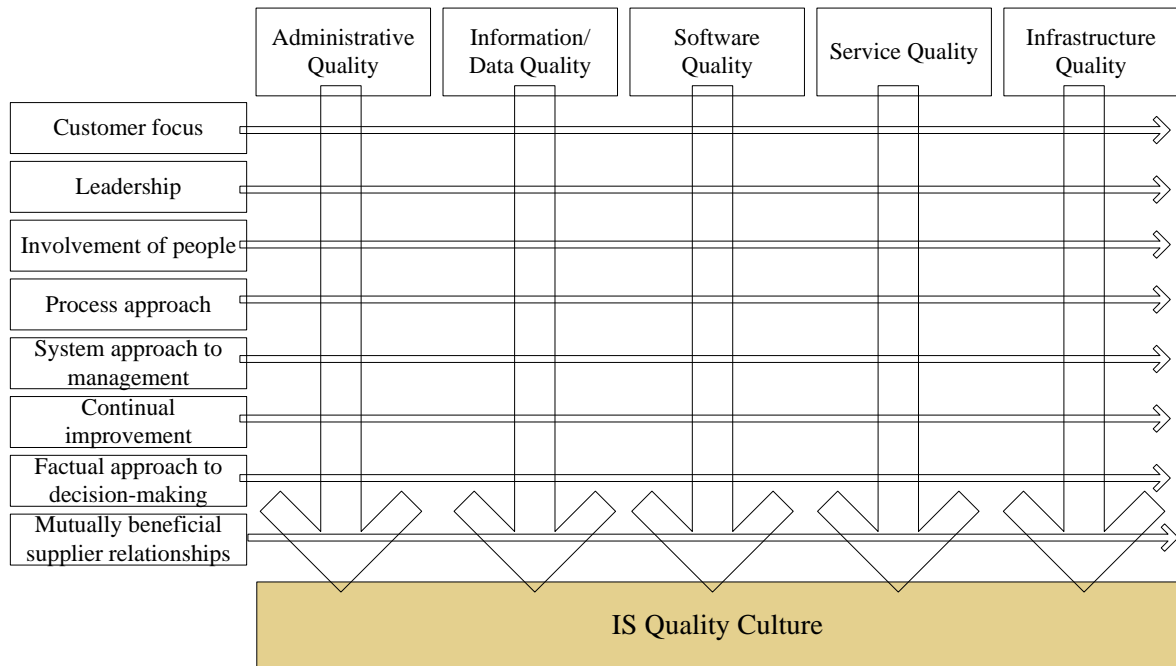
Figure 4-2. Framework for IS quality culture in the context of ISO 9001 (Barata et al., 2013b)

The framework suggests a synergistic interrelation among IS quality dimensions (represented on the top of Figure 4-2) and the eight quality principles of ISO 9001 (on the left of Figure 4-2). The IS quality culture is a dynamic concept of improvement; therefore it must be developed and adopted in daily practice. In our research we will use the framework to create a guide for developing and auditing the IS quality culture in ISO 9001 contexts. Moreover, we will propose a set of items to include in a comprehensive audit checklist able to address all the quality principles, for each IS quality dimension. One of the main challenges is to keep the audit checklist simple enough to be used by ISO 9001 auditors and organizational users.

There is an opportunity to achieve more than the sum of the parts. On the one hand, ISO 9001 suggest principles that organizations must internalize in their practices (Briscoe et al., 2005; Lascelles & Dale, 1990). On the other hand, IS quality is a multidimensional concept (Stylianou & Kumar, 2000). According to the auditors' interviews, quality principles require additional efforts to be internalized in IS quality. In turn, ISO 9001 could benefit from a multidimensional perspective of IS quality (Stylianou & Kumar, 2000), not limited to specific aspects that we found in the interviews, for example data availability (e.g., backups).The next section presents the results from our case studies in organizations.

4.3 Case studies

At this phase of the research we were seeking potential synergies for the joint development of the IS and the QMS, from the perspective of the systems' designers. Retrospective case studies

allow us to identify patterns that are indicative of dynamic processes characteristics (Leonard-Barton, 1990; Miller et al., 1997). The data gathering techniques were document collection and 28 semi structured interviews (Myers & Newman, 2007), carried out with the IS and the QMS managers of each company. The IS and the QMS managers were selected to represent a tactical level of organizational position (Tarafdar & Qrunfleh, 2009), representing key specialized informants for both systems in our study (Pérez-Aróstegui et al., 2015). The document analyses have focused on the support for ISO 9001 certification, for example quality procedures, electronic document management systems, process models, process indicators (e.g., complaints provided by a CRM or quality costs from an ERP system), and IT solutions. Two distinct teams have developed the QMS and the IS in the selected organizations.

The cases were selected from ISO 9001-certified organizations where we had contacts or where we had previously done contract work. The details are presented in Table 4-3.

Table 4-3. Research cases

Sector	Acronym	Company size (#employees)	IT support for the QMS
Ceramics [#1]	CER1	Large (>250)	Development of QMS software[a]; CRM acquisition[b]
Ceramics [#2]	CER2	Large (>250)	Development of QMS software
Ceramics [#3]	CER3	Medium (50-250)	Development of QMS software
Batteries [#4]	BAT	Large (>250)	Development of QMS software; acquisition of a process modeling software and statistical software
Agro food [#5]	AGR	Medium (50-250)	Development of QMS, production control software and a CMMS
Metal [#6]	MET1	Large (50-250)	Development of QMS software; CRM acquisition
Metal [#7]	MET2	Small (<50)	Development of QMS software
Paper [#8]	PAP	Medium (50-250)	Development of QMS software; development of B2B platform
Institute [#9]	INS1	Medium (50-250)	Development of QMS software
Institute [#10]	INS2	Large (>250)	Development of QMS software; development of B2B platform
Environment [#11]	ENV	Large (>250)	Development of QMS software; CMMS acquisition
Printer [#12]	PRI	Large (>250)	Development of QMS software; CMMS acquisition
Automotive [#13]	AUT	Large (>250)	Development of QMS software; development of CMMS
Plastics [#14]	PLA	Large (>250)	Development of QMS and production software; ERP acquisition

(a) IT applications that provide support for ISO9001 requirements, such as document management systems, training management, complaints and non-conformity, and action plans. The cases 1 to 4, 9, and 10 to 12 have also included the acquisition of at least one module of a QMS software package.

(b) The acquisition only reports to the part of implementing an IT solution already on the market.

We have created a case study protocol to describe the procedures to conduct each case, the research instruments (e.g., interview topics), and the guidelines for data collection and analysis (Benbasat et al., 1987; Dubé & Paré, 2003; Runeson & Höst, 2008; Walsham, 1995a, 2006). It was followed by an iterative process of case evaluation and comparison (Eisenhardt, 1989; Klein & Myers, 1999). An initial meeting with the IS and quality managers was conducted to present the research objectives. This introductory step helped us understand the existing QIS, collect documents, evaluate IT support, and prepare the interviews. These were carried out in a second phase, where we approached each manager separately. The interview sessions took approximately 45 minutes (a minimum of 19 minutes and a maximum of 1h09 minutes). We have used a smart pen (Livescribe, 2013) to record the onsite interviews, and specifically asked previous authorization to record sound. We ensured confidentiality and the strict use of their opinions to our research. Figure 4-3 presents the interface of Livescribe software, presenting an annotations page.
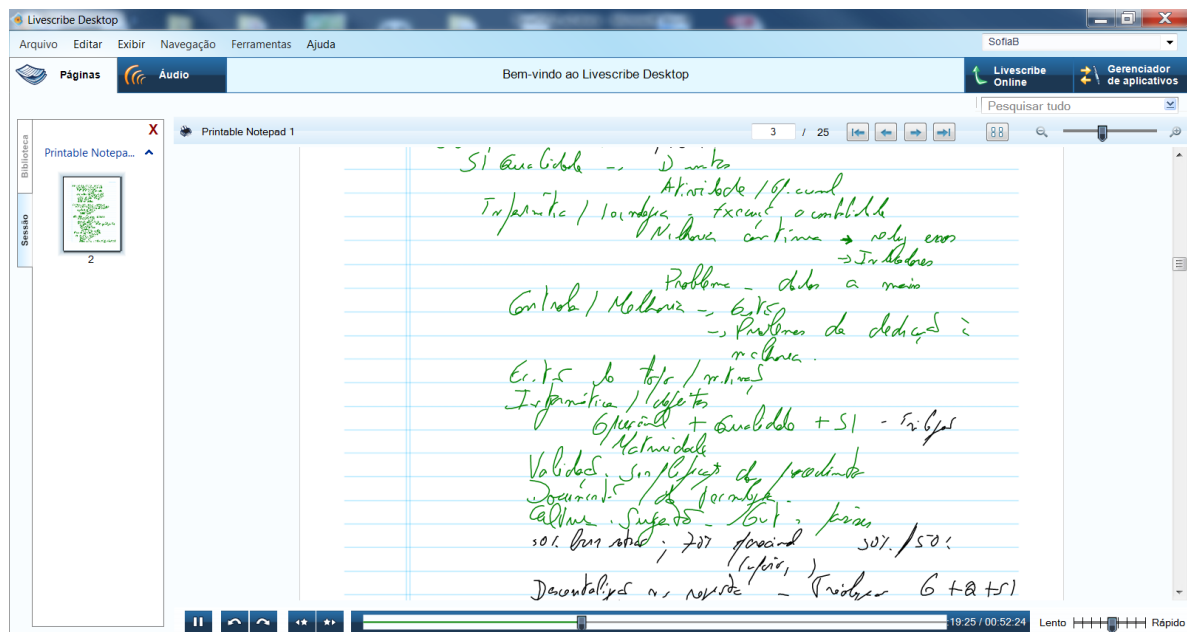
Figure 4-3. Livescribe software interface (Livescribe, 2013)

The smart pen allows to record sound while taking notes regarding the interview. It is possible to ear specific parts of the interview that occurred at the moment that notes were taken (controls at the bottom of the window). This type of functionality was helpful in the cross case comparison phase, allowing to ear different answers for the same question that we coded in the hand notes. Another advantage is to focus in the conversation because we only need to write simple key topics that allow us to return to that part of the conversation while evaluating results. The device that we used to record sound and write notes in the Livescribe templates is similar to a pen, for that reason the interviewed easily forget that sound is being recorded. This is an

advantage to facilitate a more informal environment, but care has to be taken to warn about sound recording when someone enters the room or for pausing recording, for example, during parallel conversations that may occur in organizational setting.

In all the cases there are IT applications to directly support the QMS, such as document management and complaints management. Some of these have been developed in-house, while others have been acquired in the software market. We also asked about other IT solutions that provided support to quality, even if they were not directly associated with specific quality requirements, for example in the case of enterprise systems. The CRM and the CMMS, were the most cited, perhaps due to the focus of ISO 9001 in the areas of customer and asset management. Although IT is only one of the IS dimensions, we wanted to ensure that all the organizations could express their perspective in each of the five dimensions of an IS that we identified in chapter two: context, people, process, information/data, and IT. Contrarily to the auditors interview, this time we had the opportunity to observe the IS and the QMS integration (or lack of) directly in the organizational setting. We found additional elements for our research and had the opportunity to assess daily problems that even the auditors that we previously interviewed could miss in their work, since they usually spend only one or two days in their client organization.

4.3.1 Development of the IS and QMS: insights from the cases

Table 4-4 provides an overview of the findings, (I) before, (II) during and (III) after the IS and the QMS development in our case studies.

Table 4-4. Findings from the retrospective case studies (Barata & Cunha, 2014a)

(I) Before	The ISO 9001 certification was a top management decision, motivated by a combination of factors such as internal improvement or the external company image. However, the development or acquisition of IT was in the majority of the cases (11), a quality manager's decision. In 12 of the cases, the development of the IS was planned after the QMS project started, therefore, only at this stage the IS team was involved.

(II) During

In the prevalent scenario, the IS team supports the quality requirements by developing or buying software – a *supplier role*. The IS team defines the technologies and the preferred ISD approach. Curiously, when asked about the selected ISD method, 9 of the teams could not identify a specific one. The QMS team establishes priorities, IS requirements and workflows. The QMS team has adopted a *customer role*. Independently, the QMS team creates procedures and the IS team creates IT solutions, for the same processes and users. Top management involvement is not significant in this stage. In most cases, it is merely needed to approve the investments. We found that the IS team was not completely aware of ISO 9001 (13 cases) and the standard was not used as an input for the ISD requirements. In the same cases, the IS team reported not being well informed about the development of QMS processes or documents. They also pointed out the lack of communication as a cause for delays in the IS implementation, late changes, and misfit between quality procedures and the developed IS. The process model of the QMS was mostly reported (12 cases) as useless by the IS team.

(III) After

In 4 of the cases, the IS manager also participated in the quality improvement teams. These cases present a closer relation between IS departments and top managers. In the 10 remaining, the QMS managers monitor the information effectiveness, user satisfaction, and improvement suggestions. The IS seems to have a more reactive role. Even after 3 years of certification (4 of the cases), the IS interest in ISO 9001 seems to be on the part that directly concerns with IT (for the ISO 9001-based QMS audit). Ten of the IS development cases were still ongoing by the time of the final audit. Due to this delay, some users have started to develop their own tools. In 13 cases, surprisingly, the persons responsible for managing software verification (mostly the calculations) are the QMS managers. Both the IS and the QMS managers have complaints. The most common from the latter is that the IS does not correspond to their information needs (9). The majority (7) said that they prefer to build their own tools (e.g., spreadsheets, unofficial databases that run parallel or complement the official systems) than waiting for IS changes. The IS managers complain that the QMS is a bureaucratic system (14) that does not correspond to practice (8). Additionally, part of the problem was precisely the parallel tools that the QMS team develops (3).

The lack of systems' integration in these cases occurs from the beginning, continues during the development, and propagates the problems afterwards. This disconnected approach does not explore potential synergies between the IS and the QMS, possibly compromising the full benefits in adopting ISO 9001. Even worse, when the integration fails, each system may become a burden to the other. On the one hand, the IS team may see limited use in QMS procedures because they do not adhere to practice (gap between what is written down and what is really performed in the organization) so the IS requirements are not precise; on the other hand, the QMS team may see

limited use of IT due to the inflexibility to change and lack of effective support to quality requirements.

All the interviewees agreed that a joint development approach could bring significant advantages. Regarding the benefits of that approach, we highlight four statements that support that view (1) "*improving the communication process* [tactical level by the QMS and IS]", (2) "*encouraging the involvement of the top managers*", (3) "*accomplishment of the project calendar*", and (4) "*avoiding duplicated tasks that damage our* [IS] *internal image, creates systems that are more permissive to errors and harder to manage*". There is an opportunity to change the *customer – supplier* relation existing between QMS and IS teams, respectively, turning it into a partnership of equals in organizational practice, respecting their differences. The first two sentences above (1) and (2) address people involvement in the development of both systems, that requires improving the collaboration between managerial functions. The lack of visibility of the IS and the QMS, usually seen as "support systems" in these organizations, could equally benefit from a common approach. However, we also found that the QMS managers acknowledge that their system was closer to top management when compared to the IS. They transmitted us the idea that top management needs to participate in the QMS (by requirement of ISO 9001), approve documents, and design business processes. They also underlined top management's interest in quality indicators and action plans. This daily interest in quality issues is a possible explanation for the better "visibility" of the QMS to top managers when compared to the IS. Our results suggest that a synergistic approach to the development could have added benefits to the IS, improving its visibility to top management, and added benefits to the QMS, regarding a better support of the IS that they consider ineffective. Sentences (3) and (4) are concerned with the process of systems design, regarding a mutual benefit and coordination in the tasks. There is a potential to develop a set of steps that both teams can follow in their joint efforts, and a set of tools that can support those steps "*avoiding duplicated tasks*", in a synchronized way, and improving both systems "*fitness for use*" (Juran, 1974).

4.3.2 Quality information system in the scope of ISO 9001

We already knew that the synergistic development of the IS and the QMS was not simply to create IT solutions for quality purposes. But what is the perspective of the IS and QMS managers? If we name that joint outcome as a quality information system, what is in reality that QIS? We propose an a priori conceptualization for QIS guided by the literature review:

> "*A system that intertwines **people** and **IT**, in a **context** that is influenced by quality policies, procedures, standards, the organizational infrastructure, and its external environment, processing **information** in cycles of planning, execution, monitoring, measurement, and improvement of the organizational **processes**"* (Barata & Cunha, 2013, p. 8)

The five main interrelated dimensions of the QIS are People: (e.g., system participants and beneficiaries of the system), IT (e.g., hardware, software), Context (e.g., infrastructure, environment, and regulations), Information/Data (required, processed, and delivered by the QIS), and Processes (e.g., procedures and workflows). We started to identify the interviewees' perception of the QIS, by questioning: "What is the definition of quality information system?". Then we asked about the characteristics of its different dimensions. The answers are presented in the next section, followed by the cross-case perspective of the IS and the QMS managers for each of the five interrelated QIS dimensions. During our work in organizations we could observe how their processes were executed and the documentation support. The acronym of the case study and the manager's area (IS or QMS) identify the interview statement, for example, CER1 IS, concerns the IS manager of company CER1.

4.3.2.1 QIS definition: an experts' perspective

Organizations with a more recently implemented QMS, with ongoing IT projects, or with a single (or few) products, tend to emphasize technology.

> *"[QIS] is a system that provides the quality documents, and allows establishing and monitoring the improvement actions. It is an essential way of diffusing quality information"* [CER2 QMS]

> *"Reliable data to be analyzed. We spend too much time trying to find errors and achieving the right information"* [PRI QMS]

> *"The quality documents and the quality set of software tools that are required to process information for the certification requirements"* [PAP IS]

> *"[QIS] is an effort to reduce paper by electronic means, reducing quality bureaucracy (...) improves quality by reducing information errors, creating alerts and providing indicators"* [BAT IS]

Organizations with more mature QMSs, more IT solutions and integration needs, and multiple products or build-to-order production, tend to focus on the social aspects.

> *"A QIS is many different things (...) It covers concepts that we want to pass to people, as well as their feedback. It is a major responsibility of the QMS manager. The IT and train that helps people manage information. It is a systematization of quality in daily practices. It is also a control system, however, is mainly an improvement system"* [ALI QMS]

> *"It is a quality literacy tool. This is why it is essential for auditors to understand if quality is a reality or only something to achieve a few days before the audit. It*

includes several media such as paper and software, but what I am most concerned with is the use of those media. Quality is not a state, is a daily effort" [CER1 IS]

"All the organizational information and tools to make it flow. I am the main responsible for it, but my main concern is to share that responsibility with others (…). Machines are working most of the time, people are different, and we can't force them for quality. We must help them to contribute to quality" [MET2 QMS]

"A QIS is a perspective of our organizational IS, involving quality issues. It is a part of our IS, which includes what we could name quality data. However, in our case this does not happen. We have data and then there are perspectives and viewpoints concerning that data. The same data can be used for quality or any other purpose. My QMS colleague is one of my most demanding customers (…) in fact, I do not think that any other department has the same influence on the IS. I need to work constantly aligned with quality, this is a partnership" [PLA IS]

We can also distinguish two perspectives when comparing the QIS with the organizational IS:

1. The QIS as a separate IS, "owned by quality" and described as a set of tools to satisfy QMS requirements of the quality department (e.g., CER2). This concept was more common in centralized QMSs, where quality managers have a higher responsibility in gathering, treating, and diffusing information. The QMS managers did not report the situation as beneficial; on the contrary, in their opinion it requires a higher percentage of work for information issues, and less time for process improvement.

2. Four organizations [INS1, INS2, AUT, and PLA] evidenced the QIS as inherent and inseparable from the organizational IS. In those cases, the IS manager seemed more involved with quality initiatives and aware of the quality benefits. Both the IS and the QMS managers in these cases acknowledge that the main users of the QIS are not themselves (as a mere tool to support their departments' needs), the QIS use is extended to the entire organization and external entities.

"We won't have success in including all the workers as QIS users if we don't make the QIS something useful for their daily work. If the user does not need it, they will not use it properly, information will be incomplete and scarce, leading to errors and more processing after [for us]. We must create a situation in which both quality and the IS are daily practice, not an additional system to deal with" [PLA QMS]

4.3.2.2   QIS: Context

In the documents collected in our cases we observed that quality information emerges from different sources such as product quality, departments' objectives, process monitoring, and financial information. Moreover, the QIS context is internal and external to the organization and involves different stakeholders. A statement from INS2 QMS manager illustrates this broad perspective of the QIS context:

> *"The QIS allows two main goals: (1), to understand if we actually can achieve organizational improvement, and (2) to be a communication tool with all the organization stakeholders. With our workers, because quality requires constant meetings and we can use those meetings to communicate about the organizational context* [e.g., information about competitors, to know best practices, improvement suggestions]. *Other stakeholders are also addressed, for instance, to provide information to our customers concerning our product quality, to give our suppliers feedback about their products* [e.g., shared quality control], *and to communicate with stockholders, because we use quality indicators in our administrations meetings"* [INS QMS]

4.3.2.3   QIS: People

We asked the managers (1) who were the main users of the QIS; (2) how did the IS and the QMS managers communicate on a daily basis; and (3) who was the fundamental responsible of the QIS.

The interviewees present the QIS as a holistic system that involves everyone, inside and outside the organization. The IS managers recognize that their specific QIS activities are mostly internal to the organization (IT support and information quality), when compared to the QMS managers. The latter can balance their internal (e.g., training employees in quality and improving processes) and external activities (e.g., relations with the suppliers, customers, and auditors), expressing a higher perception of the external customer, when compared with the IS managers.

Taking into account the communication between the IS and QMS manager, the opinions diverge. The majority of the QMS experts said that the IS manager was one of the most important functions to allow quality to work. In fact, they have expressed some dependence on the IS function. Contrarily, the IS managers were almost unanimous in saying that they could perform their work without the quality managers' collaboration. However, they also stated that the QMS affected their tasks more significantly than other functions, such as the financial, marketing or production managers (example: PLA IS). This occurs because they need to align their practices with the QMS documentation.

Who owns the QIS? According to a QMS manager of INS1 "*I am the owner of the QIS, but I do not want it!*". Owning the QIS means being responsible for making it work, ensuring that

information is complete and reliable, data is evaluated, and used in decision-making. This is a "*burden*" reported by the majority of quality managers. We found that in the selected cases a QMS manager spends, on average, 70% of his/her time with information related tasks. This value must be carefully analyzed, because each interviewee may interpret their information related tasks differently. However, what becomes clear in the QMS managers' perception is that they spend too much time with the QIS, thus compromising their mission.

> *"I need to behave as a policeman to ensure that procedures are followed and people have the right information"* [MET1 QMS]

> *"I have to report the top manager the quality indicators, but I am too much dependant from the others to complete this task"* [PRI QMS]

4.3.2.4   QIS: Process

The ISO 9001 standard suggests a process approach (ISO, 2008b). Therefore, process design and documentation are typical tasks of QMS managers. However, when we asked the IS managers about those processes, 12 of them identified problems. One being that process descriptions were too vague and generic to be useful. For example, the requirements of an IT application could not be extracted from the quality documentation about processes. Another problem is that, in the majority of the cases, those processes did not fit practice, as they should.

The IS managers of cases CER1 and CER3 have stated that processes are usually changed without their knowledge, leading to difficulties in aligning IT modifications (e.g., new investments in IT, changes in existing applications, changes in reports and indicators, and providing proper users training). According to their point of view, this lack of alignment can create a wrong image of the IS effectiveness.

> *"sometimes the problem is not the delay in IS development, is in lack of communication and negotiation between systems managers"* [CER1 IS]

Conversely, the quality managers also pointed to weaknesses on the IS side. For instance, there was a complaint that the IS staff could participate more in process improvement. Interestingly, the case that revealed more integration between the IS and the QMS function (PLA), also revealed that process improvement was not possible without the IS involvement.

4.3.2.5   QIS: IT

Although the majority of IS managers considers the quality software packages as the primary IT support of quality, the QMS managers reported the need for information from all the organizational IT portfolio. According to the QMS managers, quality involves the entire

organization and IT should be properly integrated. For instance, CRM were reported as critical for the quality principles of customer satisfaction and complaints management. Interestingly, the ERP was only mentioned in two cases (PLA and AUT that have developed their own specific modules). In the other cases, the ERP was one of the less used IT solutions for quality purposes, except if quality modules existed. We found out that the ERP solutions, in these cases, did not have quality functionalities as a priority. One of the managers has reported that quality required constant improvements, and having this type of dynamic in the ERP is not financially feasible. The in-house development or the acquisition of modules that are external to the ERP was the preferable solution in the researched cases.

We found three common problems in the settings we analyzed:

- Poor alignment between IT and process documentation. There was a suggestion that some process documents could be eliminated if the IT was properly developed. "*Why do we need an instruction to perform some process if the IT that supports the process can guide the user with the required information? Process documentation and IT must be developed together*" [INS1 IS]. In addition, the QMS managers should not change documents and processes without considering the existing or potential IT solutions.

- IT verification. "*We have to verify IT, but I do not know how! This should not be a task of the IS* [function]" [CER3 QMS]. The term IT verification is used according to the ISO 9001 standard "When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed (…) Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use" (ISO, 2008, p. 12).

- IT should be more "audit-friendly". When an auditor looks for evidences of quality conformance, the IT becomes part of the audit. However, it is difficult to trace the information: "*we can't directly know which IT* [dimension] *supports which process, which IT* [dimension] *provides which quality indicator*" [ENV QMS].

4.3.2.6 QIS: Information/data

Due to the principle of "*doing right at the first time*" and to give the organizational workers the tools to be autonomous in their tasks, information is essential for quality. This dynamic need of information may be from sources that are internal (e.g., departmental plans, production records) or external (e.g., government) to the organization and depends on the processes to be improved or changed to comply with the customer demands.

> "*Information of the QIS is the set of information from the global IS that we require in some time frame*" [AUT IS]

> "*Quality is not a subset of the organization, is a way of seeing the organization as a continuous improvement system*" [PLA QMS]

The list of quality indicators included very different types of data, from product characteristics to external competitors' benchmarking. The indicators can change over time and the auditors may ask for data from any source to assess quality. For instance, we found information concerning product quality (e.g., defects), process performance (e.g., delays), innovation (e.g., new products developed), and even financial aspects. Financial information was intriguing for us, because the quality literature especially focuses the non-quality costs (such as defects and rework). However, we could find arguments that quality is also "*a way of meeting stakeholders concerns, not only the customer concerns*" (INS2 IS). As a result, to integrate quality indicators with the business, we could also see financial information as "quality information" in the QIS.

> *"Contrarily to CRM systems or some ERP modules that we can more or less describe the types of functionalities and information, that is not possible with the QIS, because quality is everywhere and all the information is potentially quality information"* [INS1 IS]

4.3.2.7 Discussion of the QIS concept

The cross-case comparison confirms our a priori conceptualization for the QIS, although not all the organizations express the same priorities for each of its dimensions. Organizations with more mature QMS and IS management practices do not put the emphasis on the technological aspects, but rather focus on the development of other interrelated dimensions, especially social aspects. Inspired by the work of Chen et al. (2010), we identify three possible conceptions: the QIS as a mere support of quality; the QIS as a mere support for the IS function to comply with quality; and the most potentially valuable: the QIS as a *shared view* of the IS/QMS role in the organization.

The QIS context goes beyond the ISO 9001 requirements that are explicit in the standard. Different factors, at distinct levels, must be considered (Piotrowicz & Irani, 2008). Compliance with ISO 9001 also requires complying with other regulations, creating a wider context for the QIS. We could identify three complementary perspectives, namely:

- Outside-in, considering the external influence in the organizational QIS. This perspective refers to the QIS information from the "outside world", about competitors, stakeholders requirements, and applicable regulations;

- Within, concerning the organizational structure and internal processes. In this perspective, the managers are focused on understanding and developing the quality culture (Addey, 2004; Kanji & Yui, 1997), ensuring that the quality requirements are applied in daily practice;

- Inside-out, regarding the impact in the society, because quality requires evidences provided to stakeholders. This need may occur, for example, in a quality audit, government inspection, or be required by a customer.

All the organizational stakeholders are simultaneously contributors and beneficiaries of the QIS, but the IS and the QMS managers have a central responsibility in its design and management. These two endeavors may be unsuccessful if the managers see the QIS as a mere support for certification. One of the challenges in the synergistic development of the IS and the QMS is the need to develop a holistic view of the organization. The IS manager could benefit from following the QMS manager's example in cross functional relations, and promoting regular contacts with the customers of the firm, for instance, to improve innovation (Saldanha & Krishnan, 2011).

The process approach should be a common concern of the IS and the QMS managers. If IS managers have a higher participation in process management and modeling, from the onset, then both functions will benefit (Garimella, 2006; Pérez-Aróstegui et al., 2015). The process maps that are sketched during ISO 9001 implementation require improvement and additional tools, to be useful for the IS. The problems found in the process dimension are consistent with previous studies, sustaining that ISO 9001 adoption does not lead to an improved process approach (Iden, 2012). Our findings from more mature QIS have revealed that both the IS and QMS managers must combine their efforts in process management.

There are differences in how the IS and the QMS managers see the IT dimension. While the IS managers focus on the IT that directly supports quality (e.g., quality software packages), the majority of QMS managers report that all the organizational IT must be considered. In most cases, the IS managers see the QMS manager as a "customer", rather than a "partner". As a partner, the QMS managers should be involved in early phases of IS development. In addition, IT verification, as required by the ISO 9001 quality standard, should not be the exclusive responsibility of the QMS manager. IS managers are in a position to lead the critical aspects of data, information, and system quality. As evidenced by the literature and by the interviewees, business quality and a multidimensional IS quality are two faces of a single coin (Stylianou & Kumar, 2000), however, IS quality issues (1) have a narrow scope and a limited guidance in ISO 9001 (ISO, 2008b), and (2) could involve the participation of other organizational users in improvement efforts, for example the process owners.

We couldn't find in these cases a strict definition of "*quality information*" (Juran & Gryna, 1993), concerning the information that is exclusive to the QIS. Similarly to the IT dimension, where the entire IT portfolio is, potentially, relevant to support the QIS, also all the organizational information is, potentially, QIS information. The case studies suggest that the five QIS dimensions are interrelated and must be addressed as a whole in our research for synergies between the IS and the QMS.

4.3.3 Potential limitations of the multiple case studies

Our case study phase included the participations of 14 organizations from different sectors of activity. We did not specify beforehand the number of cases; we continued our work until we found that the findings were replicating previous ones (Iden, 2012). The cases satisfy our criteria regarding the development of ISO 9001-based QMS and the IS development with IT, but that does not mean that they are a representative selection of the ISO 9001-certified companies. The selection aimed to maximize learning in the period of time that we had to proceed with the study (Dubé & Paré, 2003), in a context of discovering IS and QMS synergies. The multiple case studies has followed a comparative logic (Eisenhardt, 1991) to identify patterns in the problems that organizations face when they don't explore synergies. However, we did not ignore differences in the cases, for example regarding the examples that presented a greater integration between the IS and the QMS managers (e.g., the case [PLA]).

The number of cases is an advantage but also the first potential limitation due to the complexity of case comparison. The second potential problem is the retrospective nature of the inquiry, because the interviewees are asked about past events, with the probability of interviewees forgetting several details that could benefit our research or change our interpretation of the facts. The third potential limitation is the selection of a tactical organizational level, not including top managers or other employees besides IS and QMS managers. Forth, the cases were restricted to ISO 9001 context and some of the organizations included additional certifications, what could cause the evidences to be biased by those standards. Fifth, similarly to the auditors, the researcher also knew the majority of the research cases from previous projects. Sixth, we had higher confidentiality concerns when compared to the auditors' interviews, because the latter were not reporting to a specific organization.

First, to overcome the difficulty of a large number of cases, we organized our findings according to three main periods (before, during, and after) of the IS and QMS development. We also focused our research in the five dimensions (context, people, process, information/data, and IT) that we present in chapter 2. We used a smart pen to assist the data collection and the comparison of the different interviewee viewpoints. Second, the facts that we asked were recent, increasing the possibility that interviewees remembered the most important details. The previous knowledge of the researcher about the organizations involved also helped to contrast the interviewees' answers. Third, we selected the managerial functions with more involvement with the IS and the QMS in the selected organizations, potentially the most benefited with a synergistic approach to the development of both systems. Regarding the forth limitation, we have guided our research by a comprehensive literature review in quality management and ISO 9001, the ISO 9001 auditors insights, and the researcher knowledge about the standard. We constantly criticized our field procedure to ensure that the context was in fact associated with ISO 9001. Yet, we found that other standards might coexist with ISO 9001 and complement its requirements for quality management, for example, in the food sector ([AGR] case). We did not exclude aspects that emerged more clearly in other standards requirements (for example, sustainability and ISO 14001), but we critically evaluated if those aspects would also fit the purpose of our research. In

spite of the potential interest of interaction between ISO 9001 and other standards, our research is limited to the ISO 9001 context and associated regulations. Regarding the fifth limitation of previous contacts with the majority of the cases, we followed the principles of Klein and Myers (1999), ensuring a proper contextualization of the problem and transparency regarding the interaction between the researcher and the organizations. Finally, we ensured confidentiality to the participant organizations, we coded each case and do not identify the source. This decision is an attempt to obtain answers that are more truthful, and having access to privileged information that could improve our interpretation of the facts.

4.3.4 Validity and reliability of the multiple case studies

The checklist presented below is based on the guidelines of Runeson and Höst (2008) to conduct and report case studies as it applies to our research.

Table 4-5. Evaluating the case studies (Runeson & Höst, 2008)

Case study design		
Criteria		**Our case studies**
1	What is the case and its units of analysis?	We described our research strategy in chapter 3, provided a description of the organizations involved, identified the group of professionals addressed, and explained the focus on ISO 9001 context.
2	Are clear objectives, preliminary research questions, hypotheses (if any) defined in advance?	We have stated clear objectives for the case studies. When applicable, a priori constructs were used (QIS definition).
3	Is the theoretical basis – relation to existing literature or other cases – defined?	A systematic literature review has preceded the case studies.
4	Are the authors' intentions with the research made clear?	The intentions and the author's relation with the cases are stated. The research strategy in chapter 3 specifies the use of case studies and its role in our overall research program.
5	Is the case adequately defined (size, domain, process, subjects…)?	We selected 14 organizations, which can represent a greater difficulty in data analysis. Some authors suggest between 4 and 10 cases but the numbers may vary (Eisenhardt, 1989), for example Iden (2012) presents a study that involved 23 ISO 9001-certified firms. Due to the specific objective of our research, we

	Criteria	Our case studies
		could focus the analysis in a more substantial number of cases. The subjects and domain was clearly defined.
6	Is a cause–effect relation under study? If yes, is it possible to distinguish the cause from other factors using the proposed design?	The cause-effect relation is not under study.
7	Does the design involve data from multiple sources (data triangulation), using multiple methods (method triangulation)?	We used interviews, observations, and document analysis. The latter included quality procedures, records, and IT documentation.
8	Is there a rationale behind the selection of subjects, roles, artifacts, viewpoints, etc.?	All the organizations share the same quality management context. We also selected organizations where IT solutions were used to support quality efforts. The interviewees were selected according to their function in the organization.
9	Is the specified case relevant to validly address the research questions (construct validity)?	We used triangulation and validated our findings with the practitioners. Our research questions were formulated in the form of research objectives.
10	Is the integrity of individuals/organizations taken into account?	Confidentiality was ensured to each organization.
Preparation for data collection		
Criteria		Our case studies
11	Is a case study protocol for data collection and analysis derived? Are procedures for its update defined?	A protocol is presented together with the research strategy, in chapter 3.
12	Are multiple data sources and collection methods planned (triangulation)?	There was an initial meeting with each organization to present our research objective and the evidences to collect. We planned each aspect to address in our interviews and the type of documents and IT to analyze.
13	Are measurement instruments and procedures well defined (measurement definitions, interview questions)?	We selected semi-structured interviews, only the main questions were prepared beforehand. The research scope, the instruments to use and the procedures were established in our research program.

14	Are the planned methods and measurements sufficient to fulfill the objective of the study?	The case studies were important to create a frame of reference for action research. We continued to involve organizations in our case studies until we found that our objectives were fulfilled.
15	Is the study design approved by a review board, and has informed consent obtained from individuals and organizations?	The study design was approved by each organization and the people involved.
Collecting evidence		
Criteria		Our case studies
16	Is data collected according to the case study protocol?	We defined the procedures for working in the field and artifacts to support that work (e.g., mind maps).
17	Is the observed phenomenon correctly implemented (e.g., to what extent is a design method under study actually used)?	The organizations implemented the systems under analysis. We collected evidences about those implementations from documents and trough the observation of daily practices.
18	Is data recorded to enable further analysis?	We recorded a part of the interviews with a smart pen and took notes in all the interviews. Some of the interviews were made by phone or Skype, complemented with field notes. We transcribed relevant quotes.
19	Are sensitive results identified (for individuals, the organization or the project)?	We wanted a full collaboration from the participants so we protected their identity, as well as the name of the organizations involved.
20	Are the data collection procedures well traceable?	The procedures we followed are included in the doctoral thesis.
21	Does the collected data provide ability to address the research question?	We gathered evidence in our research about the benefits of an integrated approach, but also the problems of not exploring the synergies between the IS and the QMS, in the selected organizations. We also gathered important information to guide the next phase of our research program.

Analysis of collected data		
	Criteria	Our case studies
22	Is the analysis methodology defined, including roles and review procedures?	The main analysis of data was made by the researcher, but there was a permanent effort to discuss the results with colleagues and organizational experts. Moreover, we published our work in peer-reviewed conferences.
23	Is a chain of evidence shown with traceable inferences from data to research questions and existing theory?	We started our research by a literature review and the development of frameworks (e.g., the five dimensions to address the QIS) from existing theory.
24	Are alternative perspectives and explanations used in the analysis?	We compared the perspective of different companies for the same domain. Moreover, we selected IS and QMS experts to understand their possibly different viewpoints in the systems development.
25	Is a cause–effect relation under study? If yes, is it possible to distinguish the cause from other factors in the analysis?	The cause-effect relation is nor under study.
26	Are there clear conclusions from the analysis, including recommendations for practice/further research?	The case studies allowed us to create a frame of reference for action research. We also contribute to knowledge creation in our specific objectives, for example, the QIS definition according to the IS literature.
27	Are threats to the validity analyzed in a systematic way and countermeasures taken? (Construct, internal, external, reliability)	We follow the literature guidance concerning the study validity and pointed to specific actions to address the potential problems.
Reporting: Criteria 28 to 38 (Runeson & Höst, 2008, p. 158) were used as a reference to report the case studies in our papers and in this thesis.		

We have created several drafts for a synergistic approach to the development of the IS and the QMS. Those drafts emerged from our literature review, contacts with colleagues, interviews with auditors, and feedback from the case studies that we present in this chapter. The next section describes a chronology of artifacts that were drafted in this phase that preceded action research.

4.4 Drafting the ISO$_2$ approach: preparing the action research

In this section, we present the starting sketch of our proposal for ISO$_2$; representing the outcome of our work before initiating action research. The outline of our embryonic proposal was developed during the research proposal of this thesis and is presented in Figure 4-4.

1 – Diagnosis – QMS and IS	1.1 – Initial Business Evaluation and Description	
	1.2 – Initial IT Evaluation and Description	
2 – Training Actions (I) – QMS	2.1 – QMS General Theory	
3 – Process Redesign – QMS and IS	3.1 – Process Mapping	
	3.2 – Process and Data Models (Application Requirements and Specification)	
	3.3 – Process Description/Writing: Quality Manual, Procedures, Instructions, Models…	3.4 – Application Development (Software Engineering Process)
4 – Training Actions (II) – QMS and IS	4.1 – Business and IS documentation Explained	
5 – Process Implementation – QMS and IS	5.1 – Process Implementation (Reality Execution)	
	5.2 - IS Implementation (Reality Description)	
6 – External Audit - QMS		

Figure 4-4. Developing the IS and the QMS – a preliminary approach

The figure presents the major steps that we identified in 2006 for the joint development of the IS and the QMS (on the left side). We envision six steps that start with a diagnosis of the current business and IT situation, ending with the external quality audit. On the right, we can observe an attempt to identify the common training concerns of the IS and the QMS teams (2.1 and 4.1), and the steps specifically designed for each team of experts, namely the IS team (1.2, 3.2, 3.4, and 5.2) and the QMS team (1.1, 3.1, 3.3, 5.1, and 6).

The description of each phase in Figure 4-4 is as follows:

1. Diagnosis phase (as-is): It addresses the initial interpretation of the existing processes, responsibilities in the organization, quality requirements, and the IT portfolio;

2. Training Actions (I): It is the opportunity for all process managers and team managers to attend QMS courses;

3. Process re-design: Covers the activities of improving and designing the business processes, supported by the diagnosis model. IS development proceeds in parallel to this stage (represented by 3.4);

4. Training Actions (II): These additional courses give end users the knowledge about redesigned processes and underlying IT that supports them.;

5. Process implementation: It refers to the implementation of the designed processes and, simultaneously, to the developed IT solutions (production versions in use by the end users);

6. External Audit: This final step reports to the QMS audit (separately to IS audit that needs to occur before the process implementation phase, for example, software testing issues).

Our literature review, the auditors' interviews, and the case studies results allowed us to identify several problems with this draft. First, it was made with the focus in the support of the consulting teams and not in the organizational users. Therefore, we concluded that it did not guide the organizational users in a participative engagement with the project tasks. Second, we considered this first version a parallel action plan, rather than an integrated action as we intended to explore synergies. Third, it focus IT development and not explore other dimensions of the IS, nor it considers cases without developing IT. Forth, it does not provide support for continuous improvement.

As research evolved, the next drafts of the approach were compared with previous ones to refine the results, as illustrated in Figure 4-5.
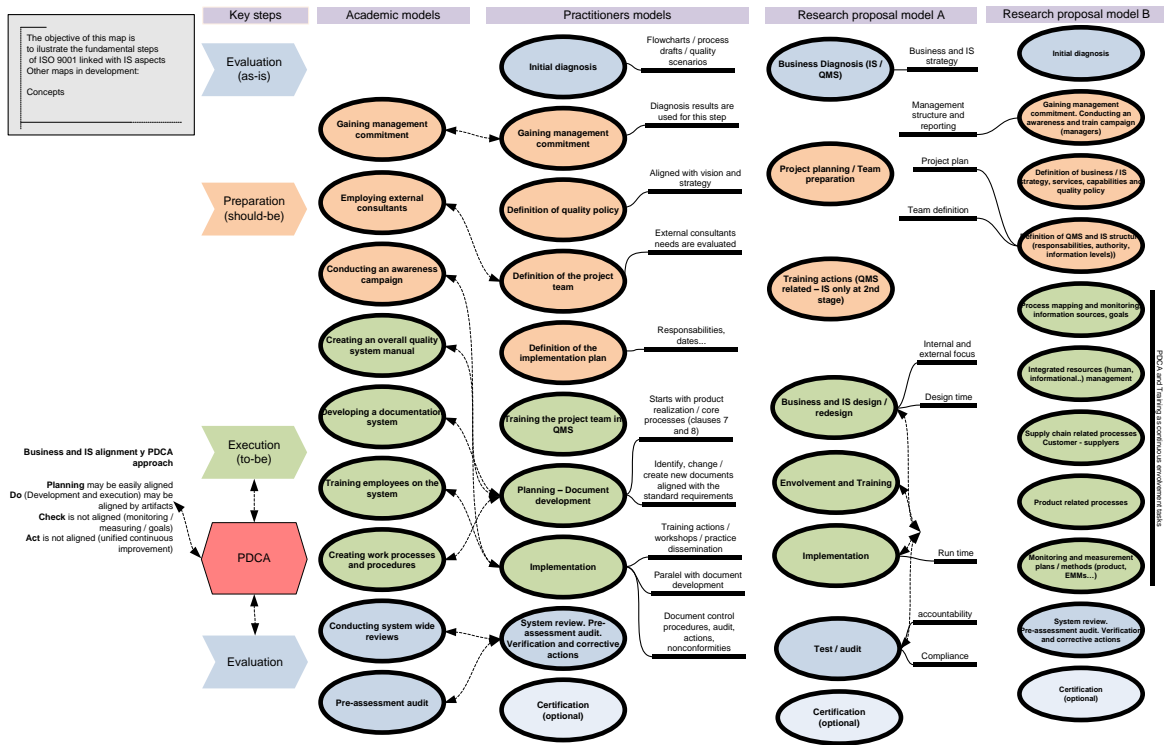
Figure 4-5. Towards a synergistic approach to start our action research: comparing alternatives

We compared ISO 9001-base QMS development approaches that we found in the literature, for example from Bell and Omachonu (2011) represented in the column 2 – Academic models of Figure 4-5; Models that we found in books (Pinto & Soares, 2010) and in contacts with consulting colleagues, compiled in column 3 of Figure 4-5 – Practitioners models; and our proposals (columns 4 and 5) – Research proposal models A and B. We tried to simplify the approach finding similar phases for the IS and the QMS development, represented with equal colors for each column in Figure 4-5.

The comparison that we present in Figure 4-5 has five main general steps: Evaluation (as-is), Preparation (should-be), Execution (to-be), cycles of Plan – Do – Check – Act, and finally Evaluation. An example of a practitioners plan is presented in Figure 4-6.
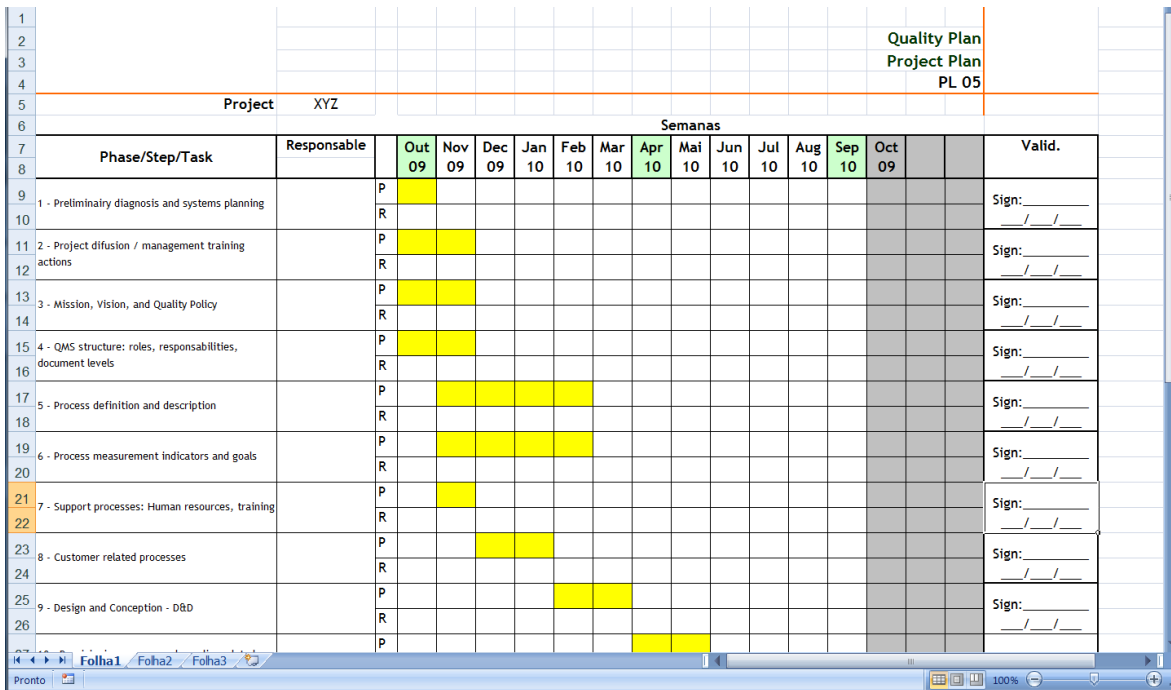
Figure 4-6. Practioners plan to implement an ISO 9001-based QMS (consulting company)

We found that the literature models and the practitioners' models that we accessed have differences. For example, the steps that we found in the literature according to Bell and Omachonu (2011) do not point out a process approach, however we found that practitioners plans is process oriented, as presented in the first column of Figure 4-6. We evaluated two practitioners' models as presented in Figure 4-6 and found the following pattern:

1. The first steps aim at creating an environment that can facilitate the ISO 9001 design. This includes meetings with managers, supplying information about the standard requirements, and about the main principles that quality suggests;

2. There is a general diagnosing of the organization to understand the level of process formalization (documentation). A draft of a global process map is developed at this initial phases and refined during the project with more detail for ach process;

3. There is a set of intermediate steps that are repeated for each process, to identify responsibilities, process tasks, information requirements, and indicators;

4. The plan concludes with audits, training actions, and the proposal of a culture to continuously improve the processes.

The consultants told us that the order of the process design may vary in each organization, but they usually differentiate support processes (e.g., human resources management, IT management, audits), customer related processes (e.g., complaints, marketing / commercial), and key processes related with the product/service of the organization (e.g., provisioning, design and development, production). This operational aspect of ISO 9001 implementation: 1– general approach to diagnosis; 2 – implementation for each process; and 3 – aiming to promote a culture

of continuous improvement, is compatible with what we found in Bell and Omachonu (2011), providing a deeper detail on the practical aspects of the development: start – detail each process – evaluation – restart.

4.5 Sum up

In Chapter 2 we reviewed the literature about the IS and the QMS fields of knowledge. It was an essential step for our research on synergies among these two pillars of modern organizations. We could understand potential problems of separated IS/QMS development and identify two stages to address in their lifecycle: the design-time and the run-time.

Our understanding of the focal problem was expanded in this chapter. We addressed "RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors" through the auditors interviews. We also addressed "RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations", and "RO5. Clarify the concept of quality information system in the selected organizations and propose a definition for our work" with the multiple case studies.

The literature review, the interviews, and the multiple case studies allowed the creation of a frame of reference, which is important for conducting action research (Checkland & Holwell, 1998a; Lau, 1999), to frame the focal problem and lead the intervention (Davison et al., 2004).

> *"These forces* [social aspects in IS design] *mold frames of reference which serve as perceptual filters through which one perceives the world and provides guides for actions"* (Bostrom & Heinen, 1977, p. 18)

The results (1) suggested the need to develop a synergistic approach to holistically address the lifecycle of the IS and the QMS development (Cunha & Figueiredo, 2005; Delić et al., 2014; Ferreira et al., 2012; Jabnoun & Sahraoui, 2004; Pérez-Aróstegui et al., 2015); (2) allowed us to extend the framework proposed by Forza (1995a, 1995b); (3) understanding the need of comprehensive regulatory compliance (Hancher & Moran, 1989); (4) and addressing the multidimensionality of IS (Böll, 2012; Hirschheim & Klein, 2012; Paul, 2007; Zhang et al., 2011); (5) including business process management (Davenport & Short, 1990; Hammer, 1990, 2010; Iden, 2012; Zairi, 1997); (6) a comprehensive perspective of IS quality (Stylianou & Kumar, 2000) in the context of ISO 9001; and (7) cultural synergies (Fok et al., 2001; Gallear & Ghobadian, 2004; Hartman et al., 2002; Philip & McKeown, 2004).

The next chapter presents our contribution for a synergistic approach for the joint development of the IS and the QMS, in the context of ISO 9001. We advanced it to become the ISO$_2$ approach.

Chapter 5

Theory building: the ISO$_2$ proposal

5.1 Introduction

The findings that we present in Chapter 4 allowed us to widen the conclusions of the literature review. The comprehensive frame of reference for action research is now informed by the knowledge of ISO 9001 of quality auditors and organizational IS/QMS experts. Moreover, we have gathered evidence in our case studies that it is desirable and possible to create synergies in the development of the IS and the QMS. However, there is insufficient guidance on how to do it in organizational practice. This chapter presents the phase of the research in which we intervened in the real world to propose a solution that we named ISO$_2$.

The chapter is organized chronologically, according to the sequence of three action research projects that we have conducted, each one with specific contributions for the progress of ISO$_2$. The rationale of our first project was to identify and apply a specific set of steps that could represent the synergistic IS and QMS development lifecycle. We have created artifacts to assist ISO$_2$ in practice, and learned how they could help users to overcome the problems found in our case studies (e.g., deficient communication between the IS and the QMS managers and misalignment of their development plans). It was a single canonical action research cycle (Davison et al., 2004; Susman & Evered, 1978) in a technological institute. We found aspects to take into consideration in our second project, namely to include regulations such as the ones that we can find in laws and customer contracts. They are needed for ISO 9001 certification and they are a basis for requirements of the IS (Abdullah et al., 2010a; Gray & Roth, 2014; ISO, 2008b). The second project aimed at evolving ISO$_2$ support for the design-time. We saw what happened in three organizations, each one representing one CAR cycle. However, we were still lacking support for the run-time of the synergistic development. We found that ISO$_2$ was too focused in designing, modeling, and representing systems. Additionally, our opinion was that ISO$_2$ was not assisting users in their systems evaluation and continuous improvement, at least not satisfactorily as proposed in the quality culture literature (Detert et al., 2000; Hildebrandt et al., 1991; Kanji & Yui, 1997). To be truly a synergistic development, the run-time phase should not be just a mere monitoring of the IS and the QMS requirements to back each other's needs. A shared view must include the continuous improvement of both systems, as we identified in the literature review of Chapter 2, later confirmed by our case studies in Chapter 4. Our third action research project addresses this requisite, extending ISO$_2$ by means of a cultural perspective that promote the

adoption of quality principles in daily practice (Barney, 1986; Kanji & Yui, 1997; Schein, 1990; vom Brocke & Schmiedel, 2011).

At the end of this chapter, we present a summary of the ISO_2 approach as well as the artifacts that we have created to assist its steps. By then, the reader should be able to:

1. Understand the evolution of the ISO_2 approach and the contribution of each action research cycle;

2. Comprehend the outline of ISO_2 and the developed artifacts.

5.2 Project AR1: proposing ISO_2

This section presents our first action research project (Barata & Cunha, 2014a). We follow the five phases of canonical action research that were presented in Chapter 2, namely, *Diagnosing, Action planning, Action taking, Evaluating, and Specifying learning* (Susman & Evered, 1978). We conclude the presentation with a comprehensive evaluation of the project according to the five principles and 31 criteria proposed by Davison et al. (2004) for CAR.

*"Eventually, they build a **proof of concept** prototype that may not be scalable, and may not be full featured, but is sufficiently robust that stakeholders can try it out with sample tasks so both the researchers and the stakeholders can learn more about the challenges they face"* (Briggs, Nunamaker, & Sprague, 2011, p. 14)

5.2.1 Project setting

We carried out this cycle in a private non-profitable technological institute founded in 1987 by a common agreement between industrial federations and governmental agencies of the Ministry of Industry and Economy of Portugal. Its mission is to provide services to its associates and promote innovation. The external stakeholders are private associations, companies, and public institutions. Its objectives are to: provide technical and technological support to the industries; promote the development and quality of industrial products and processes; promote highly specialized training to industry personnel; divulge scientific, technical and technological information; carry through and promote research, development and demonstration work, considering the scientific and technological progress of materials and processes. The institute has close relationships with several universities and research centers, both in Portugal and abroad.

Nonprofit organizations must comply with a plethora of regulations. As presented in Chapter 2, those regulations may be enforced, when concerning matters of law, but may also be voluntary, when a specific standard such as ISO9001 is adopted (ISO, 2008b). ISO 9001 is increasingly adopted by nonprofit organizations, for example, public universities and health care

facilities, associations, and research institutions. White, Samson, Rowland-Jones, & Thomas (2009) present a case of ISO 9001 adoption in this type of organizations. The authors conclude that the adoption of this standard has benefits in the identification of business process weaknesses and prevent task duplications, while IT can be adopted to solve data duplication problems (White et al., 2009).

Technological institutes develop an essential function in society, including innovating and services (Kramer, 1987). They may be subject to distinct types of audits, such as quality, financial, and contractual. With the increase of IT adoption, the audit evidences are increasingly embedded in technological media, such as databases and specific applications. When we started the CAR cycle, both the researcher and practitioners were involved in the process of developing the IS and creating business processes compliant with the standard requirements and the internal procedures. The organization wanted to improve their ISO 9001-based QMS and to develop quality modules integrated with its ERP. The modules included complaints management, nonconformities and actions, audit, and product design.

5.2.2 Potential limitations

This was our first attempt at synergistically developing the IS and the QMS. Although previous findings allowed us to create frameworks to guide our intervention, this cycle was lacking practical tools to support our approach.

The professional relation held between the researcher and the institution has advantages and disadvantages. The main advantage is the opportunity to test and understand the results of the research from an insider's point of view. There is a better knowledge concerning the organization context, its processes, and the people involved. Therefore, the changes in the way people work can be evaluated more precisely, with a direct feedback from the users. Additionally, we had a close relation with top management, facilitating collaboration in the distinct phases of CAR in this setting. However, we can identify several difficulties, for example, predetermined beliefs and opinions could bias our diagnosis. This bias is also possible when working with colleagues, which may take our personal view in consideration if they know it in advance, for example regarding the need to change work procedures.

We were aware of possible difficulties in action planning, because the influence of daily work pressures can drive the plan to specific interests of the moment and possibly reduce the research focus. When researching in our own work place, action taking is a struggle with time that must compete with several tasks. Task switching and the risk of mixing daily work with research work is a constant challenge. Moreover, a part of the information could fall in the scope of the confidentiality contract, making it necessary to code all or part of it. The potential limitations that we identify can also exist when working with external organizations, but we must account for the possibility that the troublesome situations can occur more often, due to the proximity and power relations in the site between the researcher and the client.

This organization has participated in our research from the first cycle to the last one, becoming fundamental for the evolution of ISO_2. Nevertheless, this is not the simplest setting due to the multiple standards and regulations attached to ISO 9001. There was a risk to take conclusions that would fit different standards than the one that we wanted. For this reason, we constantly compared our findings with the quality principles and applicable clauses (ISO, 2008b). To complicate matters, ISO 9001 clause 7.3 – Design and development – that we addressed in this project, is one of the most demanding clauses of the standard (ISO, 2008b).

Following the CAR approach rigorously is our first concern to deal with potential problems (Davison et al., 2004; Vries, 2007). Furthermore, a strong support from the administration and the commitment of practitioners' collaboration increased our confidence in the selection of the technological institute as our first CAR setting.

5.2.3 Diagnosing

This technological institute has a business unit that provides IS development services and support to the workers, namely general helpdesk, hardware, and communications. Several problems were identified concerning the collaboration between them and the QMS manager. On the one hand, the IS team considered the QMS as a mere compliance issue, reporting that the majority of quality documents were more problematic than helpful. For example, the software project documentation did not fit practice, the procedures were incomplete, and we could find the case of excessive bureaucracy, considering some quality records a burden that the users often forget to fill. On the other hand, the quality manager complained that she was always considered last in matters related to IS team support. She complained that the ERP and CRM were the major focus of attention, while support processes and quality issues was not a priority for the IS team.

Both teams have valid reasons to complaint. In the beginning of this diagnosis, we promoted a meeting with them to detail the potential difficulties and opportunities to explore. Experts from both camps acknowledge the existence of problems but also that it was necessary to make changes. The IS team confirmed that top management requests were especially directed towards the ERP, and that daily demands from multiple customers relegated collaboration with the QMS for a secondary position. In addition, the QMS recognized problems with the bureaucracy and disconnection between IT and quality documents. She told that she could not simply wait for the IS team to develop new tools, since the QMS needs to advance and improve continuously. They both recognized that the lack of human resources or time was not a critical problem. The main problem was the usual way of working separately, eventually getting used to complain about each other. What if the two can help each other?

The company needed a ISO 9001-certified QMS and an IS composed of heterogeneous applications that could be a part of their process improvement efforts, not a barrier to the QMS. The IT in support of the QMS included applications for complaints management, nonconformities and actions, audit, and design and development (D&D). The first four modules were already developed, so the essence of the work was to adjust them. The latter area demanded a new

development and represented a different challenge for the team, which started with a requirements specification.

5.2.4 Action planning

As a result of the diagnosis in the organization, the literature review presented in Chapter 2, and the findings that we present in Chapter 4, we shaped a first cut of ISO_2 as presented in the Figure 5-1.
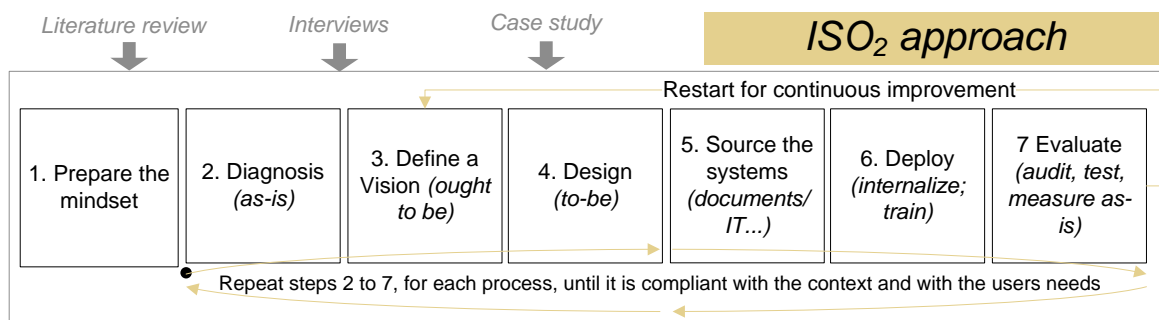
Figure 5-1. The steps of ISO_2 approach (Barata & Cunha, 2014a)

The steps of the approach were sketched by the researcher, then evaluated and approved by the IS/QMS development team of the technological institute. ISO_2 takes into account the iterative nature of the IS development (Checkland, 1981; Susman & Evered, 1978), as proposed by the PDCA (ISO, 2008b). It also interprets the need to distinguish different phases of the quality lifecycle, as suggested by the work of Domínguez-Mayo et al. (2012a), Domínguez-Mayo, Escalona, Mejías, Ross, and Staples (2012b), in the area of model-driven web engineering. These authors consider the phases of strategy modeling (ISO_2 steps 1 to 3), design (ISO_2 step 4), transition (equivalent to ISO_2 steps 5 and 6), operation (ISO_2 phases 6 and 7), and improvement (ISO_2 iteration of steps 2 to 7). The description of the ISO_2 steps is outlined in Table 5-1.

Table 5-1. ISO_2 steps

Step	Description
1	***Prepare the mindset:*** The approach to synergistically develop the IS and the QMS must be presented to all the stakeholders. We have learned from the retrospective case studies that both – IS and QMS – systems must be aligned from the start and the decisions shared by the teams from both camps. Three training actions of two hours each are proposed for (1) presenting the ISO_2 approach; (2) the main cultural aspects of the ISO 9001 standard, principles, and requirements; and (3) IS methods, the IT options and guidance for requirements analysis. This step may contribute for the team coordination, management commitment and an awareness campaign (Bell & Omachonu, 2011; ISO, 2008b);

Step	Description
2	***Diagnosis (as-is):*** Identify the current quality and IS practices, ISO 9001, and other contextual requirements (ISO, 2008c; Jacobson et al., 1999). Define and assess the current processes with a questionnaire, from the users' perspective (Antunes & Cunha, 2013);
3	***Define a Vision (ought-to-be):*** Define quality and IS policies, create the quality manual (Bell & Omachonu, 2011; Juran & Godfrey, 1998). Create the desired process map (ISO, 2008b);
4	***Design (to-be):*** Detail each process and indicators (ISO, 2008b). Establish the plan and objectives for each development (ISO, 2008c; Jacobson et al., 1999);
5	***Source the systems:*** Source the IT support (Muhic & Johansson, 2014; Zhang et al., 2011) and the QMS documents (Bell & Omachonu, 2011; ISO, 2008a, 2008b) – the support system can be in any form/type of medium (ISO, 2008a);
6	***Deploy:*** Implement the systems, train, and internalize in daily practice (Addey, 2004; Bell & Omachonu, 2011; ISO, 2008c; Jacobson et al., 1999; Kanji, 1998);
7	***Evaluate:*** Audit, test, validate and accept (Bell & Omachonu, 2011; ISO, 2008c, 2009a; Jacobson et al., 1999). Deploy the same questionnaire of step 2 (Antunes & Cunha, 2013). Restart the diagnosis to continuously improve (ISO, 2008b).

Our plan was to follow the ISO_2 steps and develop the necessary artifacts for its application.

5.2.5 Action taking

Table 5-2 summarizes what occurred for each step of ISO_2.

Table 5-2. Key findings from adopting ISO_2

Step	Description
1	***Preparing the mindset – focusing on the awareness of synergies.*** Due to the use of a common approach, the development of the IS and the QMS could start simultaneously. The presence of the top manager and the existence of a guiding approach successfully underlined the relevance of the development to the participants. It was decided that both the IS and QMS teams would work on the same processes and "documents" simultaneously, in their preferred type of medium. The joint design should make the end users' satisfaction a main concern. Additionally, the design outcome should provide a predictable, continuous, reliable, and complete information flow within the company and with its environment.

Step	Description
2	*Diagnosis (as-is) – focusing on the team designers and process participants.* We started by designing a global process map and then, for each selected process, carried out the diagnosis by observing the current practice and measuring the process acceptance by the users with the MUVE questionnaire (Antunes & Cunha, 2013). MUVE is an approach to detect and remove friction in business processes, suggesting people involvement in the process diagnosis (Antunes & Cunha, 2013), that is also a requirement of an ISO 9001-based QMS. Therefore, we decided to adopt the MUVE tool under development by their authors, contributing to its development, test, and refinement. We expected to face resistance from the QMS team in sharing their "power" over information management. Surprisingly, they were receptive to the idea because our proposal allowed them to focus on two principles of the standard: improvement and customer satisfaction. We launched the questionnaire in the D&D process that was a priority for the organization.
3	*Define a Vision (ought-to-be) – focusing on the organization.* This step was faster than we expected. We proposed a brainstorming with top manager, IS/QMS team, and D&D process participants. Recalling step 1, the participants were focused on getting synergies from both the IS and the QMS. The questionnaire inputs were used for the new vision and all the organization received information about the new process map.
4	*Design (to-be) – focusing on the possibilities and restrictions of the design teams.* We then quickly realized that the QMS design, although primarily represented as a sequence of steps in the QMS literature, is iterative and incremental. Developing documented procedures and forms was the main task of the QMS team. Developing or acquiring IT was the main purpose of the IS team. Since we intended to develop "documents", the challenge was to define an ISO_2 "shared document". We also found that the process approach (ISO, 2008b; Zairi, 1997), by itself, was not sufficient, as we already suspected from our previous work and from the literature review (Cardwell, 2008; Iden, 2012). The QMS processes were too general to be used by the IS team. Considering the ISO definition of "document" (ISO, 2008a) and the inclusion of IT in our approach, we have conceptualized the ISO_2 document as: an application of IT that enables some processes in a social structure that itself is embedded within a context (Zhang et al., 2011). We have named it O_2 artifacts.

We were facing a dilemma at this stage of the design. There are different parts of the systems to consider, for example, process documentation, IT platforms, people training, process tasks… so, how can these be represented in their design? The solution agreed by researcher and practitioners was to design the dimensions of both systems as a whole that makes sense to the IS and the QMS experts. It must also be a working tool for improvement efforts. Our idea was aligned with the definition of "synergistic", namely "*acting together*" and "*working together in a creative, innovative, and productive manner*" (HarperCollins, 2014). The O_2 artifacts represents the proposed level of abstraction for the IS and the QMS. It has a conceptual framework, as presented in Figure 5-2.
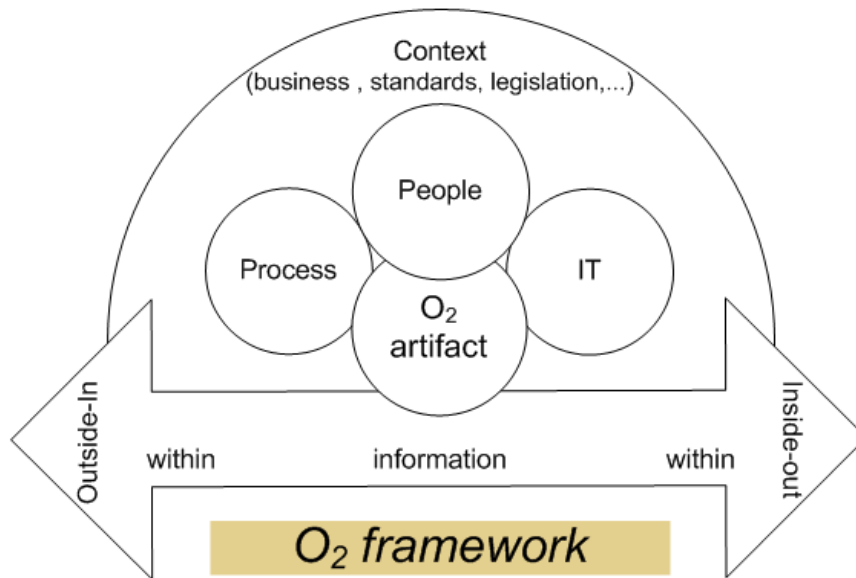
Figure 5-2. The O_2 framework

The framework suggests that the development of synergies in the IS and the QMS must consider the five main dimensions that we have identified in the literature, namely (1) context, (2) people, (3) process, (4) information, and (5) IT. Information flows outside-in, within, and inside-out the systems boundaries, represented by the arrow in the framework representation. This dynamic provides the rationale for the O_2 artifacts, remembering the IS and the QMS experts that the development outcome is a combination of different dimensions that requires and produces information in daily practice. The framework may also represent a "steering wheel" to drive the development of both systems. We found that it is useful to prepare the mindset of the participants (ISO_2 step 1) and to frame the O_2 artifacts that are built during the synergistic development of the IS and the QMS.

We will introduce the representations of O_2 artifacts developed in this CAR cycle as empty templates to simplify and focus on the explanation of their structure; afterwards we will present them, in Chapter 6, filled with the information contents provided by the technological institute for the design and development process. Examples for the representation of O_2 artifacts are provided bellow. They were jointly designed by researcher and the technological institute members, namely, the *O_2 matrix* of Figure 5-3; the *O_2 list* of Figure 5-4; the *O_2 5W* of Figure 5-5; and, finally, the *O_2 map* illustrated in Figure 5-6.

Concern type \ By		Outside-in	Within	Inside-Out
Context	Current			
	Planned			
People	Current		IS and QMS requirements	
	Planned			
Process	Current			
	Planned			
IT	Current			
	Planned			

Figure 5-3. The *O₂ matrix*

Different stakeholders may have multiple goals to address in a QMS design (Øgland, 2008). Moreover, the design must start by the identification of the goals that we want to achieve (Hammer, 1990; Juran, 1993). The O_2 *matrix* artifact is a tool that different experts use in the identification of the IS and QMS requirements. It provides a different perspective of the business process when compared to the typical ISO 9001 documentation. Moreover, the matrix includes the current and the future situations, which does not occur in process documentation (provides the current situation, "as-is"). The artifacts that we present are complementary to quality procedures, as we exemplify in Chapter 6.

The O_2 *matrix* is created for each business process, guiding the designers in the identification of the requirements for the context, people, process, information (inside the cells), and IT. The artifact is currently implemented using spreadsheets. We did not want to include many rules in the way participants use it, so we could study their adoption/adaptation for practical use. One of the problems that we identified is the different vocabularies, for example when comparing technological experts (e.g., IT function) and management experts (e.g., financial functions). To address this difficulty we suggested the designers to avoid technical jargon when filling the cells content, which can be refined with the assistance of the other designers. This decision facilitates the development of the artifacts, however, the lack of a strictly prescriptive norm causes that some of the requirements are inconsistent with its location in the matrices. For example what one could identify as a human aspect, for example "*the process participant must have specific training in…*", could be identified to be included in the IT line, as a requirement of some IT project phase that includes user training. We were aware of these problems but decided to keep the approach flexible at this stage of the research to understand which could be the simplest structure of the artifacts. We also wanted to see what would be written in the cells with minimum restrictions to the users, and assess the utility of the information obtained for process improvement.

O$_2$ artifacts (e.g., matrices, lists) are tools that allow us to represent and reflect about what will be a real output of adopting ISO$_2$ in practice (an O$_2$). The next figure represents a second artifact that we created: the *O$_2$ list*.

	Outside-in	Within	Inside-out
O$_2$ #1			
O$_2$ #2		IS and QMS requirements	
O$_2$ #N			

Figure 5-4. The *O$_2$ list*

The *O$_2$ list* artifact enumerates what needs to be developed, independently of the processes with which they are associated. Each O$_2$ can be in any type of medium as defined by ISO 9001 documentation requirements (ISO, 2008a). For example, an O$_2$ can be a spreadsheet, a database, or an ERP. At this stage we didn't have a clear definition of what an O$_2$ could be in practice; we wanted the participants to think about development outputs that could simultaneously be a part of the company QMS and an IS development project. The requirements for the IS and the QMS are merged in the cells of a unified matrix, identifying the goals and rules to comply, according to different viewpoints (Sommerville & Sawyer, 1997).

During our research, the teams found that these three artifacts were insufficient to provide all the details needed for the sourcing step of ISO$_2$. This problem happened in the case of the new IT application they wanted to build up for the design and development process. Several requirements were missing, for example, we could not identify the responsibilities in approving new product ideas or who/when evaluates the success of the design and development projects. To allow a drill-down of each goal and rule, we created an additional artifact, inspired by the Zachman (1987) framework, as presented in Figure 5-5.

O₂ goal/rule	Type	Why	Who	When	Where	What
Goal / Rule #1	*Outside-in, Within, or Inside-Out*			Comments		
Goal / Rule #2						
Goal / Rule #N						

Figure 5-5. The *O₂ 5W*

The *O₂ 5W* artifact that we present in Figure 5-5 is a table to detail each goal and rule that appears in each cell of the *O₂ matrix*. It is filled in by the IS manager and the QMS manager, assessing for each goal and rule *why* it is necessary, *who* is involved or affected by it, *when* it occurs or must be evaluated, *where* it is applicable in practice, and *what* characterizes it. We decided not to go beyond this level of detail. It was possible to create additional artifacts to detail even further each goal and rule, for example at the level of a software form (more familiar to IS teams), but we wanted to create artifacts that could be used by both the IS and QMS teams, simultaneously. All the introduced O₂ artifacts can be related in a global map, as illustrated in Figure 5-6.
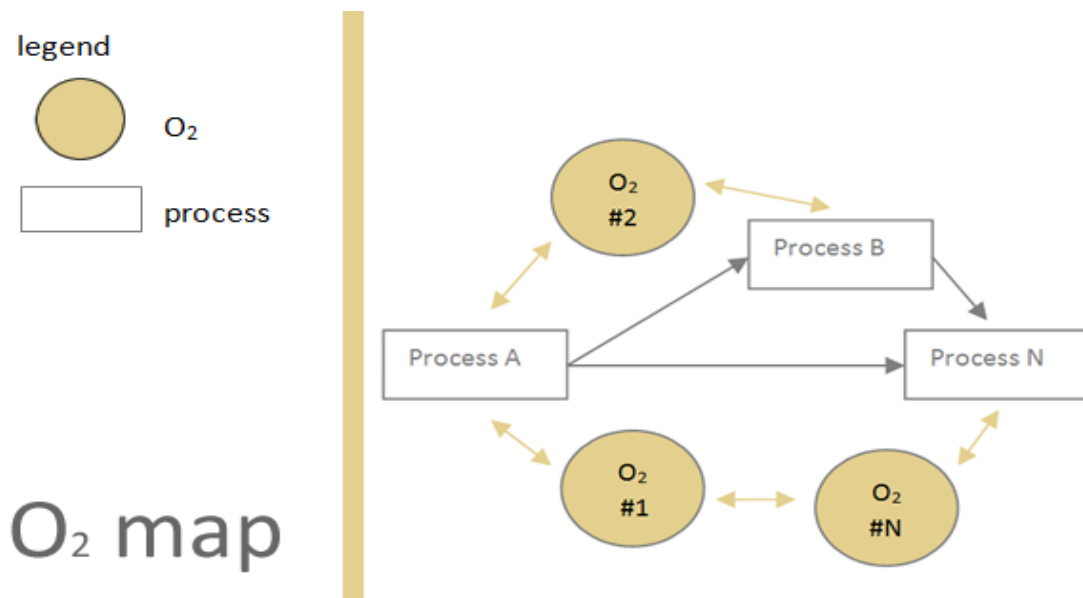
Figure 5-6. The *O₂ map*

The *O₂ map* is a basic representation that connects the processes with the O₂ artifacts that support them. Our purpose was to visually represent the IT elements (the O₂) that support daily processes execution. Only two symbols were used in the *O₂ map*, a circle for the artifacts and a

rectangle for the process. The arrows that link each O$_2$ of the map represent a mutual effect between the process and the system that supports it. If one object changes, all the related objects must be evaluated concerning that change. Figure 5-7 presents the transition of the goals and rules between the artifacts, with data from the technological institute to clarify with an example.
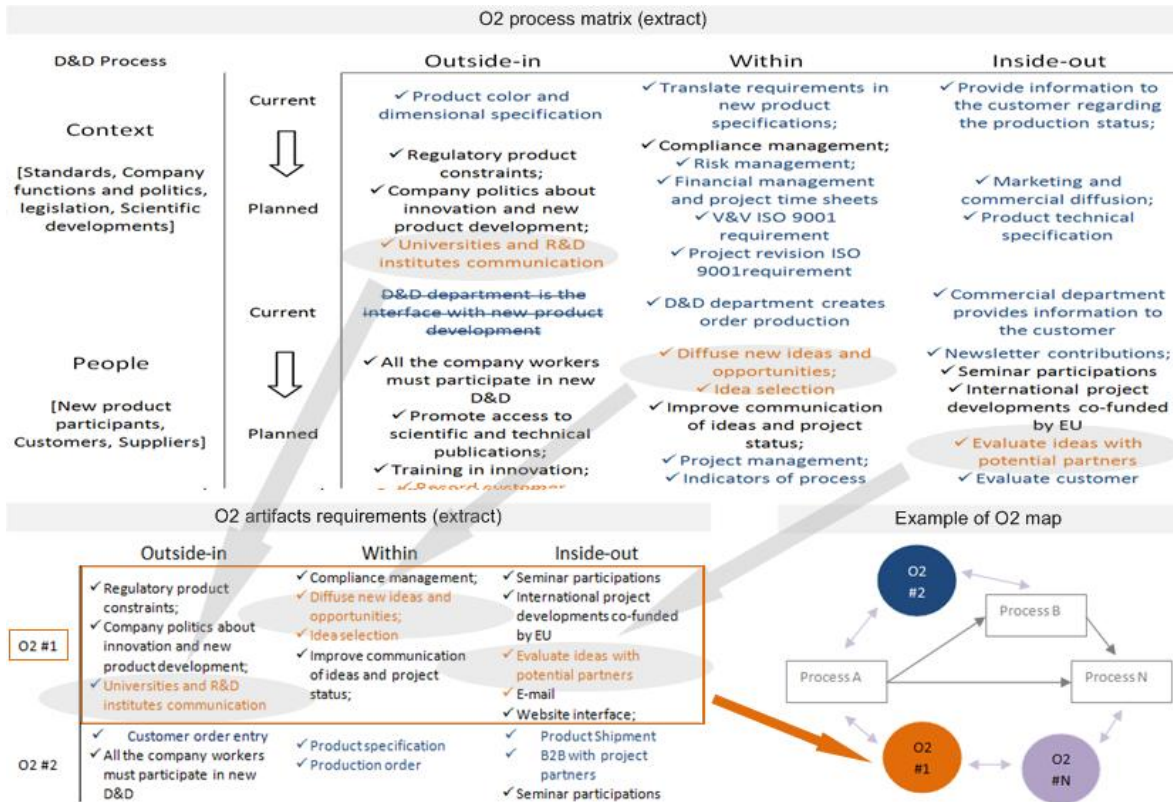
Figure 5-7. The *O$_2$ matrix* (on top), the *O$_2$ list* (bottom-left), and an *O$_2$ map* (bottom-right)

The figure illustrates the three main artifacts of the O$_2$ framework. On top of Figure 5-7 we present an *O$_2$ matrix*. In each line we can identify a current/planned goal/rule that the designers identified for the process. For example, in line 2, outside-in column, the "regulatory product constraints" is required as an input for the process that emerges from context. The designers do not consider that product regulations are properly applied so they put it at the level of a planned requirement (the second column of Figure 5-7 indicates the state "current" if it is implemented or "planned" when it is not). On the bottom-left of Figure 5-7 we find the *O$_2$ list* where we can see the "regulatory product constraints" in the first line of the outside-in column. It is identified as a requirement implemented in the O$_2$ #1 (an output that must be developed). On the bottom-right of Figure 5-7 we can see how each O$_2$ is connected with the process map. In our example the O$_2$ #1 is a system that support "Process A", while O$_2$ #2 (another output that was identified by the designers) is in support of two processes of the organization.

The O$_2$ design is executed as follows:

(O$_2$1) For each process, identify the requirements according with the dimensions of process tasks, people, IT, and context needs (matrix lines). Consider the current and the planned.

Take into account the outside-in, within, and inside-out perspectives (matrix columns) of the process;

($O_2$2) Group the requirements by colors (the color black represents a shared requirement), each one representing an O_2. It may be a new IT platform, a part of an already existing system such as an ERP, or any other means to allow the information flow, providing to each end user the vital process information. For the D&D process, two IT applications are identified: Innovation management (orange) and a Cloud project management platform (blue);

($O_2$3) Repeat $O_2$2 to each process until an ecosystem of O_2 artifacts are designed. All the requirements in the *O_2 matrix* must be included in the *O_2 list* to ensure that each goal or rule is addressed by (at least) one O_2;

($O_2$4) Connect all the O_2 with the processes, completing the *O_2 map*.

Now that we had new artifacts to support our design, we preceded our research according to the ISO_2 steps. The findings are presented in Table 5-3, continuing from the step 4, where we stopped to create the O_2 artifacts.

Table 5-3. Findings from the action research using the O_2 artifacts

Step	Description
4	***Design (to-be) – focusing on the organization.*** The teams understood that they could help each other and promote synergies in the design of the IS and the QMS. Interestingly, the IS/QMS team found that when designing the O_2 artifacts, the process activities were easier to identify. The synergistic development of the IS and the QMS may influence how the company wishes to operate. The O_2 framework had a major impact in our research and has become the focus of the following steps, aiming to improve the business processes design with the collaboration of quality management and IS.
5	***Source the systems – focusing on each O_2 artifact.*** The development team has stated that the approach was simple to use and provided an initial guidance for the systems development. The language was familiar to both teams and the metaphor achieved the desired effect (Lakoff & Johnson, 1980; Lakoff, 1986; Steen, 2008), which is to be adopted simultaneously by the teams and to improve communication among the teams and with the end users.
6	***Deploy – focusing on the development results and the people usage of the O_2 artifact.*** A number of documented procedures and IT platforms were implemented at this point. Contrarily to what we thought, the artifacts were not helpful for the training to end users (the cells had too much information to present in training sessions). The O_2 artifacts were best fit for the step 5. Nevertheless, the new platforms that were developed incorporated the QMS procedures and rules, contributing to internalize the QMS practices, in the opinion of the development team.

Step	Description
7	*Evaluate – focusing on people satisfaction with the O₂ artifact.* We have launched the same questionnaire of step 2 (Antunes & Cunha, 2013). The process pain points were reduced when compared with the initial results of step 2. Later, the auditors have recorded the integration as strong point of the QMS in an external ISO 9001 audit. One external consultant of the institute said that "*It's common that IT supports quality, what is uncommon is that we do not need to surf blindly in a jungle of disconnected software to find evidences of each requirement (...) for each process what we look for are those O₂ elements (...) QMS process maps usually represent what people do, scarcely how they do it*". We add that why they do it is also essential. The O₂ artifact shows the organizational interfaces and the evolution from a plan to the real. After five months, 85% of the quality preventive and improvement actions aim the IS or are achieved through the IS and the QMS joint developments.

The next two sections present the evaluating phase of CAR (Susman & Evered, 1978). We start with the evaluation of ISO₂ that is our main research focus. Complementarily, we contributed to the evaluation of MUVE in the context of the ISO 9001-based QMS (Antunes et al., 2014), as presented in the sequent section.

5.2.6 Evaluating ISO₂

According to the IS/QMS practitioners, ISO₂ helped them in the identification of the IS and the QMS requirements according to the dimensions of *context*, *people*, *process*, *IT*, and *information/data*. Furthermore, the integrated perspective provided by the O₂ artifacts included both, the management and the process participants' viewpoints. First, the use of the matrices guides the designers to think about all the different information that can be useful to characterize the situation of the organization, that is the *context* (Dey, 2001). Second, the ISO₂ approach starts from a general preparation but then evolves towards the *process* level, aiming at reducing process friction (Antunes & Cunha, 2013). Third, the *IT* becomes an intrinsic part of the synergistic design, with the identification of new opportunities for IT development and also with the effort of mapping the existing official and unofficial IT applications of the organization (Handel & Poltrock, 2011) with formal and informal business processes (Paul, 2007). Forth, information/data is presented as a flow that is obtained from the exterior of our systems (outside-in), is enriched and changed trough the system (within), and then delivered (inside-out).

However, there is a need to consider some type of improvisation while using ISO₂ and the proposed artifacts. We agree with the warnings and suggestions of Pentland and Feldman (2008) regarding the differences between routines and artifacts. Although managers design artifacts that may embody a guidance for routines, there may be different patterns of action through those artifacts (Pentland & Feldman, 2008). The authors suggest several guidelines to assist in the development of routines; we highlight (Pentland & Feldman, 2008): (1) understand that practice develops patterns of action, where artifacts can help in conjunction with training, incentives, and

organizational policies; (2) consider the distinct points of view of the participants; (3) think about design points rather than decision points, so that users become the designers, not simply selectors of alternatives imposed by management; and (4) prepare for continuous engagement and change.

The approach was evaluated as simple to adopt by its users. We found the results encouraging, namely the feedback of the quality auditors and the increased participation of the IS team in the QMS development. However, ISO_2 was still incomplete regarding our research purposes. First, it mainly tackled the design phases of the systems, providing limited support for run-time after IS and QMS are in use. Second, several details were missing from the requirements of the developed IT solutions (the O_2), namely those concerning regulations. To comply with those regulations (e.g., customer contract agreements) is a part of ISO 9001 requirements (ISO, 2008b) that we did not address in the information of the matrices (a problem that the IS team identified due to late requirements concerning legal aspects and policies of the organization). Third, pedagogic aspects of quality were missing, namely how ISO_2 supports the principles of quality management, contributing for people learning and change of practices.

Next, we will describe the evaluation of MUVE because it was conducted in parallel to our main research purpose.

5.2.7 Evaluating MUVE: contribution to a complementary research

We had the opportunity to assess the consequences of the experiment in regards to changes in BPM approaches. There are known problems in adopting a process approach in ISO 9001-certified organizations. According to Iden (2012), there is the risk of the quality system being perceived as something that is forced upon the organization, instead of an opportunity to generate value. In this case, we were told that the experiment with MUVE produced a positive effect in three process management dimensions considered by this author, namely (1) process awareness, (2) process measurement, and (3) process improvement.

First, the organization believes that MUVE promotes process awareness by guiding process participants to reflect beyond the mere sequence of activities. They become engaged in the development of a comprehensive outlook of the processes they are involved in, as these become the main organizational unit to improve. This stems from the efforts to reduce the friction, and also leads to narrowing the gap between how a process is described and how it is actually executed by the employees. The technological institute's manager that implemented MUVE said:

> *"(...) it is a framework to extract process knowledge from the process participants and, at the same time, guide them in the creation of a new vision for the process that needs to be negotiated with distinct stakeholders (...)".* She also stated *"(...) some of the employees initially felt that MUVE was implemented to assess and improve their work motivation* [since] *(...) they were asked to think about a process beyond the conventional task sequence. Now they have a more accurate perspective of what a process really is about (...)"*

The top management also found benefits in the approach, because:

"(...) top management does not need to know all the details of every single process, but it is important to understand the perspective of our employees and compare it with the perspective of the managers. Moreover, it is important to provide information to the employees regarding the effort that the organization makes in improving the processes with their contributions (...)"

Second, the organization believes that MUVE is useful in addressing a less explored process measurement: sustainability. This depends on participant adherence, which, in turn, is tied to their satisfaction with the processes. Although measuring the satisfaction of employees was already a concern of the quality manager, this assessment was not process oriented, rather focusing on general aspects such as the motivation and the resources that the employees have available to perform their work as a whole. The experiment with MUVE provided a finer grained perspective of the employees' satisfaction with the processes they were involved in. For the future, the organization intends to explore how this process satisfaction and overall employee satisfaction correlate. Nevertheless, at this point, the findings already suggest that the MUVE can provide a form of evaluating satisfaction that is complementary to the usual ISO 9001 inquiries. This, in turn, is another contribution towards strengthening the process approach in the organization.

Finally, the technological institute believes that MUVE contributes to process improvement. Specifically, in a structured bottom-up approach, involving process participants, instead of the more traditional top-down mandate that is frequently seen in quality systems (Iden, 2012). The identified improvements thus mainly fall under people involvement and process alignment (with the organizational structure, strategic planning, and information technology), two key concepts for the success of BPM and organizational performance (Hung, 2006). For an ISO 9001-certified organization, avoiding deviations from the established processes is particularly important, so as to avoid nonconformities in quality audits. Another aspect that the organization intends to explore further is the ability of MUVE to elicit suggestions for improvement in processes that are adjacent to the one under analysis. For example, while discussing the results obtained when using MUVE to evaluate the innovation process, suggestions emerged regarding improvements to the marketing process:

"(...) [innovation department] *need to think about the commercial presentation of the new product as a critical activity of the innovation process (...)"*

Curiously, the innovation process was not even linked to marketing in the process map (but rather to the development process). In this case, the results suggest that MUVE can go beyond process-focused improvement and into a comprehensive and interconnected view over the process map. Nevertheless, new variables must be considered in this scenario, because changing multiple processes simultaneously was not a purpose of MUVE. The technological institute's manager reported the need to address that possibility by:

"(...) including action negotiation, and a global improvement plan, to avoid the risk of reducing friction in one process, and, at the same time, increasing friction in a distinct process (...)"

From this case, we gathered indications that MUVE can be used with ISO_2 to evaluate problems and improvement opportunities, according to the viewpoint of process participants.

5.2.8 Specifying learning

We include this section to highlight specific aspects learned. However, learning is present in the entire CAR cycle (Davison et al., 2004; Lindgren et al., 2004; Susman & Evered, 1978) and across the different sections of the research description. Moreover, the learning outcomes "*are also recognized as temporary understandings that serve as the starting point for a new cycle of inquiry*" (Lindgren et al., 2004, p. 441).

The first thing we learned it that it is possible to improve the practices of developing the IS and the QMS in the context of ISO 9001. Second, the proposed ISO_2 approach improves a problematic situation, has the potential to be adapted to specific situations, and has margin for progression. Third, a sequence of steps can provide a high-level guidance for the IS and QMS teams, but there is a need to provide artifacts that practitioners can use. Forth, the O_2 artifacts can be used as "glue" that bonds systems' dimensions to assist the IS and the QMS teams to continue their work in a coherent and collaborative way. The fragile connection between process change and IS development is one of the major contributors for systems failure in the opinion of Baxter and Sommerville (2011). We found that ISO_2 has the potential to provide a better connection between process change and IS development, however, it requires more studies to become effective for practice, during design-time and run-time.

5.2.9 Rigor and validity

Table 5-4 compares our action research instance with the principles of CAR and associated criteria to guarantee rigor and relevance (Davison et al., 2004; Lindgren et al., 2004).

Table 5-4. Evaluating the first action research project (Davison et al., 2004)

Principle of the research-client agreement (RCA)	
Criteria	Our action research
1a Did both the researcher and the client agree that CAR was the appropriate approach for the organizational situation?	The initial objectives aimed at using an applied research process, capable of combining theory building and solving specific problems in organizational setting. CAR was considered suitable, by the researcher and the client, for the complex problem identified, iteratively combining analysis, action, evaluation, and learning.
1b Was the focus of the research project specified clearly and explicitly?	The focus of the research was specified in the Ph.D. proposal, presented to the organization, and approved by the administration.
1c Did the client make an explicit commitment to the project?	We established a protocol that explicitly committed the organization with the research. Additionally, the client partially supported the research costs, considering the research essential to its future and improvement. The technological institute included this research and the objective of supporting the Ph.D. thesis in its strategic plan for 2008-2015. A majority of their associates approved the plan in the general council.
1d Were the roles and responsibilities of the researcher and client organization members specified explicitly?	The researcher specified his role in the research project, differentiating his unit manager role and his researcher role. The organization was responsible for supplying the required resources for this project.
1e Were project objectives and evaluation measures specified explicitly?	The project description approved by the organization identified the objectives for both theory and practice.
1f Were the data collection and analysis methods specified explicitly?	The methods for data collection and analysis were specified in the research proposal. The project plan allowed specifying them in even more detail, defining the tools to use in the research, and confidentiality issues to ensure.
Principle of the cyclical process model (CPM)	
Criteria	Our action research
2a Did the project follow the CPM or justify any deviation from it?	The project proposal and the detail plan considered all the phases of a CAR cycle, namely diagnosis, action planning, action taking, evaluation, and learning. Later in

		this chapter we present additional cycles of CAR that we conducted in the technological institute.
2b	Did the researcher conduct an independent diagnosis of the organizational situation?	We conducted an independent diagnosis to identify the opportunities and the problems in the organization. The diagnosis was transparent and considered by the client as the most adequate way of starting improvement. The organization is subject to several internal and external audits that allow framing an independent view of the situation.
2c	Were the planned actions based explicitly on the results of the diagnosis?	We based our plan in the results of the literature review and diagnosis of the client-setting infrastructure.
2d	Were the planned actions implemented and evaluated?	We implemented the preliminary ISO_2 approach and used the artifacts in daily practice. The evaluation has included the insights obtained from the organizational users.
2e	Did the researcher reflect on the outcomes of the intervention?	We reflected about the actions taken and their outcomes. The sequent cycles, in distinct settings, benefited from input resulting from our reflection.
2f	Was this reflection followed by an explicit decision on whether or not to proceed through an additional process cycle?	There were interesting findings in the first research cycle; however, many questions were raised justifying additional cycles in distinct settings.
2g	Were both the exit of the researcher and the conclusion of the project due to either the project objectives being met or some other clearly articulated justification	Although the organization considered the results as an advance to their practice, we found the justified need to continue this intervention. The organization was willing to participate in sequent cycles.
Principle of theory		
Criteria		Our action research
3a	Were the project activities guided by a theory or set of theories?	The project was preceded by a systematic review that identified the key literature to consider in the design-time and run-time phases of the synergistic QMS and IS development. Additionally, the case studies created a frame of reference to use when starting with action research. Theory was compared with CAR findings and used to guide our activities in the field.
3b	Was the domain of investigation, and the specific problem setting, relevant and	We identified the research objectives in collaboration with the organization to ensure that they represented a

	significant to the interests of the researcher's community of peers as well as the client?	problem of their interest, as we also identified in the literature. From an academic perspective, the problem was previously identified by Cunha and Figueiredo (2005). The action research results were presented in a conference (Barata & Cunha, 2014a), a journal paper (Antunes et al., 2014), and a book chapter (Barata, Cunha, & Barata, 2014).
3c	Was a theoretically based model used to derive the causes of the observed problem?	We created a theoretical model according to the results of a systematic literature review. We framed the scope of quality to ISO 9001, although different standards and regulations were complementarily used.
3d	Did the planned intervention follow from this theoretically based model?	The ISO_2 approach and the O_2 framework guided our intervention plan. The foundations to our plan were set according to theoretical models that we presented in Chapters 2 and 3.
3e	Was the guiding theory, or any other theory, used to evaluate the outcomes of the intervention?	Simultaneously to the practitioners' evaluation, we have used the lens of the guiding theory to evaluate the outcomes. We compared our results with the problems identified in the literature review and case studies presented in Chapter 4.
Principle of change through action		
Criteria		Our action research
4a	Were both the researcher and client motivated to improve the situation?	The client's mission is to support innovation in organizational practices (usually participating in international research projects). They were motivated to implement the results internally. Our motivation was to solve a practical problem in the researcher's own professional setting, simultaneously contributing to science, following CAR.
4b	Were the problem and its hypothesized cause(s) specified as a result of the diagnosis?	The problem and the potential improvements were initially specified as a result of the literature review that preceded the diagnosis. Then, a collaborative diagnosis detailed the problem and specific issues to address in the action plan.
4c	Were the planned actions designed to address the hypothesized cause(s)?	The diagnosis allowed us to identify the problems of not having an IS/QMS joint development. The lack of an integrated approach was a cause identified by the organization for the IS and QMS problems. In the first cycle reported, the planned actions aimed at developing and refining ISO_2 approach.

4d	Did the client approve the planned actions before they were implemented?	The client approved the research actions as defined in our proposal. Due to the need to report regularly to top management, the actions were previously evaluated and approved.
4e	Was the organization situation assessed comprehensively both before and after the intervention?	The IS and the QMS managers have participated in our case studies preceding CAR. The researcher had a complete and comprehensive knowledge of the organization situation. After the intervention, the researcher continuously challenged the results gathering feedback from the process participants and the quality auditors.
4f	Were the timing and nature of the actions taken clearly and completely documented?	Throughout the project actions, all the activities were documented and reported by (1) summary reports to the Ph.D. supervisor, (2) research papers, (3) documents that now integrate the QMS of the organization, and (4) internal progress reports to top management of the institute.
Principle of learning through reflection		
Criteria		Our action research
5a	Did the researcher provide progress reports to the client and organizational members?	Executive summaries and research papers were provided to the client. Research papers were included in their annual balance, publicly accessible to companies, other institutes, and governmental agencies. We provided oral communication on a regular basis, with top managers and other members of the organization.
5b	Did both the researcher and the client reflect upon the outcomes of the project?	Reflection is an important part of CAR (Susman & Evered, 1978), conducted in meetings with the organizational members. We collaboratively reflected about the benefits of this ISO_2 and the shortcomings that required continuing the research in different organizations.
5c	Were the research activities and outcomes reported clearly and completely?	We published research papers concerning this case. Additionally, we provided work reports and quality documents for client use.
5d	Were the results considered in terms of implications for further action in this situation?	We used the results to prepare the next action research cycle. We also reflected on how to use future results in the technological institute, ensuring that their participation will continue.

5e	Were the results considered in terms of implications for action to be taken in related research domains?	The results were discussed regarding its implications in the consulting services that the institute provides. The research implications are relevant for quality and IS consultants, but also ISO 9001 auditors. We identified the need to address regulatory management in our sequent cycles.
5f	Were the results considered in terms of implications for the research community (general knowledge, informing/re-informing theory)?	The implications of the results are important for both IS and quality researchers. Our research adds to the knowledge of synergistic developing the IS and the QMS, providing tools to assist practitioners, and reporting the findings in the selected organization.
5g	Were the results considered in terms of the general applicability of CAR?	The limitations are discussed in this case. We followed the phases of CAR in our project, leading to results that can benefit both theory and practice. CAR was applicable to this complex context. The technological institute considered that CAR has the potential to increase research and development in organizations, involving researchers and practitioners in search of solutions for concrete organizational problems.

5.2.10 Conclusions of project AR1

We gathered indications during our research that a synergistic approach to the joint development of the IS and the QMS can individually improve them, as well as the organizational outcome of their integration. To the best of our knowledge, ISO_2 is the first practical approach meant for the synergistic development of the IS and the QMS, in the context of ISO 9001. According to the auditors and the IT personnel, ISO_2 improves the results when compared with the practice of developing the two systems independently. We combined aspects of IS and QMS methodologies in ISO_2, coping with the IS problems of diversity, knowledge, and structure (Kautz et al., 2007). A common abstraction level is determinant for the teams' communication and, eventually for the success of a joint development. The O_2 artifacts are that construct, built to complement existing business process documentation, accessible to different experts, including goals and rules that both the IS and the QMS must implement in daily practice. The developers found the ISO_2 suitable when developing the IS and the QMS from scratch or after a certification. A benefit of this approach is to focus the participants in the steps and the development outcomes, providing detail to the process layer. The O_2 matrices can assist ISO 9001 auditors in the traceability of requirements, processes, and IT.

In spite of the obtained insights, several limitations can be identified in this cycle. First, the ISO_2 approach was still under development. Our main effort in this first cycle was to create the artifacts, therefore, we still have little evidence about the result of its use in practice. Second, the O_2 framework creates a structure of several O_2 artifacts, which are not yet completely defined at

this stage of the research. Third, we have considered a case with the existence of internal IS and QMS departments but the positive effect that we found may not be replicable in distinct client settings. Forth, the positive results must be carefully evaluated because a socio-technical intervention has risks, for example the Hawthorn effect which suggests that the participant intervention can change the situation and potentially interfere with the observed behavior (Myers & Newman, 2007), which could be "*related only to the special social situation and social treatment they received*" (French, 1950).

Several issues remain open. For instance, how both IS and QMS teams can deal with a stronger interdependence of both systems and include other managerial functions in their construction. The number of companies that adopt multiple standards, creating a system of systems with ISO 9001 at its core, has been increasing (ISO, 2012b). The auditors have pointed out that ISO_2 can be adopted for managing organizational legislation awareness (outside-in), the internal application of the law (within) and how to comply with the report obligations (inside-out). The layers of the O_2 framework can be adapted or extended to include requirements and policies related with the environment management, health and safety, social responsibility, or the integration of other standards (Jørgensen et al., 2006). These inputs from the technological institute give us a strong motivation to proceed to the next action research project, which aim at studying and refining the ISO_2 support for the design-time (Barata & Cunha, 2013b).

5.3 Project AR2: refining ISO_2 for design-time

> "*In the **proof of value** step, researchers design a prototype with sufficient robustness and functionality to solve at least one important real-world problem. (…) Theoretical insights may be derived to explain effects that only emerge when people try to do real work*" (Briggs et al., 2011)

After the first action research cycle there was a first version of ISO_2 and a set of artifacts to use in practice; however, we need to increase the complexity of the second project to: (1) include additional experts in the design-time effort, namely other managerial functions of the organization; (2) work in different industrial client settings; (3) widen the context of regulatory support with ISO_2. These objectives are justified with the findings from the first cycle and the ISO 9001 principles that envisage (ISO, 2008b): (1) people involvement; (2) adoption of the standard in multiple economic sectors; and (3) conformity to applicable regulations.

The organizational regulatory space (ORS) is a key element of contemporary societies, as discussed in Chapter 2, shaped by laws and standards, internal policies, norms, contract agreements, and corporate procedures (Hancher & Moran, 1989; Parker, 2000). Distinct experts with financial, legal, technological, and managerial knowledge design the ORS. However, more than a complex set of business rules, the ORS is a holistic conceptual space where people develop

specific processes, interacting with each other and with the environment, and exchanging information (Parker, 2000). The regulatory space becomes unique for each organization.

Although a number of studies address the problem of compliance modeling and checking (Kharbili, 2012), we could not find a framework for cooperation in the initial phase of designing the goals, rules, and boundaries for the compliant behavior in the context of ISO 9001. Moreover, there is a gap concerning the compliance extraction and elicitation, and the holistic representation of the regulatory space. To increase the chances of developing a joint design of the ORS, all the stakeholders must work together from the beginning. The second action research project addresses several regulatory management problems identified by Abdullah et al. (2010a, 2010b), namely, the lack of compliance culture; top level management support; perception of compliance as a value-add; communication among staff; compliance knowledge base; holistic practices; and IT support/tools. The next section explains our project setting.

5.3.1 Project setting

This project started with four organizations, but, unfortunately, one of them did not complete an entire CAR cycle. There is a company from the ceramics industry (case #2.1), a company from the food industry (case #2.2), the technological institute from the previous cycle (case #2.3), and a company from the aeronautics industry that later canceled their participation (case #2.4w). The company from the ceramic industry was having difficulties in managing regulations required by customer audits. Moreover, they had nonconformities from external audits that urged to be solved. We also presented the project to a food company, immediately capturing their interest in participating. We saw the opportunity to refine the approach in a very demanding context regarding human health, which is the case of the food industry (Bernstein, 2009; Meijboom, Visak, & Brom, 2006; Wognum, Bremmers, Trienekens, van der Vorst, & Bloemhof, 2011). The technological institute is the third case that we report and started after the other two organizations. The diagnosis included a fourth company (case #2.4w), in the aeronautical sector. This last setting was not addressed in sequent phases of CAR, because the company decided to postpone the project when its administration changed. Nevertheless, we decided to report the findings for the diagnosis phase due to the interest of identifying a regulatory context in distinct settings.

Table 5-5 lists the action research cases together with the main quality standards that influence the regulatory space of the involved companies.

Table 5-5. Action research cycles of action research project 2

Case/sector	Standards
#2.1: Ceramics	ISO9001, ISO14001, OHSAS18001, SA8000
#2.2: Agro-food	ISO22001, ISO/IEC17025, BRC, and IFS Food Safety
#2.3: Technological Institute	ISO9001, ISO/IEC17025, OHSAS18001
#2.4w: Aeronautics	ISO9001, EN9100, and AS9100

The ceramic company is currently one of the most modern companies in the porcelain and earthenware industry sector in the European Union. The company exports the majority of their production, has qualified human resources and is permanently committed to the training of its personnel and the updating of its processes. For this reason, the company has an effective position in the markets where it operates and its business model is clearly customer-oriented, as suggested by ISO 9001. Its equipment is based on the most advanced technology, and it uses strictly selected national and international raw materials. The quality department carries out work on a continuous basis in terms of assessment and control, and in close collaboration with scientific departments of universities and technological institutes. The company underwent a phase of changes inherent to the evolution of its organizational system, by implementing Kaizen (continuous quality improvement as presented by Chen, Dahlgaard-Park, and Yu (2014)) as a means to improve the productivity and lead time, through a profound restructuring/optimization in the work stations as a means to respond to an increasingly more competitive market. The company holds multiple certifications. Thus, the company undertakes and is committed to an active contribution to the preservation of the environment, by continuously improving its environmental performance, reducing its environmental impacts, and fulfilling the legally imposed requirements. This commitment has been incorporated into the company´s strategic goals in order to further its reputation as a social and ethically responsible company. Besides ISO 9001, the company is also implementing other standards including ISO 14001, OHSAS 18001 for health and safety, and the SA 8000 standard pertaining to social responsibility. This is the culmination of a set of concerns, which the company has at the quality, environmental, social level, and which directly or indirectly interferes with the daily lives of the people in the facilities and the surrounding areas. The company has to comply with over 500 national and international laws, in the scope of their certification. For each one, the company needs to identify the requirements, establish a monitor plan, and compliance actions, if applicable.

The food company dates back to the thirties and it is in the sector of olive production. Its product range was extended to other stock keeping units, such as pickles, lupini beans, hot sauce, and mustard condiment, in a permanent inter-relation with the market. This medium-sized organization employs over 150 people. They export to pizza restaurant chains and supermarkets around the globe. Besides ISO 9001, the company is implementing different food quality standards (Havinga, 2006; ISO, 2005a): International Food Standard (IFS); British Retail Consortium Food Global Standard (BRC); and ISO 22000. The latter, regarding food safety, combines the key components of interactive communication, system management, prerequisite programs, and the principles of Hazard Analysis Critical Control Point (HACCP). BRC was created in 1998 for UK retailers and manufacturers, while German, French, and Italian counterparts developed IFS. Complementarily, the organization also follows the ISO/IEC17025 guidelines concerning its laboratorial activities. Product traceability, law, market regulations, standards checklists, and contractual agreements are major concerns in the company from the food industry, regarding product quality and the production process. Audits by customers, government bodies (e.g., FDA – Food and Drug Administration), and certification authorities are quite regular, at four times on average each month.

The technological institute has already been described. Its purpose in this cycle is to continue with the improvement of the approach and its internal application. The other three participating organizations were customers of the technological institute. Both the ceramic company and the agro-food company had ongoing work with them and participated in the initial set of case studies presented in Chapter 4.

The aeronautics company was created in the nineties and provides technical coatings for engine parts. Their major customers in this field are airplane constructors and aeronautical maintenance industries. They are regarded as a leader in supplying industrial applications of the use of new materials and coating technologies and lauded for a very prompt service on short notice. It is a small company with highly specialized personnel, and an innovation department that works in close collaboration with the quality department. The customers' audits are frequent and the contract agreements in the aeronautics company involve a continuous effort in regulatory management. The company competes in several European markets and belongs to a multinational group that has subsidiaries in different continents.

5.3.2 *Potential limitations*

There is professional relation between the researcher and the organizations in these CAR cases. In the cases of the organizations from the ceramics industry, aeronautics industry and the food industry there was a customer–supplier relation with the technological institute, of which the researcher was staff. The advantages that we found in the deep knowledge of the technological institute' processes and people did not occur with the other cases, because our previous contacts were confined to specific departments of those industries, namely the IS and the QMS departments. To address the potential difficulties that could arise from confusing our research

with other projects (e.g., past consulting projects) we presented to the top managers our research proposal, stating its purposes clearly.

This action research project had multiple cycles in different sites, different economic sectors, and dealt with multiple regulations: there was a risk of losing focus in ISO 9001. Once again, we carefully evaluated our results regarding the requirements of the standard to ensure that we were addressing the ISO 9001-based QMS and not other systems that may coexist with it, such as environmental management or health and safety, supported in different standards. However, this diversity was an opportunity to improve our ISO_2 approach in several ways: first, we could test the use of the developed artifacts in different settings; second, we expected that the different sectors were not a problem because ISO 9001 is applicable to them, but our confidence was not the same regarding other regulations, which are required by the standard, but may be restricted to specific sectors or products; third, the potential high number of laws and the different types of regulations was a concern. Due to these potential restrictions, our diagnosis included the analysis of the type of regulations that we needed to address and the impact that they had in the daily work of the research participants, as we present in the next section.

5.3.3 Diagnosing

The initial diagnosis was conducted simultaneously in four organizations, to understand the regulatory context and the artifacts used (Perry & Sanderson, 1998). This information was important to adjust our action plan. Initially, we aimed at specifying which organizational management functions were most involved with regulations, their perspective of the regulatory space, and cooperation between functions. We used an accessory quantitative tool to identify (1) key management players of the regulatory space and (2) regulatory influence in each management function. We used the data gathering techniques of document collection, and interviews conducted with several managers of each organization (Myers & Newman, 2007).

We now invite the reader to imagine the multiplicity of opinions when: the chief executive officer (CEO), the integrated systems manager (IMS – integrating quality, environmental, health and safety), the chief financial officer (CFO), the legal adviser (LA), the marketing manager (MM), and the chief information officer (CIO) are designing the ORS. The scenario may involve different viewpoints and concerns, although they are all interested parties in the regulatory goals and rules. The regulatory perspective of these stakeholders is described as follows.

The food company and the aeronautics organization presented a higher diversity of laws and contractual agreements, when compared to the other cases. The four companies acknowledged the relevance of the regulatory space, although they could not represent it clearly, as an holistic model. Citing a top manager of the company involved in the food sector: *"we need a map or we get lost in a jungle of regulations (...)"*. Each interviewee had his/her own partial perspective of the regulatory space. Although the four companies had different managers for different standards, they all had an integrated system manager (IMS) to coordinate the company certifications. According to the interviews, the primary concerns of the IMS were the requirements of the standards and the regulatory audits. The CFO was also head of human resources management in

the four cases. All the LAs were external and concerned with the legal context. The LAs recognized that they made preventive work, such as to notify the organization of the most relevant legislation, although the majority of their interventions were originated at the request of the CEO. The contractual agreements were central issues for the MM and the CEO. While the CFO was mostly concerned with financial regulations, the CIO was specially focused on IT to support compliance and the regulations.

The four companies use IT to support regulatory management, including the subscription of web portals for legal information, multiple disconnected spreadsheets of legal obligations (e.g., compliance checklist, product specifications list, external documents control lists), and content management systems for regulatory documents, such as laws, standards, contracts, and procedures. According to the managers' feedback, the IT support was insufficient for an effective regulatory management, because it consisted of mere lists of obligations. Worse, regulatory management was burdensome, with no added value for practice of these organizations. The ceramic company IMS manager reported "*It is a disappointment when we realize that there is an enormous effort of regulations management, but I am the only one that uses this spreadsheet* [their main IT support for regulatory management]. *It is difficult to make it an effective tool for other departments. Regulations are not a shared issue*".

To identify key management players of the ORS, we asked the top and intermediate managers of the four organizations to classify from 1 (none) to 5 (very high) their regulatory cooperation. We have defined regulatory cooperation as the need to work with other management functions, taking into account communication frequency, and/or dependence on the other functions to achieve regulatory compliance. The median values of those classifications are presented in Table 5-6.

Table 5-6. Regulatory space cooperation: the manager's perspectives

With / Manager	CEO	IMS	CIO	MM	LA	CFO
CEO		3	3	3	5	5
IMS	5		4	4	2	3
CIO	5	2		2	2	4
MM	4	3	2		2	2
LA	5	2	2	2		4
CFO	5	2	3	2	3	

The table presents the median classification according to the perspective of each manager (table lines) regarding the regulatory cooperation that she/he had with the other managers (table columns). It is possible to contrast the managers' perspectives. For example, while the CEO scored 3 in the need to cooperate with the IMS (second column of results in the first line), the IMS ranked his/her need to cooperate with the CEO with the maximum value of 5 (first column of results in the second line). These answers are pertinent to understand the setting of the selected cases, according to the persons that we contacted. They suggest that all the interviewees need to communicate in the regulatory space. The CEO and CFO are core players of the space (both reported 5 in the need to cooperate with each other). The LA does not appear to have a central role in the ORS. The reasons differ. For instance, in case #2.1 and #2.3, the legal regulations are less significant when compared with other types of regulation. In all cases, the LA communicates sporadically with the managers. Although some functions report lower levels of regulatory cooperation (e.g., the CIO and MM, with the value of 2), the goal of our approach is that all may be involved in the ORS design.

The CEOs of the four organizations reported that managing of the regulations, people, IT, and processes was independent and difficult to reconcile. For instance, a number of employees did not know all the essential legislation applicable to their work; internal procedures did not properly reference legislation; there was a lack of awareness on how each regulation was supported by IT; and it was difficult to link IT and organizational processes. Subsequently, we asked the managers about the most relevant types of regulations for their daily activities. The results are presented for each case, because we found more differences among the sectors.

The next table presents the case in the ceramics company.

Table 5-7. Regulatory influence in each function, by type of regulation: ceramics

Type \ Manager	Law	Standard	Contract	Internal procedure
CEO	2	4	4	4
IMS	4	4	3	5
CIO	2	3	4	4
MM				
LA	5	3	4	3
CFO	5	3	4	4

We could not interview the MM so the results are not included for that line. We could talk to him later and found out that contracts and laws are considered the most important regulations; conversely, internal procedures had the lowest influence. Legal aspects are concentrated on

specific managerial functions, namely LA and CFO. This occurs due to the high-value contracts involved in this sector (export industry, many products, and several deliveries to the same customer). The IMS is mainly focused on internal procedures, since the contact with external entities is mainly a responsibility of the marketing department and the provisioning department. This characteristic may differ in smaller organizations that we found in the cases studies presented in Chapter 4, where the IMS also deals with customer requests and suppliers relations. The organization does not adopt specific IT standards (e.g., ISO/IEC 20000 for IT service management, or ISO/IEC 27001 regarding information security management). The CIO participated in specific projects that included prototype development, mainly affected by contracts and internal procedures. Legal aspects were the main type of regulation for the work of the LA and CFO, as we expected. It is important to mention that these answers are according to each manager's perception. Table 5-8 presents the result of the food company.

Table 5-8. Regulatory influence in each function, by type of regulation: food company

Type / Manager	Law	Standard	Contract	Internal procedure
CEO	5	5	5	5
IMS	3	5	3	5
CIO	3	3	3	4
MM	2	2	5	4
LA	5	4	5	4
CFO	4	3	2	5

When compared to the first case, this organization seems to be more influenced by regulations. This could be due to the government and customer influence in both the process and the product regulations. The CEO is much more involved with regulations in this case, also concerning contacts with associations of the sector. The IMS presents similar results when comparing to case #2.1, with less influence from legal aspects, explained, according to her, due to the other managerial involvement with those issues. Also in this case, the internal procedures are a major concern of the CIO. The MM told us that she was constantly involved with supermarket chains, so the contractual agreements were the most important regulations. The LA is also involved with internal regulations in this setting and, finally, the CFO stressed the internal procedures impact due to the type of work involved and human resource management concerns. Again, in this case, our purpose is to understand the perception of the managers involved, representing only the specific case.

Table 5-9 presents the evaluation for the technological institute.

Table 5-9. Regulatory influence in each function, by type of regulation: technological institute

Type / Manager	Law	Standard	Contract	Internal procedure
CEO	5	3	2	4
IMS	3	5	2	5
CIO	2	2	3	4
MM	2	2	5	3
LA	5	3	4	4
CFO	5	3	4	3

The organization regularly conducts projects that are funded by government authorities. The CEO mentioned this aspect to justify the higher evaluation of laws. Regarding contract agreements, the CEO assigned a lower grade for impact, justifying his interpretation of the common contracts of the technological institute, usually consulting and laboratorial related. Consistent to the other cases, the IMS stressed the major influence of internal procedures, one of the most demanding tasks that she has. It not only influences her work, but also consumes her time with its changes and adaptations. Due to the concentration of legal aspects with the LA, CEO, and CFO, the MM told that her most important regulations were contract agreements, especially concerning laboratorial projects, consulting, and technology transfer. The CIO was more influenced by contract agreements and internal procedures, similarly to the previous cases.

Finally, Table 5-10 presents the results for the aeronautics company that we visited.

Table 5-10. Regulatory influence in each function, by type of regulation: aeronautics company

Type / Manager	Law	Standard	Contract	Internal procedure
CEO	4	4	4	5
IMS	2	5	3	5
CIO	3	3	3	4
MM	2	2	5	5
LA	4	2	5	2
CFO	3	3	4	3

The CEO reported that all types of standards influenced his work, but he assigned higher importance to internal procedures, constantly audited by certification auditors and aeronautics customers. For this reason, contracts and procedures was also an essential part of the MM work with regulations. The complexity of those contracts frequently involved the participation of the LA. Also, in this case, the CIO work was mostly influenced by internal procedures.

To provide a global outlook over all the cases, the median values of the results in the four companies are presented in Table 5-11.

Table 5-11. Regulatory influence in each function, by type of regulation: median values

Type / Manager	Law	Standard	Contract	Internal procedure
CEO	4,5	4	4	4,5
IMS	3	5	3	5
CIO	2,5	3	3	4
MM	2	2	5	4
LA	5	3	4,5	3,5
CFO	4,5	3	4	3,5

The median of all the table values is 4 (high). The answers show that each manager has a distinct perspective of the regulatory space (e.g., contract agreements by MM; standards goals and rules by IMS). Concerning the CEOs and IMSs, they justify the high classification of the internal procedures (median of 4,5 and 5 respectively) with the "*need to set the example*" to others. This effect was not found in law, standards, and contract regulations. Is possible that when defining internal policies or converting a law to internal rules or goals (internalization), the compliance may be improved by "setting the example". Nevertheless, we must be conscious of the risk to "*face temptation to be content with creating appearances that will promote confidence and to be less concerned with ensuring that this confidence is actually warranted*" (Shearing, 1993, p. 76).

Our work of diagnosing was mostly influenced by the interviews, but we found this type of quantitative evaluation a useful complement for the study. The most important advantage that we found in using this quantitative data, even more relevant than the numerical interpretation, was to focus the interviewees in the conversation we had, suggesting their reflection about the cooperation with colleagues and about the type of regulations they dealt in practice. We found that the ORS is not designed by one person; it is a result of a socially constructed negotiation (Hancher & Moran, 1989). The experts unanimously confirmed the importance of both internal and external regulations, safeguarding the differences: they had less influence in external regulations, except in the case of lobbying by their associations; and internal regulations were seen as a mixture of the

management policies and the external influence of law and standards. The next section presents the action planning.

5.3.4 Action planning

We have started to explore possibilities for our action plan with a process approach to design the ORS, finding regulations for each process. We found in our diagnosis that although a process was a familiar concept to the CIO, CEO, and IMS; the legal, marketing, and financial managers were not comfortable with the concept. The CFO, the MM, and the legal experts stated that contractual agreements and law – their main sources of regulation – were addressed to organizations and people, not internal processes or activities. We also identified problems when the IMS and CIO recognized that the process map and procedures were not detailed enough to design the ORS. A BPMS system (Shaw et al., 2007) could help, but the research would be dependent from new investment that required approval by the CEO. Moreover, the organizations couldn't consider to immediately migrate all the IT to a new paradigm or forgetting the shadow applications (Handel & Poltrock, 2011), such as spreadsheets and desktop databases that seem to have an important role in the regulatory space. We were stuck with different viewpoints, and extended the ISO_2 approach and the O_2 framework to assist different organizational managers in the design of the regulatory space.

The regulatory goals and rules must be identified from the organizational context (outside-in), incorporated in daily practice (within), and then provide external evidence of compliance (inside-out). The construction of the O_2 artifacts is done for each organizational process, this time including more participants in the design of the matrices besides the IS and the QMS managers addressed in the first CAR project. A process approach is fundamental for the IS and for the QMS development in the context of ISO 9001, but some regulations are not process-oriented (e.g., financial regulations) and we also identified potential problems with process approach in the context of ISO 9001 (Iden, 2012). Therefore, we suggest that ISO_2 can be used to achieve a synergistic design of the regulatory space, involving the joint effort of different experts. We started our work with the same *O_2 matrix* template that we had developed in the previous cycle, represented in Figure 5-8.
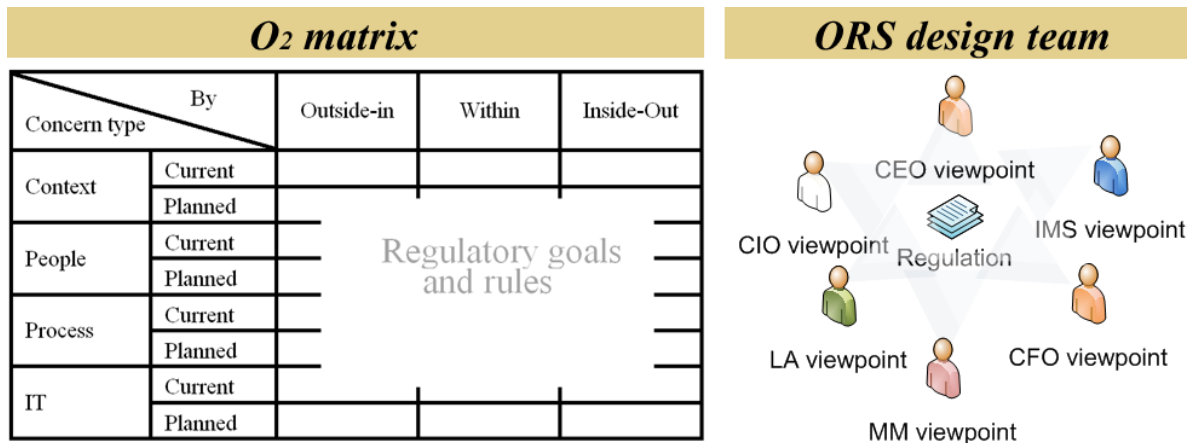
Figure 5-8. The *O$_2$ matrix* (on the left) and the O$_2$ design team (on the right)

While creating the matrices as represented on the left of Figure 5-8, different views of the regulatory space are merged in a common document. The design team is selected by the organization; in our cases they included the managers of different departments. With this mind set, a regulatory space is not a burden, it is a space in which organizations must cooperate and learn to design as a whole, according with multiple viewpoints and concerns (Sommerville & Sawyer, 1997). The use of the O$_2$ framework bridges distinct paradigms of interrelations, such as the organization and the environment (outside-in and inside-out information flows), the processes and the structure (under the context layer), and the inner and outer worlds (van Fenema, Pentland, & Kumar, 2004). However, the O$_2$ framework is only a graphical representation of the main dimensions that must be considered in the IS and the QMS development. After creating all the O$_2$ matrices for the organizational processes, in a sequence of four steps (O$_2$1 – O$_2$4) presented in our first CAR project, we must then proceed to:

- (O$_2$5) Identify other regulations that are not explicit as standard requirements and specify the goals and rules that must be accomplished by the organization;

- (O$_2$6) Identify the cells in the O$_2$ matrices that are affected by the regulation (outside-in), help to comply with the regulation (within) or are meant to provide evidence of compliance (inside-out). New information for the matrix cells may be discovered at this stage;

- (O$_2$7) For each O$_2$ artifact, create a list of the applicable regulations and update the *O$_2$ map*, as illustrated in Figure 5-9.
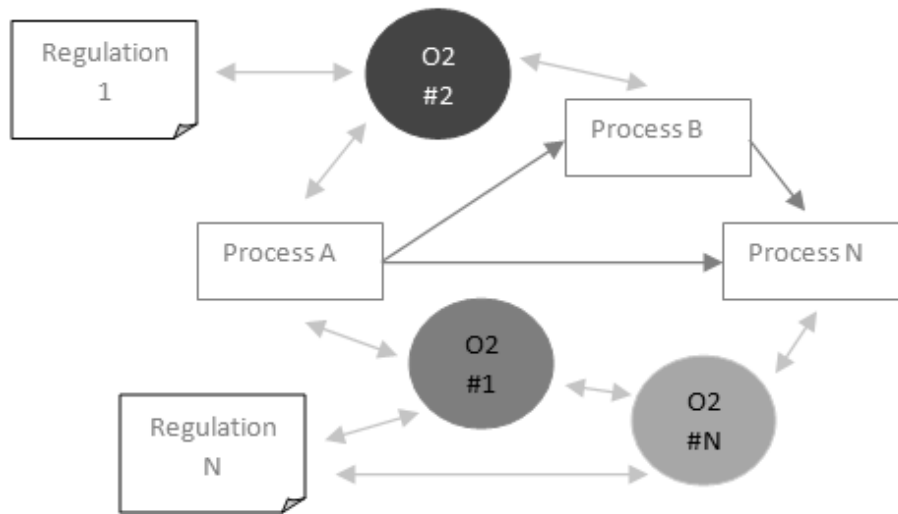
Figure 5-9. The extended O_2 *map*, representing the ORS

The regulations are not directly connected with processes, as expressed in Figure 5-9, but with the elements that the organization uses to manage regulations: the O_2. As we saw in the previous cycle, they may exist in any form or medium (such as paper or electronic) and its requirements are identified with the O_2 artifacts (O_2 *matrix*, O_2 *list*, and O_2 *5W*). This is easier for designers that may not be so familiar with processes; for regulations that are not "process-friendly"; in organizations with deficient process approaches; and, hopefully, more useful for the development of the obtained O_2 artifacts. The O_2 can also be connected with each other, for instance, two systems that need to be integrated or share information. ISO 9001 is a generic standard used by small, medium, and large organizations; therefore, we continue to aim at simple representations that may be accessible to the majority of ISO 9001-certified organizations.

Our decision to employ the ISO_2 approach and the O_2 framework as the action plan was agreed in initial meetings with the top managers of our clients. We also showed them the results of the case study in which they participated, and the sequence that we gave at the technological institute, presented in the first CAR cycle.

The step to identify additional regulations and decompose them into goals/rules ($O_2$5) was simplified when we started the CAR's action taking phase. The organizations already had a list of applicable regulations due to the multiple ISO certifications and constant audits. Step $O_2$6 seemed to be the most demanding if many regulations exist. The difficulty is that for each regulatory goal or rule, we must seek the requirements in all the matrix cells that are somehow related with the regulation (influenced by the regulation, processing the regulation or providing evidence of compliance).

There were three complete cycles in which we applied and refined ISO_2. In spite of the diagnosis that was initiated simultaneously (considering the specificities of each client-system infrastructure) and a global action plan, each site had distinct contributions to the ISO_2 approach. Moreover, the progress of the sequent CAR phases was not simultaneous in the three cycles that

we present. Proceeding with action taking asynchronously across organizations allowed us to introduce specific changes during the research; for example, focusing the technological institute cycle in the development of an application to assist ISO_2 adoption. Therefore, we will synthesize the phase's action taking, evaluation, and learning (Susman & Evered, 1978) according to each client setting. Our findings are focused in ISO_2 design-time and, more specifically, in the use and adaptation of the O_2 artifacts to address regulatory management, in the context of ISO 9001. The presentation starts with the company operating in the ceramics industry.

5.3.5 *Action taking, evaluating, and specifying learning for Cycle #2.1*

First, the design team created the O_2 matrices for the selected organizational processes. They have selected the same processes defined for ISO 9001 certification. Then we have opted to continue steps O_25 to O_27 with a set of the most relevant regulations. As iterations evolve, there is a deeper understanding of the impact of a specific regulation in our context, processes, people, and IT. How that regulation affects the organization (outside-in), how to apply and monitor its compliance (within), and how to provide evidence of compliance in our inside-out activities.

This ORS design with close to 100 regulations (a small set of their applicable regulations) was completed and peer reviewed for 3 weeks, coinciding with an external audit from a major customer. We still didn't have a complete representation of the ORS, but the managers said that even the preliminary presentation with the O_2 matrices provided a better description when compared to their original spreadsheets. According to the IMS manager, one problem is that "*the spreadsheets do not connect regulations with daily work* [processes]*, they only present an inventory of laws and the list of actions to check and ensure compliance*". The customer was interested in evaluating quality and social practices, such as people's work processes and compliance with laws. Interestingly, the O_2 *map* became the instrument for their audit program. The customer decided to ask for each O_2 artifact, which, in some cases, was an IT application (e.g., survey platform for customers and personnel satisfaction), in other cases a documented procedure describing work practices. The auditor made inquiries regarding each function expressed in the O_2 matrices to understand the correspondence with practice.

Creating matrices for regulations, even if not very detailed in a first round, was a slow task. Part of the problem is that we did not have a software tool to support the ORS design. However, by creating the matrices we improve regulatory awareness by the ISO_2 participants, progressively involving more people in regulations, and discovering their real impact in the organization. When compared with the original spreadsheets, this type of modeling is far more complete and accurate, according with the team.

The conclusions of this cycle may be summarized as follows:

- The extended O_2 *map* is a possible representation of the ORS;

- The O_2 matrices and the O_2 *map* were easy to understand by internal staff, and external auditors/customers;

- The ORS designed using our approach may be used for audit programs.

5.3.6 *Action taking, evaluating, and specifying learning for Cycle #2.2*

We initiated action taking in the food company two weeks after the ceramics company started. This company did not have a process map, because the adopted food safety standards did not require or suggest a process approach. Therefore, they have decided to consider their five product production lines as the core business processes. However, some regulations were not specific to production lines but to other processes, such as provisioning, sales or people training. For this reason, as the regulations applicable to their case were evaluated according to the algorithm for designing O_2 artifacts ($O_2 1 - O_2 7$), new processes were identified.

In one of the meetings, the IMS presented a process map proposal to the team. Although considering that process map a first draft, they found that the O_2 matrices had facilitated the identification of their processes, especially the most regulated and vital to people's safety. One example is assets management to ensure safety (e.g., to avoid product contamination in production lines and to ensure the safety of equipment users). This occurred because the regulations have pointed to other critical activities that they performed, not yet systematically managed as processes, or even evaluated in terms of regulations.

The *O₂ map* was presented to the top manager, which had to prepare a meeting in the national association of their sector. The agenda included the discussion of a specific law that required changes. The *O₂ map* and a fragment of the matrices were used to represent the impact of the law in their organization. Until that moment, we had not explored the possible use of the ORS for external communication, except with auditors.

The conclusions of this cycle were:

- The ISO_2 approach and the O_2 framework may be used for the first steps of business processes identification;

- According to the quality manager, the CEO was now more interested in the regulatory design, seeing more benefits from an holistic ORS design;

- The resulting artifacts may be useful for external cooperation.

5.3.7 *Action taking, evaluating, and specifying learning for Cycle #2.3*

This cycle addressing ORS modeling is a sequence of the first CAR project that we presented in section 5.2. The phase of action taking at the technological institute started after the conclusion of the CAR cycles involving the cases in the ceramics and the in the food companies. For this reason we could adapt our action plan and take advantage of the IT development capabilities that the organization possessed. Since we had already developed O_2 matrices in the first project with them, we decided to concentrate focus the case in the development of a software tool and in a prototype of a more advanced ORS map. The experience obtained from the ceramic and the food companies was also valuable for the development of the support tool, whose main screen is presented in Figure 5-10.
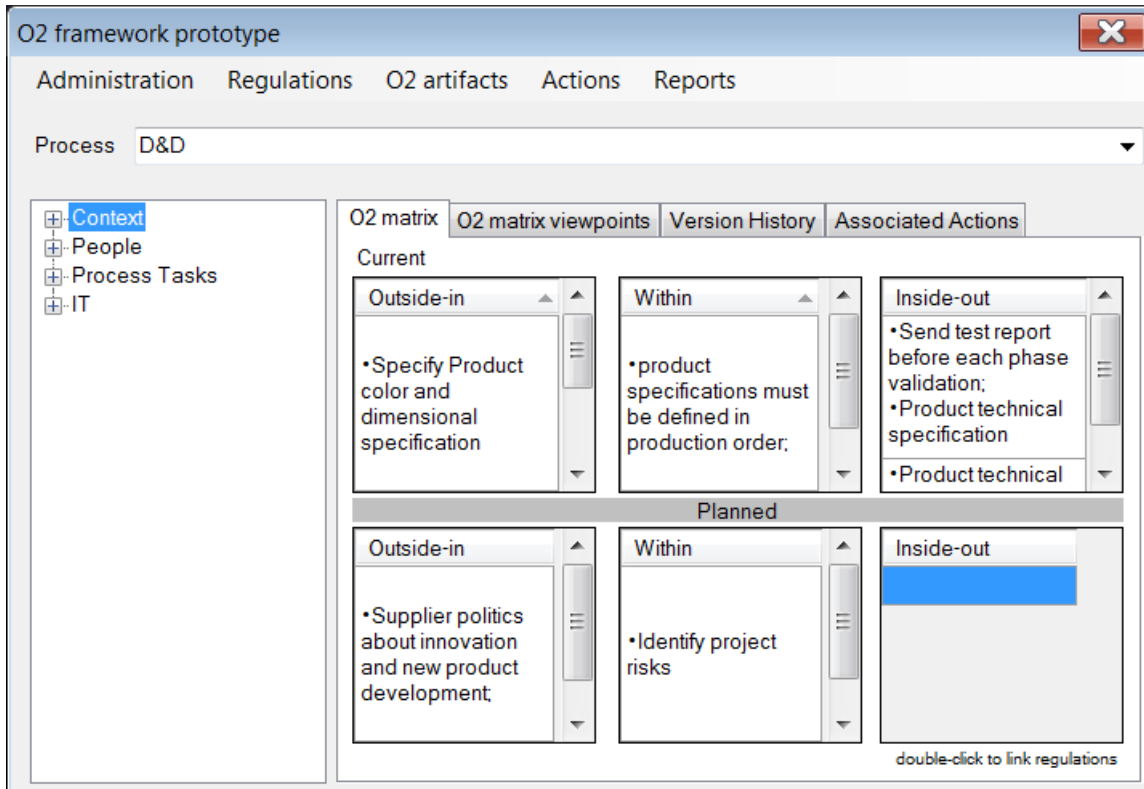
Figure 5-10. The O$_2$ software tool

The app was developed with technologies that are well known to the technological institute, namely Microsoft Visual Basic® .NET and Microsoft SQL Server Express® 2008. The menu on top of the window is organized as follows:

- Administration: Enables the configuration of the application: user management (each user generates a viewpoint); business processes; and the tree view levels presented on the left: it is possible to specify IT, people functions, tasks, context nodes (e.g., equipment list, company departments);

- Regulations: Listing of the applicable regulations with the link to the file content, the current state (e.g., active, abolished, replaced);

- O$_2$ artifacts: Visualization of O$_2$ matrices using grid views that allows to filter the information;

- Actions: Definition of actions to implement the requirements in practice, their responsibilities, schedule, current state, and attached files;

- Reports: Printing of specific lists such as the regulations that are associated with each process, the IS and the QMS requirements for specific processes, or the current action plan.

On the left of the interface we have a tree view to navigate into the requirements and a tab control that provides access to the IS and the QMS requirements. The interface allows saving the

distinct viewpoints from designers, and combining the viewpoints in a single joint matrix. There is a version control, and the functionality to manage action plans to accomplish requirements. Because each requirement is now in a separate cell, it is easier to link requirements with regulations (double-click). The main filter is the process (combo box) and the tree view control on the left. We identified several additional functionalities for the software that were postponed for future work as we focused on proceeding with the research. Those functionalities involve the interface improvement, the multi-user support (e.g., web interface), the use of graphical process maps, and enhanced search capabilities (for example, to allow end users to navigate in the regulations applicable to their processes, equipments, or functions). According to our Internet search, there is no similar tool that can support regulatory compliance while cooperatively designing the IS and the QMS, which creates the possibility for a commercial development.

Another aspect that we were interested in this cycle was to provide different views of the O_2 *map* to different stakeholders. Although a representation such as the one in Figure 5-9 can be used, the users who tested the software suggested that a 3D model would be more appealing and intuitive. This is possible because all the O_2 framework dimensions of context, people, processes, and IT, are connected directly (e.g., processes and IT) or indirectly (e.g., people and IT trough processes). The ORS map evolved to a layered presentation, illustrated in Figure 5-11.
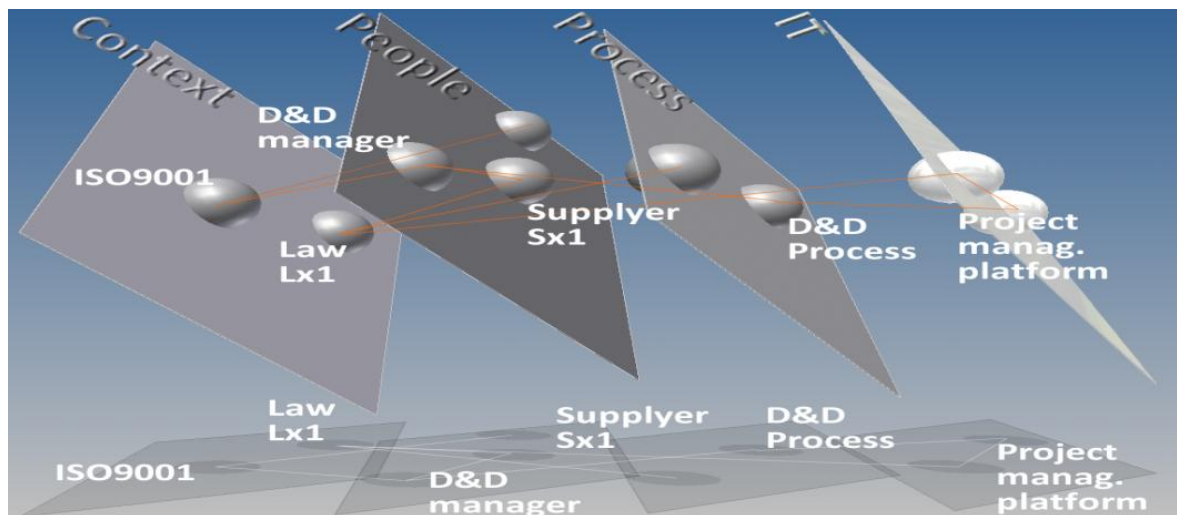
Figure 5-11. The O_2 *map* evolution: conceptually linking different concerns at distinct layers

At this stage of the research, the tool does not create a 3D map as represented in the Figure 5-11, but the technological institute plans to proceed with this development. We only illustrate how the representation can be achieved. A future model should be guided by the principle of parsimony, reducing complexity and choosing the most simpler model for the specific decision phase (Gallagher & Watson, 1980). The map provides a high level view when compared to BPMN models (Businska, Kirikova, Penicina, Buksa, & Rudzajs, 2012), but this can be an advantage in early stages of the ORS design, and for communication of the ORS with external entities. An analogy between O_2 *maps* and satnav maps can be made, both having options to add or remove layers of information (e.g., with/without road names or buildings). We can select only one concern, such as an IT application, and see all other related concerns of distinct layers (the IT

application links with context regulations, processes, people, and other IT). We may also separately obtain one or more layers (e.g., only the IT layer for potential application integrations).

The conclusions of this cycle were:

- There are benefits in using a software application to support ISO_2 (e.g., integrating data in a single database, improving search of specific requirements, and reporting capabilities);

- The ISO_2 approach and the O_2 framework may be used as a basis for creating 3D models of the ORS;

- Those models can support and improve the communication of the ORS, within the organization and with external stakeholders. The existence of a structured approach can also improve the regulatory awareness among the designers.

5.3.8 Rigor and validity

Table 5-12 compares our second action research project with the principles of CAR and validation criteria (Davison et al., 2004). We present the evaluation for the three completed cycles, similar to Lindgren et al. (2004) that performed an evaluation for the two CAR cycles of their project.

Table 5-12. Evaluating the second action research project (Davison et al., 2004)

Principle of the research-client agreement (RCA)	
Criteria	Our action research
1a Did both the researcher and the client agree that CAR was the appropriate approach for the organizational situation?	The technological institute considered that CAR was an appropriate approach to continue their participation in this research. CAR was summarily presented to the other clients that agreed to its adoption, especially due to the perspective of field intervention.
1b Was the focus of the research project specified clearly and explicitly?	The focus of the research that included ISO 9001 and related regulations was presented and approved by each organization. The findings from the previous case helped to explain the possible benefits and outcomes of the research project.
1c Did the client make an explicit commitment to the project?	The ceramics and the food companies confirmed their participation, respecting data confidentiality. The technological institute had made an explicit commitment to continue its participation and provided technical resources for our development efforts.

1d	Were the roles and responsibilities of the researcher and client organization members specified explicitly?	The researcher specified his role in the research project. The scope of the consulting activities and the research was clarified from the beginning. The client organization members and their roles for designing the ORS are presented for each case.
1e	Were project objectives and evaluation measures specified explicitly?	The project identified the objectives for both theory and practice. The ceramics and the food companies aimed to synergistic develop their IS and their QMS, addressing regulatory compliance issues.
1f	Were the data collection and analysis methods specified explicitly?	The participants approved the use of their documents, the field observation, and the interviews. The researcher assured confidentiality. The methods for data collection and analysis were specified in the action plan. The individual results of the diagnosis were communicated only to the specific organization and discussed to prepare the action plan.

Principle of the cyclical process model (CPM)	
Criteria	Our action research
2a Did the project follow the CPM or justify any deviation from it?	The project considered all the phases of CAR, namely diagnosis, action planning, action taking, evaluation, and specify learning. There was an exception that we report as case 2.4w, concluded after the diagnosis.
2b Did the researcher conduct an independent diagnosis of the organizational situation?	We conducted an independent diagnosis, identifying the opportunities and the problems in each organization. The diagnosis involved managers in each site, at data gathering and evaluation.
2c Were the planned actions based explicitly on the results of the diagnosis?	This CAR project included inputs from the diagnosis in each organization, but also from the previous findings. In the previous project we have proposed an approach to use in our actions. Then, the results from the diagnosis confirmed the problems in regulatory management. The actions were explicitly suggested to improve the situation that we found in the diagnosis.
2d Were the planned actions implemented and evaluated?	We implemented the ISO$_2$ approach and used the artifacts in daily practice. The evaluation has included the participation of organizational users.
2e Did the researcher reflect on the	There was a personal reflection and a collaborative

	outcomes of the intervention?	reflection with the organizations. We identified benefits and the possibilities for future work. The reflection was used to prepare a third action research project, to refine ISO_2 in what regards synergies of IS and QMS at run-time.
2f	Was this reflection followed by an explicit decision on whether or not to proceed through an additional process cycle?	We found it was necessary to improve the run-time support of our proposal for synergistic development of IS and QMS. The ISO_2 approach was not developed enough to guide organizations in evaluation and improvement. We had already identified that shortcoming at the end of the first project and we did not address the run-time in this series of three CAR cycles.
2g	Were both the exit of the researcher and the conclusion of the project due to either the project objectives being met or some other clearly articulated justification	The exit involved a discussion about the future steps of the research. We considered that ISO_2 was improved for the design-time and now the run-time phase required our attention. The technological institute was committed to continue their participation in the refinement of ISO_2 regarding run-time of IS and QMS. The company in the food company also identified opportunities to improve their audits, especially regarding customers demanding. The company in the ceramic company found the results satisfactory, but internal changes created difficulties for their involvement in a new cycle at this time.
Principle of theory		
Criteria		Our action research
3a	Were the project activities guided by a theory or set of theories?	The project was preceded by a systematic literature review. The results of the first project were published and the findings used to prepare the new action research cycles that we presented. Theory was constantly compared with action findings, used to refine the results, and plan additional steps.
3b	Was the domain of investigation, and the specific problem setting, relevant and significant to the interests of the researcher's community of peers as well as the client?	There was a previous identification of the challenges for regulatory compliance and integration of different standards (Abdullah et al., 2010a, 2010b; Jørgensen et al., 2006). All the organizations shared the research objectives. The action research results were presented in a peer-reviewed conference and published by Springer LNBIP series.
3c	Was a theoretically based model used to	We used a theoretical model according to the results of

	derive the causes of the observed problem?	the systematic literature review and the findings from the previous CAR project.
3d	Did the planned intervention follow from this theoretically based model?	The ISO_2 approach, the O_2 framework, and the O_2 artifacts guided our intervention. The plan was according to the extended O_2 steps, according to the frame of reference that we created from theory (Chapter 2) and practice (Chapter 4).
3e	Was the guiding theory, or any other theory, used to evaluate the outcomes of the intervention?	Simultaneously to the practitioners' evaluation, we compared our results with the problems identified in the literature review regarding regulatory management.
	Principle of change through action	
Criteria		Our action research
4a	Were both the researcher and client motivated to improve the situation?	The technological institute was creating a service for legal and regulatory surveillance to their clients. They also saw this research as an opportunity to solve internal problems of regulatory compliance. Both the ceramics and the food companies had problems with regulatory management for their certification. The three organizations had suffered from nonconformities in previous quality audits concerning regulations, giving them a strong motivation to improve the situation.
4b	Were the problem and its hypothesized cause(s) specified as a result of the diagnosis?	The problem and hypothesized causes were specified as a result of the diagnosis that involved both researcher and practitioners.
4c	Were the planned actions designed to address the hypothesized cause(s)?	The findings from the previous CAR project and the diagnosis of the current CAR project allowed us to identify the problems of managing regulations. The ISO_2 approach required improvements to include regulatory management. We also saw that it was necessary to involve different practitioners to design the ORS.
4d	Did the client approve the planned actions before they were implemented?	The clients approved the planned actions before implementation. They also participated in their definition, namely the institute that decided to proceed with the ISO_2 refining, and the two organizations wanted to implement a high-level map of their regulatory space.
4e	Was the organization situation assessed	The researcher had previously worked with the three

	comprehensively both before and after the intervention?	organizations that concluded CAR cycles, being aware of their activity, main market, internal structure, and quality systems. We performed a diagnosis to clarify the existing problems and identify possible improvement actions. The results were discussed between the researcher and different managers of the client organizations.
4f	Were the timing and nature of the actions taken clearly and completely documented?	We continued the documentation tasks initiated in the first project, namely by (1) reports to the Ph.D. supervisor, (2) documents that now integrate the organizations' QMSs, and (3) internal progress reports to each organization.
Principle of learning through reflection
Criteria		Our action research
5a	Did the researcher provide progress reports to the client and organizational members?	We provided progress reports and, complementarily, we conducted project meetings that included several organizational managers and process participants. Oral communication was provided on a regular basis to the top managers, IS managers, and QMS managers of each organization.
5b	Did both the researcher and the client reflect upon the outcomes of the project?	We conducted specific meetings to reflect with the organizational members.
5c	Were the research activities and outcomes reported clearly and completely?	We published a research paper concerning this specific project (Barata & Cunha, 2013b). Additionally, work reports were developed for the clients.
5d	Were the results considered in terms of implications for further action in this situation?	The results of each cycle were used to prepare the next one. We considered implications for research and practice. At this second action research project, we identified additional aspects to deal with concerning synergies of the IS and the QMS at run-time phase, especially regarding audit and improvement. Both aspects were considered for further actions.
5e	Were the results considered in terms of implications for action to be taken in related research domains?	The results were discussed regarding its implications in the consulting services that the technological institute provides. The research implications are relevant for policies related to ethics and legal compliance; for example environmental and social responsibility. We considered the risk of deviating from the core of ISO 9001 with these cases. However, as research evolved we confirmed that regulations and quality management are

		integrated topics in ISO 9001 (ISO, 2008b) that reinforce each other.
5f	Were the results considered in terms of implications for the research community (general knowledge, informing/re-informing theory)?	Our contribution was published in a conference that focused on IS and enterprise modeling (Barata & Cunha, 2013b). Our study adds to the synergistic development of the IS and the QMS, including regulatory management.
5g	Were the results considered in terms of the general applicability of CAR?	We considered CAR appropriate to our multi site action research project. The literature present cases of multiple clients that are a part of the same corporate group, as presented in the CAR study by Lindgren et al. (2004), or related by their economic sector, as proposed by Braa et al. (2004). In our CAR, three independent organizations, from different economic sectors, shared the difficulties in synergistic IS and QMS development and agreed to use and refine ISO$_2$, respecting their specificities, an in their own schedule. There were issues of confidentiality to respect and the interest in cross-case comparison to prepare our future actions. CAR provides a rationale to use in the type of research that we present, benefiting from a rich context provided by multiple sites.

5.3.9 Conclusions of project AR2

Organizations have difficulties in formal mapping between regulations, processes, people, and IT. Existing approaches for managing regulations do not holistically represent the regulatory space, addressing the cooperation with internal and external entities. Even when a business rule engine exists (Steinke & Nickolette, 2003), its use is mostly focused in the technological aspects, and it is difficult to be used as a working tool for all the business managers and external consultants. An extension to our preliminary approach and the artifacts that we created with the O$_2$ framework provided guidance for the regulatory analysis and elicitation. During design-time, distinct experts negotiate and validate the goals and rules of the ORS. ISO$_2$ was able to provide a common level of abstraction, in our three cases, for both business and IT to align their models and improve consistency (Branco, Xiong, Czarnecki, Küster, & Völzer, 2014).

There are a number of benefits with this approach. The process of ORS design will identify the regulatory requirements with the participation of managers, and there is an opportunity to reduce the "burden" of this task while improving communication in practice. With the *O$_2$ map*, the organization can provide evidence for auditors and other external entities, such as associations and customers. The O$_2$ framework focuses the participants in important dimensions of the IS and the QMS, namely the (1) context, (2) people, (3) process, (4) information, and (5) IT. The creation of synergies (Cunha & Figueiredo, 2005; Pérez-Aróstegui et al., 2015) is proposed from the beginning of design, as opposed to the traditional customer–supplier relation that sometimes

happens (Branco et al., 2014), for instance, between IT departments (supply solutions) and other management systems experts (define goals and rules).

This project also raised new issues to consider in sequent cycles. The organizational managers (ORS designers) were indicated by each organization, but other functions could be also considered. The *O₂ map* is a simplification of the complex system it represents, and as all regulatory models, it faces inherent uncertainties (Holmes, Graham, McKone, & Whipple, 2009). Finally, in spite of the positive results for organizational communication, joint modeling, and audit, we do not yet have evidences of compliance improvement, such as reducing nonconformities or guidance for process improvement actions. There is a need to examine the run-time of the ORS and compliance management after the modeling steps, especially when the literature points to difficulties in process improvement with ISO 9001 (Iden, 2012), a possible decay of process compliance over time, and a decrease in ISO 9001 perceived benefits (Gray & Roth, 2014; Karapetrovic et al., 2010).

5.4 Project AR3: refining ISO$_2$ for run-time

Our third action research project deals with the run-time phase of ISO$_2$ fostering (1) an IS quality culture (Barata et al., 2013a) and (2) a business process quality culture (Barata & Cunha, 2014b). For project AR3, we once more reflected on the main steps of ISO$_2$ devised in our first CAR project, when we obtained preliminary results with ISO$_2$. The second CAR project allowed us to deploy, understand and refine the synergistic design-time of ISO$_2$ that takes place in regulated environments (Bonazzi et al., 2010; Hancher & Moran, 1989; ISO, 2008b; Sadiq, 2011).

As discussed in Chapter 2, the IS and the QMS have an increasing influence on social interaction, work practices, and their underlying business processes (Iden, 2012; ISO, 2008b; Kautz et al., 2007; Paul, 2007), influenced by organizational culture (Barney, 1986; Curtis et al., 1988). In our literature review we found inspiring theory to guide the creation of a quality culture (Briscoe et al., 2005; Gallear & Ghobadian, 2004; Hildebrandt et al., 1991; Kanji & Yui, 1997) that involves the quality principles proposed by ISO 9001 (ISO, 2008b). Moreover, the interviews with the auditors and the multiple case studies presented in Chapter 4, confirmed the importance of continuously improving the IS and the QMS. There should exist an iterative process of design and operation of the quality management lifecycle (Domínguez-Mayo et al., 2012a).

The next section provides a description of the project setting. Then, we present the potential limitations of this action research project, followed by the diagnosis of the first two cycles. Both cycles were conducted in the same scope of developing the IS quality culture, so we decided to merge their diagnosis and the lessons learned (Barata et al., 2013a). Afterwards, we present the third cycle that addressed the development of a business process quality culture (Barata & Cunha, 2014b).

5.4.1 Project setting

There are three cycles in three different organizations. The technological institute (cycle #3.1), a paper company (cycle #3.2), and the food company (cycle #3.3). The technological institute and the company from the food industry had previously participated in our research and had decided to continue with their ISO_2 adoption. Both, the paper and the food companies, share similar quality requirements, because the paper production, in this case, is for food packages (eggs and fruit). We had contacts with the paper organization while they were preparing a European R&D project submission, regarding the adoption of international guidelines for food packaging. They became interested in our goal of synergistically developing the IS and the QMS and its cultural implications.

We planned the research intervention in the two initial organizations in sequence, namely the technological institute and the paper company. The cooperation with these organizations enabled us to propose and implement a *checklist for auditing IS quality culture*. The decision to start with the technological institute was due to our deeper knowledge of their processes and the availability of internal auditors that could assist us. We expected to create some artifacts in the technological institute before intervening in the paper company to refine the results. The third cycle, at the food company, aimed at a deeper connection between the quality principles suggested by ISO 9001 and daily practice (ISO, 2008b; Kanji & Yui, 1997; Schein, 1990), at a process level (Ahmad, Francis, & Zairi, 2007; Schmiedel et al., 2014; vom Brocke & Schmiedel, 2011). We were inspired by studies that combined organizational culture and process management (Schmiedel et al., 2014; vom Brocke & Schmiedel, 2011) and proposed to adapt ISO_2 to our purpose to integrate quality culture and process management, in the context of ISO 9001.

This action research project is presented as a chronological sequence of cycles and their interconnections. Similarly to the previous CAR projects we selected a structure to enhance the research recoverability (Holwell, 2004). The diagnosis of cycle #3.1 and #3.2 occurred in parallel and are provided in a single section. We started action taking in cycle #3.1 and, when it finished, we initiated action taking in cycle #3.2. The action plan of cycle #3.1 was to develop and test a *checklist for auditing IS quality culture*, mainly addressing the evaluation step of ISO_2. Cycle #3.2 aimed at refining that checklist while introducing the support for improvement actions. We merged the description of the action plan and action taking of each cycle in the same section. The evaluation phase is presented in separate sections to highlight the differences of the two initial cycles. We conclude with a common section for specifying learning in cycle #3.1 and cycle #3.2. The third cycle of this project started after cycle #3.2 ended. It is the last cycle of CAR in our Ph.D. program and has the input of all the previous CAR cycles.

5.4.2 Potential limitations

Some limitations are similar to those of previous cycles, namely the professional relation of the researcher with the selected organizations and the multiple regulations involved in the client settings. Moreover, the organizations have different processes, products, and market. However,

we already confirmed in our previous project that ISO 9001 provides a background of specific principles, clauses, and quality requirements (ISO, 2008b), common to different types of organizations. Multiple standards and regulations can increase the complexity of the research setting, but also provide a holistic set of requirements and potentially more realistic approaches to organizations that are interested in developing an ISO 9001-based QMS.

During this third project there was the risk of adopting an "auditor perspective" with excessive focus on process evaluation. Although auditing concerns are not excluded from ISO$_2$, our approach is to be primarily adopted by internal staff of the organization, not specifically by auditors. Audits "only" occur a few times each year, and our goal is to improve cultural issues that permeate daily practice. We found this risk more evident in the first cycle (#3.1, technological institute) because the outcome was mainly an audit tool, which made us introduce adjustments to our action plan. For example, in the second CAR cycle (#3.2) we contrasted the perspective of the auditors with that of the organizational users. Similarly to the first and second CAR projects, we wanted to improve routines and artifacts, considering multiple viewpoints, while exploring the IS and the QMS synergies.

Finally, as identified in our auditors' interviews and case studies presented in Chapter 4, it was necessary to evaluate and improve multiple dimensions of the IS and the QMS, in the context of ISO 9001. We decided to keep a flexible action plan, evolving with the findings gathered at each CAR cycle. In each one we evaluated if our focus was appropriate to a synergistic development of the IS and the QMS, making the necessary adaptations.

5.4.3 Diagnosing Cycle #3.1 and Cycle #3.2

The two clients shared a common concern: to evaluate and improve the IS and the QMS in a synergistic way, and fostering an IS quality culture (Hildebrandt et al., 1991; Stylianou & Kumar, 2000). The diagnose included meetings with the IS and the QMS managers of each organization, complemented by two research tasks, (1) an extension to the literature review of the IS quality and quality culture, that we included in the Chapter 2; and, (2) interviews with quality auditors presented in Chapter 4, round 3.

The next sections present the research to develop and validate the checklist in the context of ISO 9001 audits. We had the collaboration of [AUD2] and [AUD6], that were mentioned in the third round of interviews with auditors, in Chapter 4. Their organizations are client settings for our action research, namely the technological institute (cycle #3.1) and the paper company (cycle #3.2).

5.4.4 Action planning and action taking in Cycle #3.1

With the insights provided by the quality auditors and by the technological institute team managers, we have developed a preliminary version of a checklist to audit and guide the development of IS quality culture, in the context of ISO 9001 principles (ISO, 2008b). We started this cycle with the plan to use and refine the audit checklist in practice. We wanted to understand

if the checklist was accessible to different experts and if the set of questions to audit IS quality culture needed changes. The checklist was first tested in the technological institute, due to the existence of several internal ISO 9001-certified auditors. Their expertise guided the improvements that we made to the text of the checklist items, considering their usefulness and accessibility to IS non-experts. Figure 5-12 presents the final version of the auditing checklist.

P	Administrative Quality Checklist
CF	(1) The feedback of users is registered (e.g., questionnaires) and considered for budgets and plans of the IS department; (2) The IS management directly interacts with end customers, to understand needs and opportunities
LE	The IS has a defined strategy that aligns business and IT
IP	Distinct functions are involved in establishing IS plans and acquisitions; for example, the process participants are involved in evaluating requirements for new IT initiatives
PA	Processes of IS management are defined (the process approach is used for IS administration)
SA	(1) There is an established procedure that defines the IS in all its dimensions of people, process, information, IT, and quality context; (2) The potential of IS standards is known and used as a guidance for the organization
CI	The projects and budgets are monitored and evaluated at the end. Preventive and improvement actions are established (e.g., risks are identified before each project and actions planned)
FA	The plans and budgets are evaluated and lessons are used in future IS projects
SR	Suppliers have documented procedures and adopt standards for each key service/product

	Information/Data Quality Checklist (for each organizational process)
CF	(1) Process participants are inquired on the quality of input data and actions are taken to improve information processing; (2) Incomplete information/data is identified and treated as nonconformity. Actions are taken to solve the identified problems (e.g., minimize errors, provide indicators that are more representative of process performance)
LE	Information quality is recognized as an essential aspect of quality, in the scope of ISO 9001
IP	(1) Users are aware of the need to protect access to sensitive data; (2) Users participate in data validation tasks (e.g., validate calculations of a specific software or spreadsheet) and consider information/data quality as an issue concerning all the stakeholders of the organization
PA	Information requirements can be associated with organizational processes and activities
SA	There are no "islands" in the IS: the users have the required information to develop their work and consider that information reliable
CI	The organization is concerned with improving the quality of information, such as accuracy, objectivity, believability, access, security, value-added, timeliness, completeness, interpretability, and ease of understanding (Wang, 1998)
FA	Records allow traceability, for instance, to know by whom and when important records are created, changed, or deleted
SR	Information provided by suppliers can be validated (evidences of quality, such as digital signature, test reports)

Software Quality Checklist	
CF	(1) Software requirements were identified by the users; (2) User requests are recorded and appropriate actions taken to improve the software
LE	(1) Business-IT alignment is a permanent concern of management and evidenced in corporate reports and plans; (2) There is a strategic plan that includes IT
IP	User satisfaction is monitored concerning software solutions
PA	The organization is able to identify every process that each software application supports (IT inventory for the process)
SA	There is an integrated perspective of software applications (integration, software is managed as a valuable asset)
CI	(1) There are maintenance contracts for the most relevant software (if applicable); (2) There is a plan for the evolution and update of internally developed software (if applicable)
FA	There is evidence of software testing, software validation, and acceptance (not only for clause 7.6)
SR	(1) Suppliers provide validation evidences for software products; (2) improvements are suggested to the suppliers

Service Quality Checklist	
CF	(1) There is a help desk procedure; (2) There are adequate tools to monitor service quality (e.g., response time is recorded, as well as user validation of the interventions)
LE	Quality principles are applied to IS management
IP	The service is evaluated (e.g., questionnaires) and actions taken to ensure that user suggestions are followed upon
PA	Nonconformity or user requests can be traced for each process
SA	The IS function considers both technical (e.g., hardware and software support) and human aspects of service (e.g., identify training needs, provide training for internal and external elements of IS service)
CI	There are quality indicators for the service (e.g., number of interventions and mean time) and improvement actions are taken
FA	(1) There are evidences of each intervention. The time, scope, and solution are recorded; (2) The satisfaction of users is monitored, for instance by validating concluded IS requests or with specific questions in questionnaires
SR	When services are outsourced, the supplier maintains complete records according to the adopted service procedure

Infrastructure Quality Checklist	
CF	(1) The network performance is adequate both for internal and external access (see users feedback); (2) Computers are suitable for each function – It is possible to identify infrastructure requirements for each organizational function
LE	Organization considers IT requirements when planning process changes and new organizational investments
IP	There is feedback from users concerning infrastructure performance (e.g., workers satisfaction inquiries include items concerning computers or network compliance with their functions)

PA	IT can be connected with the process map. IT requirements are identified for specific activities and responsibilities (for instance, process X, developed by function Y, requires operating system Z, and internet access G)
SA	(1) Organizational infrastructure is identified (e.g., IT network map); (2) Backups of data/information and software applications are identified and there are recovery plans (and contingency plan)
CI	Organization updates IT according with the needs of the processes and technological innovations
FA	The selection of IT includes criteria other than price, for instance, process requirements, performance requirements, specific applications for the function
SR	(1) IT suppliers provide clear and timely information concerning new IT in the market; (2) The IT interventions (e.g., repair) is recorded by the suppliers IS

Legend of column 1: [QP] Quality Principle; [CF] Customer focus; [LE] Leadership; [IP] Involvement of people; [PA] Process approach; [SA] System approach to management; [CI] Continual improvement; [FA] Factual approach to decision-making; [SR] Mutually beneficial supplier relationships.

Figure 5-12. *Checklist for auditing IS quality culture*: fostering a cultural perspective (Barata et al., 2013a)

The groups of questions in Figure 5-12 correspond to the holistic IS quality dimensions proposed by Stylianou and Kumar (2000): Administrative Quality, Information/Data Quality, Software Quality, Service Quality, and Infrastructure Quality. For each dimension we added lines according to the principles underlying an ISO 9001-based QMS (ISO, 2008b). The information in each table cell is not exhaustive and may be adapted to the organizational setting. However all the IS quality dimensions and ISO 9001 principles must be addressed to promote learning and improvement of an holistic IS quality culture (Briscoe et al., 2005; Kanji & Yui, 1997; Kanji, 1998; Stylianou & Kumar, 2000).

5.4.5 Evaluating cycle #3.1

The organizational managers found the checklist simple to use. They considered it an advance when compared to their regular practice in the context of ISO 9001. As we have seen in Chapter 4, ISO 9001 audits traditionally only address a small set of IS quality concerns (e.g., data backups).

The IS quality awareness among the project participants seemed to improve. For example, critical laboratorial software of the technological institute suffered changes after the using the above checklist, because they found problems on the information and software dimensions (Stylianou & Kumar, 2000). The problems included lack of traceability in deleted records, insufficient tracking of user requests, and inexistent evidence of user acceptance when software changes are applied in daily practice. The checklist also helped the quality auditors on what to ask for during audits.

The auditor said that:

"The audit process is nearly the same that was followed in previous audits, but there is a change in the focus of the audit and the depth of IS quality issues that we can search for and improve (...)to audit IS quality all over the organizational processes. This is a potential tool to train the organization in IS quality" [AUD6]

However, we identified three major drawbacks: (1) lack of impact if the checklist is seen as a mere tool for audits and used once or twice a year; (2) the approach only takes into account the perspective of the quality auditor; and (3) not enough guidance in the internalization of practices, dynamic of improvement, learning and people focus, as demanded by our IS quality culture framework (Barata et al., 2013b). For example, the artifact does not provide any support for the improvement actions that materialize from audit results. There was a need to create support for change and improvement, not only evaluation and learning. The next section explains how we addressed these problems.

5.4.6 Action planning and action taking in Cycle #3.2

The intervention in the company from the paper industry started a few weeks after the first CAR cycle of our current action research project. The action plan was the adoption of the checklist, the assessment of its practical use, and the identification of possible improvements. We made changes and adjustments to our checklist presented in Figure 5-12: first, we included two columns that allow the IS manager and the ISO 9001 auditor (usually the QMS manager when the audits are internal) to classify each item in a scale from 1 (nonexistent) to 5 (very good). We intended to combine the perspectives of the IS and the quality experts. This apparent minor change fosters a conversation between the auditor and the IS manager that may promote the achievement of a common understanding. Second, we included two more (rightmost) columns to detail improvement actions and the state of their implementation. Each action is monitored considering the PDCA (ISO, 2005b). We exemplify this change in Figure 5-13.

Quality Principle	Service Quality Checklist	IS Function*	Auditor*	Action	Action Stage
Customer focus	There are adequate tools to monitor service quality	2	2	(A1) Implement help desk portal	
				(A2) Online questionnaire	

*evaluate from 1(nonexistent), 2(weak), 3(satisfactory), 4(good), and 5(very good)

Figure 5-13. IS quality dimension: service [excerpt of one line of the checklist]

After implementing actions, the users re-evaluate the checklist item and propose new actions to continuously improve. The steps involved in creating the checklist can be synthesized as: *1-Complete/adapt the Checklist to the characteristics of the organization* (if necessary); *2-Evaluate each item with the checklist*; *3-Propose and monitor the actions to improve the state of the principle adoption*; *4-Re-evaluate and propose new actions* (if required).

The ISO 9001 audit is the moment to update the auditors' column, compare their evaluation with the organizational assessment, and propose actions. The confrontation of viewpoints reveals benefits to develop a "*way of working*" guided by quality principles, agreed by the firm elements (Barney, 1986; Gallear & Ghobadian, 2004; Irani et al., 2004; Schein, 1990).

5.4.7 Evaluating cycle #3.2

The client organization decided to create ISO 9001 quality indicators for IS quality, to pass the message that this topic is a priority for top management, that it has impact in everyone's work, and that it must be improved by everyone. ISO 9001 proved to be a good vehicle of IS quality in this case. The administration of our two clients struggle everyday with IS quality issues, mostly information/data errors and IT that does not support daily activities as it should. They expect that the approach may increase everyone's responsibility in IS quality. However, as stated by the IS manager of this case, this is not a one-time approach, it is a continuous process. A holistic perspective of IS quality creates challenges; for instance, the need to map processes and IT; organizational functions and IT; training actions; improve software auditability; and detailing information requirements for each process. We underline that the new checklist is a mean for guiding the IS quality culture, not an end.

Nevertheless, we found restrictions to the checklist. While ISO_2 design could be performed at a process level (using O_2 artifacts), the checklist tool that we developed was created at the organizational level. Could we apply the same logic of quality principles for specific business processes? Additionally, could we go beyond the thematic of IS quality, which has a limited impact in ISO 9001 certification requirements? For example, the IS function (third column) in Figure 5-13 can be changed to include the process owner evaluation. While being far from unsuccessful, our outcomes for the run-time was clearly below our expectations for a cultural approach, adopting quality principles in business processes.

5.4.8 Specifying learning for cycle #3.1 and cycle #3.2

It is not possible to evaluate and improve IS quality culture with just a checklist. That was our starting point in the first cycle at the technological institute, then complemented by the refinements in the cycle at the paper company. However, it is the work supported by the artifacts that can contribute to the creation of an IS quality culture. People can learn and develop a quality culture and the artifacts are a part of the process (Pentland & Feldman, 2008).

"Participants may have a generative, improvisational mindset, where they are empowered to make significant choices about how work gets done. To the extent this is true, users become designers" (Pentland & Feldman, 2008, p. 248)

One of the most important advances that we found in the two research cycles was the focus on issues that everyone agrees are important, but that are not a central concern to the organizational practice. An holistic IS quality in the context of ISO 9001 (ISO, 2008b; Stylianou & Kumar, 2000) is a unanimous priority for top managers, auditors, IS managers, QMS managers, and process participants, in all our cases. However, when we diagnosed the first two organizations involved in our third CAR project – technological institute and company from the paper industry – we saw that little is done to ensure IS quality in daily practice. We cannot claim that ISO_2 builds a culture of IS quality, but we had evidence in our studies that it is a first step to place IS quality concerns in the agenda of continuous improvement efforts, according to ISO 9001 quality principles.

The next cycle introduces high-level principles at the process level in the run-time concerns of ISO_2.

5.4.9 Diagnosing Cycle #3.3

One of the major problems of the company operating in the food industry was managing the maintenance process of their industrial equipment. Records were scarce and the process must conform to the standards, laws, and quality principles. When we conducted this cycle, one team of consultants was assisting the organization with the QMS and a different one was responsible for the IS. According to the company's quality manager:

"There is a gap between policies and processes (…) top level quality principles are translated into standards requirements that, in turn, direct our process information requirements. Ok, processes comply with requirements, but they should conform to the principles"

She presents an example:

"We comply with the complaints management requirement in commercial process, which is the 'rule' (…) [although] *that does not mean that we are fully integrating customer focus principle in the process. A traditional process matrix links the requirements with clauses, not with the higher principles that truly matter"*

"People issues are our problem, not the technological ones. Our team is competent, they know 'what' to do and 'how', but we want them to incorporate our values. People must understand the importance of the 'why', being aware that, across the globe, a child may be eating our product and laughing with their parents. Our work contributes to that moment success, to the child health, to that family happiness"

Quality requires transparency towards government entities, business partners, and the consumer society in general (Trienekens, Wognum, Beulens, & van der Vorst, 2012). A case study to achieve transparency by cooperating in the supply chain is presented by Beulens, Broens, Folstar, and Hofstede (2005), pointing to the need to share quality standards and information between the different actors. However, the food industry must not only provide information about "what" is done to achieve quality, but also "how" they achieve it, and which values ("why") are followed (Meijboom et al., 2006).

During the diagnosis, evidence from literature regarding the food industry revealed that the IS is a present concern. For example, Sørensen et al. (2010) propose a conceptual model for a farm management IS. The work of Lehmann, Reiche, and Schiefer (2012) explores a more technological perspective reviewing opportunities and difficulties of IS adoption in production, logistics, and consumer support. Wolfert, Verdouw, Verloop, and Beulens (2010) consider both the organizational and technical aspects for process management in food sector. Still, existing studies do not include a cultural quality perspective in business processes (Kanji & Yui, 1997; Schmiedel et al., 2014), applicable for the entire IS and QMS lifecycle. The principles to implement a quality culture in the organization (Kanji & Yui, 1997) are frequently neglected, when compared with operational requirements and rules of business processes. This raises the question: "How to create a business process quality culture?".

Given this context, we understood that our action plan could not simply be a matter of ensuring compliance to requirements, or assess whether the IS and the QMS "violates or not a set of obligations". Quality culture requires people involvement in the development of practices that are guided by quality principles (Gallear & Ghobadian, 2004; Kanji & Yui, 1997; Schein, 1990).

5.4.10 Action planning for Cycle #3.3

We outlined a plan to refine and extend the ISO_2 approach, now addressing a business process quality culture perspective. The company decided to focus on the maintenance management process that was a priority for them at the time. The initial meetings aimed at drafting a plan with the managers (IS, QMS, and maintenance). We updated the initial *O_2 map* (Figure 5-6) to include the functions and main regulations that are related with the process, according to the update we proposed in Figure 5-11. The managers from the food company approved that change and told us that it provided a more complete description of the process, whilst keeping it simple enough to be interpreted by all their process participants. Figure 5-14 presents an extract of the *O_2 map* for the maintenance process.
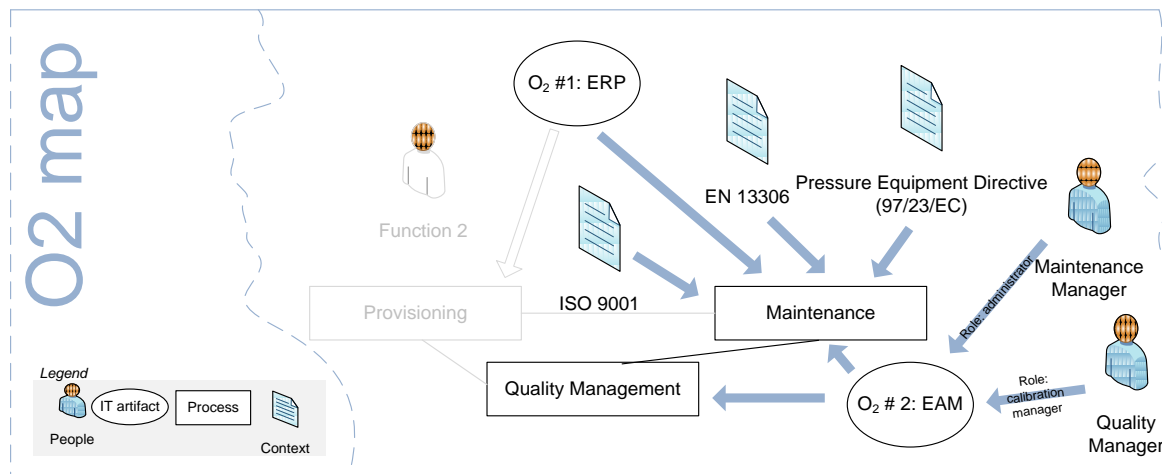
Figure 5-14. *O$_2$ map* extract for the maintenance process at a high-level of abstraction

The *O$_2$ map* provides the portrait of which major regulations affect the process, their users, and the IT artifacts that support them. In our current case, there are two main IT systems to support the maintenance process – the ERP and a new EAM – Enterprise Asset Management system. Additional spreadsheets and desktop databases, specific laws and procedures were omitted to simplify the figure at the highest abstraction level.

ISO$_2$ required changes to fit this scenario, so we decided that our action plan should include the development of new artifacts to include quality principles, as presented in the next section.

5.4.11 Action taking for Cycle #3.3

This section summarizes the extension we made to ISO$_2$, by creating three additional artifacts:

- *O$_2$ principles evaluation*: to describe the adoption of quality principles to the organizational process;

- *O$_2$ principles matrix*: to detail the IS/QMS goals and rules regarding the adoption of quality principles to the organizational process;

- *O$_2$ principles development checklist*: to assess each goal/rule in daily practice and suggest improvement actions.

Figure 5-15 presents an excerpt of the first one, the *O₂ principles evaluation*.

Principle	General Description	Business Process Quality Culture
Customer focus	Organizations depend on their customers and therefore must understand their present and future needs, satisfy their requirements and make an effort to exceed their expectations.	Consider external and internal customers. External customer interest includes the safety of materials used in maintenance, avoiding food contamination. They may ask for maintenance evidences in case of product traceability. Maintenance must ensure that (…)
Factual approach to decision-making	Effective decisions are based on data analysis and information.	Maintenance IS quality must be measured and continuously improved. Records must ensure traceability and proper identification (…)
(…)	(…)	(…)
Ethics (company policies)	Our stakeholders must ensure transparency and a code of conduct that respects our tradition.	Acquisition of materials and services must be decided after requesting proposals from at least three suppliers. Maintenance personnel must have required documentation to (…)
Sustainability (company policies)	Our activity must respect the environment and ensure energy optimization.	Maintenance must ensure the minimum waste in equipments. Suppliers must be identified to handle dangerous materials and their disposal (…)

Figure 5-15. *O₂ principles evaluation* for the maintenance process (excerpt)

The organization selected eight principles drawn from ISO 9001 (ISO, 2008b), and added other three, namely: safety, ethics, and sustainability. These are core values for their future, so they decided to evaluate them specifically (column 1). Column 2 provides a brief description of the quality principle, according to ISO 9001 and the company policy (for safety, ethics, and sustainability). By creating the *O₂ principles evaluation*, the users perceive the process by the lens of the principles that they defend. Column 3 describe the *"ways of working"* (Gallear & Ghobadian, 2004; Philip & McKeown, 2004), according to the perspective of the process participants.

The second artifact, the *O₂ principles matrix*, is presented in Figure 5-16.

Figure 5-16. *O₂ principles matrix* (excerpt)

The *O₂ principles matrix* identifies the outside-in, within, and inside-out requirements of the IS and the QMS (the three columns on the right) related with quality principles (on the leftmost column). This matrix complements the original O₂ matrices (we changed its first column to include the principles identified in the *O₂ principles evaluation*), which focused on operational requirements for the process. By combining the matrix cells into a new matrix, new goals and rules are added, and others, that are redundant, can be eliminated.

There were two team meetings: first to analyze the process under the light of the principles and build an initial draft of the *O₂ principles matrix*. A week later, the team refined the information. If we combine the information of the same lines of all process matrices, we can identify how the organization globally internalizes each principle. There is the potential of identifying processes that do not adhere to the policies and principles, as they should, or principles that are not addressed by the processes. This cannot be achieved with traditional matrices that are common to ISO 9001, connecting business processes with the ISO 9001 standard clauses. Note that the extension that we introduced to ISO₂ is not specific to the food industry; however, this sector provides an example that can benefit from the approach due to its increasing need for transparency and quality culture in its business processes.

> *"A system must have an aim. Without an aim, there is no system. The aim of the system must be clear to everyone in the system. The aim must include plans for the future. The aim is a value judgment"* (Deming, 1993, p. 50)

Next, we generated the improvement plan with the *O₂ principles development checklist*. This is an adaptation of the artifact that we present in Figure 5-13 to support improvement actions, implemented at a process level. The purpose is to establish actions to implement the planned requirements of the *O₂ principles matrix*, to evaluate them, and to improve. Figure 5-17 presents

an example regarding the goal established in the second line of Figure 5-16, third column (inside-out).

Quality Principle	Goal/Rule Checklist	Process Owner *	Auditor*	Action	Action Stage
Customer focus	Maintenance plan must be timely supplied to the production sector	3	2	(A1) Integration between maintenance plan and ERP purchase plans	
				(A2) Develop a decision support system to simulate plan changes	

*evaluate from 1(nonexistent), 2(weak), 3(satisfactory), 4(good), and 5(very good)

Figure 5-17. *O₂ principles development checklist* (excerpt)

The first column identifies the quality principle; the second describes the goal/rule for that principle. One principle may have several goals/rules. Since our purpose was also to perform an evaluation, we added two columns to compare the perspective of the process owner and that of the quality auditor (internal or external). The last two columns identify the improvement actions and their development stage. Actions must be planned for each line that does not reach a satisfactory grade. Each action is monitored considering the PDCA cycle (ISO, 2008b).

The artifacts are created according to the following steps, for each business process:

1. Identify the adoption of quality principles to the business process (*O₂ principles evaluation*);

2. Define outside-in, within, and inside-out information required to develop the quality principle in the process (*O₂ principles matrix*);

3. Establish an improvement plan (*O₂ principles development checklist*);

4. Continuously revise the O₂ matrices and propose improvement actions.

5.4.12 Evaluating Cycle #3.3

Our previous version of ISO₂ approach, without these new artifacts, could provide some support for process design. However, we did not have a quality culture perspective with the initial tools, justifying the new artifacts introduced in this third AR project. Interestingly, the use of the *O₂ principles matrix* allowed the identification of new requirements for the IS and the QMS that would be missed when using the original O₂ matrices. In our opinion, this effect was obtained because the users are critically evaluating their processes according to high level principles, not just operational aspects of the process under consideration.

A few months after this cycle concluded we called the maintenance manager to obtains his opinion about its effects. According to him:

"Quality principles are important, but at the same time they are far away from our daily concerns. We can easily talk about them regarding our policies printed somewhere, however it is more difficult if we try to bring them to small things that occur every day, some of them apparently with no link with such "high-level" and abstract guidelines (...) the result was positive, and this happened because our team was "remembered" why their work is important for the entire organization and we talked about processes in a positive and free way. [We asked to be more precise] *(...) maintenance team felt that they are the owners of their processes, deciding about important things that were not a result of some hierarchic order (...) in a certain sense, the process seemed more important than it usually is recognized* [maintenance is sometimes seen in organizations as a matter of costs, rather than an investment] *".* He found another benefit with the artifacts we developed that was *"the possibility to justify to top management the need for some actions, not because they are important to our team, but because they are important to everyone in the organization"*

The maintenance manager also warned us about difficulties: *"(...) I see risks of loosing benefits if the other processes do not follow the same principles or if process participants do not see their efforts recognized by top management"*. He presented the example of the production team – one of the clients of maintenance – stating the importance of having a similar concern from them. According to him "[maintenance] *process is one part of the machine and the system depends on all its parts (...) during this process we identified actions that should be done by other sectors* [for example, changes to the production plan report] *so we depend on their involvement"*.

The maintenance manager confirmed that the meetings were effective for learning-by-doing, increasing process knowledge by process participants, sensing their motivation, and perceiving effort/value to follow the process principles. The evaluation made possible by the O_2 *principles development checklist* was used to produce different charts and indicators for the IS and the QMS. According to a major customer of the organization: "*the approach puts forward the company interest in improvement, and their commitment with the policies they defend*".

5.4.13 Specifying learning for Cycle #3.3

"We propose that IS researchers should adopt a more dynamic view of culture – one that sees culture as contested, temporal and emergent" (Myers & Tan, 2002, p. 24)

It is time to incorporate quality principles in the synergistic development of the IS and the QMS. Although ISO 9001 is built according to high-level principles that shape a quality culture (ISO, 2008b; Kanji & Yui, 1997; Kanji, 1998) , there is a risk of those principles being forgotten in daily practice. By including attention to cultural aspects in a process oriented approach, the findings suggest that we can increase the internalization of quality principles (Briscoe et al., 2005). The matrices provided auditing support in our case company, with the potential of diffusing the approach to other suppliers of the food chain. A customer of the firm suggested using the average evaluation of the *O₂ principles development checklist* to measure the quality principle internalization, comparing distinct processes. The crosscheck evaluation by process owners and auditors is an opportunity to contrast perspectives of improvement. It is difficult to connect generic principles such as "customer focus" with specific goals/rules. With the proposed approach, we challenge the process participants to think *why* their work is important, for them, for other stakeholders, and ultimately for the society.

We extended the previous iteration of the ISO_2 approach to bridge the gap between overarching quality principles and business processes, when considering the synergistic design of the IS and the QMS across the lifecycle. With the support of the O_2 artifacts, users can collaborate in the synergistic design of the goals and rules for each process. At run-time, there is guidance to internalize quality culture in daily practice. Moreover, we gathered evidence during this cycle that the ISO_2 approach presented benefits for interactive communication throughout the supply chain (ISO, 2005a). The company from the food industry asked us to create an "ISO_2 kit" that they could distribute to their partners and suppliers, representing a distinctive image of their process quality culture.

5.4.14 Rigor and validity

The evaluation of our action research is presented in Table 5-13, once more according to the criteria put forward by Davison et al. (2004).

Table 5-13. Evaluating the third action research project (Davison et al., 2004)

Principle of the research-client agreement (RCA)	
Criteria	Our action research
1a Did both the researcher and the client agree that CAR was the appropriate approach for the organizational situation?	The technological institute and the company from the food industry had previous experience with CAR and agreed that it was appropriate for this situation. The managers of the company from the paper industry considered our CAR proposal an opportunity to solve their problems and benefit from previous findings, from distinct settings.

1b	Was the focus of the research project specified clearly and explicitly?	Our focus was specified: to foster a quality culture, improving ISO_2 run-time (more specifically, the ISO_2 steps regarding evaluation and improvement). It was presented to the organizations and approved by each one.
1c	Did the client make an explicit commitment to the project?	There was an explicit commitment to continue the research in the organizations that participated earlier. The company from the paper industry also confirmed their commitment in our initial meeting.
1d	Were the roles and responsibilities of the researcher and client organization members specified explicitly?	The researcher specified his roles and responsibility in the research project. The roles and responsibilities of client organization members are described for each cycle.
1e	Were project objectives and evaluation measures specified explicitly?	We identified the objectives and evaluation measures for theory and practice. The initial two cycles addressed the IS quality culture and the third cycle objective was to foster business process quality culture.
1f	Were the data collection and analysis methods specified explicitly?	The participants approved the document collection, observation, and the interviews. The researcher assured confidentiality of their data. The three organizations agreed to share their findings with the other participants in this project.
	Principle of the cyclical process model (CPM)	
Criteria		Our action research
2a	Did the project follow the CPM or justify any deviation from it?	The three cycles considered all the phases of CAR, namely diagnosis, action planning, action taking, evaluation, and specify learning. We combined the presentation of cycle #3.1 and cycle #3.2 because their action plan was prepared as a sequence of events. We also combined the lessons learned, while stating to whom our comments were related. The project follows the CPM in spite of the presentation structure that we selected to achieve a clearer message and enhanced research recoverability (Holwell, 2004).
2b	Did the researcher conduct an independent diagnosis of the organizational situation?	The diagnosis involved managers from each site in data gathering and evaluation. We conducted literature reviews when it was necessary to support our diagnosis, for example regarding food industry specificities.

2c	Were the planned actions based explicitly on the results of the diagnosis?	The plan was based explicitly in the results of the diagnosis, which involved literature review, interviews with auditors, and meetings with each participant to understand their specificities.
2d	Were the planned actions implemented and evaluated?	We designed artifacts and used them in practice. The evaluation has included the participation of organizational users.
2e	Did the researcher reflect on the outcomes of the intervention?	There was a personal reflection and a collaborative reflection with the organizations.
2f	Was this reflection followed by an explicit decision on whether or not to proceed through an additional process cycle?	The reflection has influenced the sequence of each cycle, from the initial checklist that we proposed in cycle #3.1, its refinement for improvement activities in cycle #3.2, and the inclusion of quality culture issues at business process level in cycle #3.3.
2g	Were both the exit of the researcher and the conclusion of the project due to either the project objectives being met or some other clearly articulated justification	The cycles evolved until the project objectives were met. We plan to continue our research with other organizations in the future. One of them is a small firm in the mechanical industry that recently accepted to collaborate in the adoption and refinement of ISO_2. This project is out of the scope of our Ph.D. program, but may contribute to evolve even further the ISO_2 approach.
Principle of theory		
Criteria		Our action research
3a	Were the project activities guided by a theory or set of theories?	The activities were guided by the findings of our systematic literature review, interviews, and case studies. Moreover, our intervention used the findings from our previous CAR projects, for example, the ISO_2 steps and the O_2 artifacts.
3b	Was the domain of investigation, and the specific problem setting, relevant and significant to the interests of the researcher's community of peers as well as the client?	We confirmed the interest of the participants in the synergistic development of the IS and the QMS. The action research results were presented to the research community in the form of a book section (Barata et al., 2014) and two conference papers (Barata et al., 2013a; Barata & Cunha, 2014b).

3c	Was a theoretically based model used to derive the causes of the observed problem?	Our literature review allowed us to identify a lack of synergistic approaches for the joint development of the IS and the QMS. We confirmed this necessity in the field and proposed solutions to address the problem.
3d	Did the planned intervention follow from this theoretically based model?	The ISO_2 approach, the O_2 framework, and the O_2 artifacts guided our intervention. The artifacts that we built in support of ISO_2 followed our literature review (Gallear & Ghobadian, 2004; Hildebrandt et al., 1991; ISO, 2008b, 2009a; Kanji & Yui, 1997; Myers & Tan, 2002; Schein, 1990; Stylianou et al., 1997).
3e	Was the guiding theory, or any other theory, used to evaluate the outcomes of the intervention?	Simultaneously to the practitioners' evaluation, we have evaluated the outcomes of our approach according to the literature review. We found improvements in our intervention when comparing to the problematic development of the IS and the QMS that emerged from our case studies.
	Principle of change through action	
Criteria		Our action research
4a	Were both the researcher and client motivated to improve the situation?	The technological institute's mission motivated them to foster a quality culture and to improve their auditing practices (internally and to external clients). Both companies – in the paper industry and in the food industry –play an important role in environmental protection and human safety. Due to this reason they were highly motivated to improve their synergistic development of the IS and the QMS trough a sustainable cultural perspective. The researcher motivation was to solve a practical problem while contributing to science.
4b	Were the problem and its hypothesized cause(s) specified as a result of the diagnosis?	During the diagnosis, the researcher and the organizational managers collaboratively specified the problem and its hypothesized causes.
4c	Were the planned actions designed to address the hypothesized cause(s)?	The first and second cycle addressed the hypothesized cause that was the lack of auditing guidance and improvement actions to IS quality culture. The third cycle was designed to address a business process quality culture. In the three cases we found that one major cause of not promoting a synergistic IS/QMS development was the lack of an approach to support the practitioners, in the context of ISO 9001.

4d	Did the client approve the planned actions before they were implemented?	Each client approved the planned actions in initial project meetings.
4e	Was the organization situation assessed comprehensively both before and after the intervention?	Two of the organizations were already known from previous cycles. The third was initially assessed using meetings, observation, and document collection. We evaluated what happened after each cycle, contributing to knowledge creation.
4f	Were the timing and nature of the actions taken clearly and completely documented?	The activities were reported by (1) reports to the Ph.D. supervisor, (2) documents that guide internal audits, and (3) executive summaries and meetings to report the findings to the organizational managers. The sequence of cycles was reported according to its timing and contribution to our overall research program.

Principle of learning through reflection		
Criteria		Our action research
5a	Did the researcher provide progress reports to the client and organizational members?	Executive summaries were provided to the clients. Oral communication was provided on a regular basis.
5b	Did both the researcher and the client reflect upon the outcomes of the project?	There were specific meetings to reflect about the outcomes of the research. The collaborative reflection was summarized in the evaluation and learning sections of the thesis, and in research papers.
5c	Were the research activities and outcomes reported clearly and completely?	We presented the research in this thesis and published research papers concerning this project.
5d	Were the results considered in terms of implications for further action in this situation?	The second cycle had a direct input from the first one, aiming to improve the auditing checklist. The third cycle had a broader influence of the previous cycles, including the first and second action research projects. An additional company showed interest in using ISO_2 and, in the process, contributing to further refinement of the approach. This will be done out of the scope of the Ph.D. project.
5e	Were the results considered in terms of implications for action to be taken in related research domains?	The results were considered in terms of implications for different levels of abstraction, namely the organizational and process level. We discussed implications for both the internal and external audits in different industrial sectors. Moreover, we discussed the findings that could affect the customers of our clients,

		namely in the food supply chain.
5f	Were the results considered in terms of implications for the research community (general knowledge, informing/re-informing theory)?	The implications of the results are important for researchers working with synergies between the IS and the QMS. We empirically tested our ISO_2 approach and the artifacts. A new synergistic approach for the joint development of the IS and the QMS is available. It can continue to be tested, adapted, and improved in different settings.
5g	Were the results considered in terms of the general applicability of CAR?	CAR was applicable to our three cycles and has provided guidance for the research in the client settings. According to our experiences, we found CAR applicable for cultural studies that emerge from social interaction in daily practice.

5.4.15 Conclusions of project AR3

The run-time part of the IS and the QMS lifecycle involves different stakeholders in the systems evaluation. Then, it is necessary to propose improvement actions at organizational and business process levels. To assist in the systems evaluation, we proposed checklists and the collaboration of process managers and users. The quality audit is a moment of interest for evaluating both the IS and the QMS, but it is not sufficient for fostering a quality culture in daily practice. There is a need to evaluate and improve the IS and the QMS in a continuous manner, as we already knew from the literature review, confirmed in our case studies, and during our action research cycles. We advanced the topic by suggesting a possible way to do it with ISO_2.

We selected the IS quality culture and business process quality culture as our focus to this phase of the research. Checklists and other artifacts can help, but are not enough (Pentland & Feldman, 2008). There is an opportunity to compare different perspectives of the same process, discuss the discrepancies, and through those discussions, identify new improvement actions.

Professor George Box, a distinguished statistician said that "*all models are wrong; some models are useful*" (Box, 1979). ISO_2 is well founded in our cases but we cannot claim that it is a total solution to synergistically developing the IS and the QMS in every possible case or scenario. At each step of the research ISO_2 evolved, and we expect that it continues to evolve even further as it is applied in new settings. Currently, ISO_2 presents a model, and, as all models, we simplify the real system by selecting specific elements that we found more relevant than others, according to our cases. ISO_2 proved to be useful in our action research cases, and its imperfections and shortcomings are opportunities for future improvement. Its sequence of steps is familiar to the IS/QMS managers, consultants, and process participants. Still, this does not mean that those professionals do not develop other activities besides the ISO_2 steps in their daily work; for example, the quality manager may have to supervise laboratorial experiments and the IS manager

may have to coordinate an help desk team. The difference is that now they have ISO_2 to assist their synergistic development activities.

This part of the study also has limitations. First, the scope is restricted to specific quality principles, namely those used by the particular companies involved. Second, our contribution only addresses the quality culture dimension, according to a set of predefined principles selected by the organizations. Cultural studies are complex and we did not consider individual or national culture aspects (Ali & Brooks, 2008; Kanji & Yui, 1997; Myers & Tan, 2002; Schein, 1990). Finally, in spite of the positive results that we observed for integrating cultural aspects, the approach still lacks a tool to support its expedite use by practitioners. This difficulty is amplified as we advance our research, because new artifacts emerge. The prototype that we developed during the second CAR project requires enhancements to support ISO_2 in its IS and QMS run-time forays.

5.5 ISO_2: a summary

Our ISO_2 proposal started with an extensive literature review. Then, we interviewed quality auditors to balance our interpretation of the data (Barata et al., 2013b). We carried on with fourteen case studies that allowed us to better understand the problems and opportunities of the synergistic development of the IS and the QMS (Barata & Cunha, 2013a, 2014a). Finally, our action research program of three CAR projects allowed us to define a sequence of steps and artifacts to guide the practitioners (Antunes et al., 2014; Barata et al., 2013a; Barata & Cunha, 2013b, 2014a, 2014b). Figure 5-18 summarizes the main steps of the ISO_2.
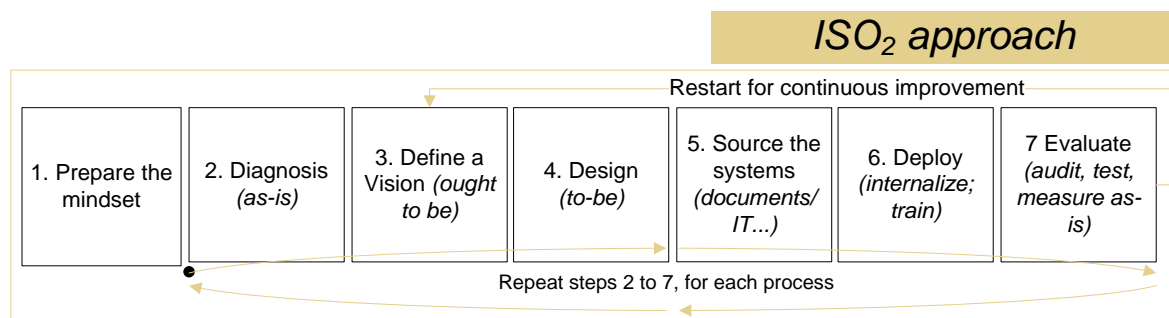
Figure 5-18. The steps of ISO_2 approach (Barata & Cunha, 2014a)

The steps of ISO_2 have not changed since the first CAR project, as we presented in section 5.2. Those steps were easy to understand by the participants and proved to be sufficient to guide the teams as intended. The participants considered that the ISO_2 steps were appropriated to represent development actions. Table 5-14 summarizes the ISO_2 approach, the O_2 artifacts in their final form, and the outcomes expected at each ISO_2 step.

Table 5-14. Summary of ISO_2 steps and proposed artifacts

ISO_2 step	Support artifacts	How / outcome
Prepare the mindset	O_2 framework	This is achieved through team meetings. Our ISO_2 steps illustrate the main development action and the O_2 framework provides a visual representation of the systems dimensions to take into consideration in ISO_2 artifacts. The development team becomes aware of the synergies and understands that they are going to act as partners.
Diagnosis (as-is)	MUVE provides a set of artifacts for diagnosing each process	It is conducted via questionnaire and interviews / meetings. The organization identifies and understands their processes from the perspective of their managers and users.
Define a Vision (ought-to-be)	*O_2 principles evaluation*	The main principles are decided by top management, aligned with the quality principles defined in their quality policy. The principles are then evaluated by the process participants.
Design (to-be)	*O_2 matrix;* *O_2 list;* *O_2 5W;* *O_2 map.*	O_2 artifacts are created to identify goals and rules for the joint development of the IS and the QMS.
Source the systems – focusing on each O_2 artifact.	N/A	It represents the action to convert O_2 artifacts into real objects to use in practice. The development team may use the type of technology or methodology they prefer, according to the organizational guidelines. The O_2 artifacts may provide them the goals and rules for the products they source.
Deploy – focusing on the development results and the people usage of the O_2 artifact.	*O_2 principles matrix*	The resulting "real" O_2 are put to daily use and people are trained.

ISO$_2$ step	Support artifacts	How / outcome
Evaluate – focusing on people satisfaction with the O$_2$ artifact.	*Checklist for auditing IS quality culture*; *O$_2$ principles development checklist* (the columns for evaluation); MUVE can be used to measure process improvement by comparing to the answers obtained during diagnosis.	Understand if requirements are implemented properly and if quality principles are actually being applied. Aims at identifying the gaps between what is intended and what is done in practice.
Improve – Towards an IS quality culture and business processes quality culture	*Checklist for auditing IS quality culture* (the columns that identify the actions and its execution phase); *O$_2$ principles development checklist* (the columns that identify the actions and its execution phase).	This is an ongoing activity that may lead to new ISO$_2$ cycles, achieved by actions to promote improvements.

The first column in Table 5-14 introduces the ISO$_2$ step. The artifacts are represented in column 2 of Table 5-14, associated with the most relevant step to their use, however there are artifacts that support more than one ISO$_2$ step (e.g., the *O$_2$ principles development checklist* also supports the improvement step). The third column summarizes the routines (Pentland & Feldman, 2008) for a synergistic development of the IS and the QMS. As we found in Chapter 2, dedicated to the literature review, "*ways of working*" are not enforced, they are learned, adapted, and developed by people (Barney, 1991; Hildebrandt et al., 1991; Schein, 1990; Schmiedel et al., 2014).

5.6 Conclusions

We described how ISO$_2$ evolved within three action research projects. The first CAR project had a single cycle in a technological institute. It allowed us to experiment ISO$_2$ steps and understand what changed during that cycle. We materialized some benefits of a synergistic approach to IS and QMS design, but also identified limitations that ISO$_2$ presented to effectively address the entire development lifecycle. The second CAR project was carried out in three different organizations (a forth cycle ended after diagnosing), with the purpose of refining ISO$_2$ at design-time. We tested the ISO$_2$ artifacts and improved the approach while dealing with applicable regulations in the context of ISO 9001. The third project involved three additional cycles and was motivated by the lack of support of ISO$_2$ to deal with the operation (run-time) of

the jointly designed IS and QMS Just before this conclusion, we summarized the final version of ISO_2 routines and artifacts that emerged from our research.

In the following chapter, we will present a complete example of application of ISO_2 to a specific process: the "D&D – Design and Development", included in the clause 7.3 of ISO 9001. The objective of Chapter 6 is to complement the presentation of the templates of artifacts in this chapter with real data from one organization (Barata et al., 2014). Along with the presentation, we will reveal relevant facts and lessons learned for both the design-time and run-time for the joint development of the IS and the QMS.

Chapter 6

ISO₂ in practice: an application case

6.1 Introduction

In the previous chapter we have explained how the ISO_2 approach and its auxiliary O_2 artifacts have emerged. In this chapter we present the results from the application of the approach to a real case, that occurred in a technological institute (Barata et al., 2014). We will use this context to exemplify in detail the adoption of ISO_2 for a specific process: the D&D – Design and Development. D&D is an important process for ISO 9001 certification, deserving an explicit clause in this standard: 7.3 (ISO, 2008, p. 8). The ISO_2 application that we present in this chapter evolved along our three action research projects. We believe that it is the case with the most potential to exemplify a comprehensive application of ISO_2.

This chapter is structured according to the previously presented lifecycle phases of ISO_2. After this introduction, section 6.2 presents the D&D process at the client setting. Then, sections 6.3 to 6.10 detail each step of ISO_2, namely: prepare the mindset, diagnosis (as-is), define a vision (ought-to-be), design (to-be), source, deploy, evaluate, and improve (restart to continuous improvement). At the end of the chapter, the reader should be able to:

1. Realize how ISO_2 can be applied to a specific process, to leverage synergies between IS and QMS, at design-time and at run-time of the lifecycle;

2. Identify the potential benefits of ISO_2 in the context of ISO 9001;

3. Adapt and employ ISO_2 for different business processes.

6.2 The D&D process

The D&D process is central to technological institutes, in the context of ISO 9001 (ISO, 2008a, 2008b). It is at the core of new products design and for conducting innovation projects, such as the European co-funded projects that are significant to the institute's resources. Interestingly, D&D is one of the most problematic processes of the technological institute. It is one of their processes with higher number of nonconformities in the ISO 9001 audits. Adding to the business process complexity, each D&D must comply with distinct regulations, which can

include, for example, customer agreements, laws concerning the product to be developed, and national/international regulations for co-funding of D&D.

Figure 6-1 present the main stages of the D&D process established in the institute, as required by sub clause 7.3.1 of ISO 9001 (ISO, 2008b).
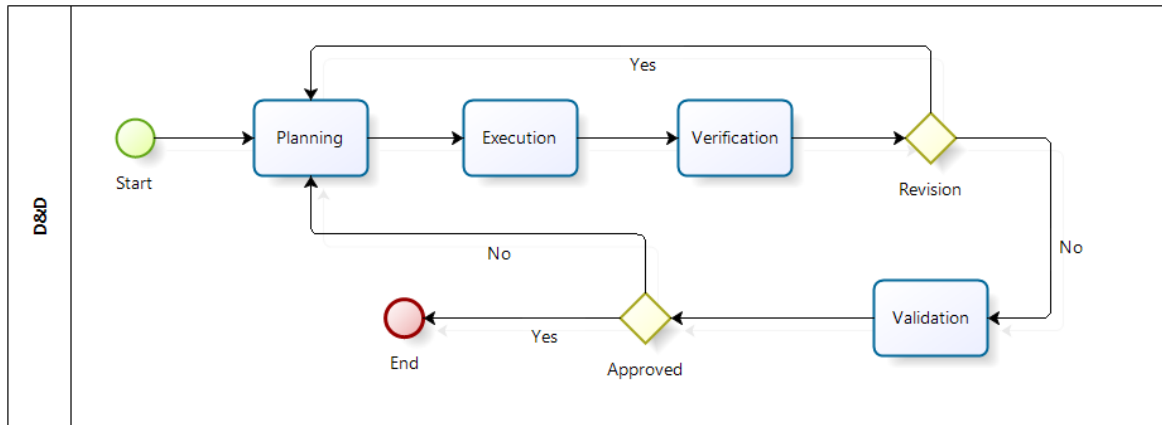
Figure 6-1. The D&D process at the technological institute (process diagram)

We now provide a brief review of the requirements of ISO 9001 clause 7.3. It mandates that the organization shall plan and control D&D, determining the (1) D&D stages, (2) the review, verification and validation at each stage, and (3) the responsibilities and authorities. Moreover, "*the organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility*" (ISO, 2008b, p. 8). The inputs for this process required by and ISO 9001-based QMS are the D&D requirements, as they are stated in clause 7.3.2. Those include functional, performance, statutory, and regulatory requirements. The outputs shall meet the inputs for D&D, specifying the product characteristics, their acceptance criteria, and providing sufficient information for product purchasing, production, and service provision. According to ISO 9001 clause 7.3, the organization shall perform periodical reviews to ensure that D&D keeps according to the requirements, proposing actions for possible problems, and controlling changes in D&D projects.

In our case setting, there are difficulties in the communication between the IS and QMS departments of the organization regarding the D&D process. The technological institute has an internal IS development team, dealing with innumerous requests from multiple departments. The IS manager has an overall IT development plan which is evaluated and tuned in regular meetings with the CEO. The selection of priorities is tricky, due to daily demands on IT, sometimes in conflict with the planned and approved roadmap (e.g., urgent requests). As new applications are built and the overarching information system of the organization grows, more adjustments, errors, changes, and improvement suggestions arrive each day. Moreover, both IS and QMS managers sometimes face contradictory requests, for example, when a specific laboratory of the organization needs operational changes in their systems that are against requirements or institutionalized procedures.

6.3   Prepare the mind set

The first step of ISO_2 is to prepare the setting for a synergistic development of IS and QMS. As we have seen in Chapter 2, the success of the IS and the QMS depends on the users involvement (Addey, 2001; Baroudi et al., 1986; ISO, 2008b; H.-W. Kim & Kankanhalli, 2009), and their support and interest to collaborate in systems construction, on a daily basis. There was a broad agreement at the technological institute about the necessity to improve the joint development of the IS and the QMS. Moreover, the D&D process participants, concerned with innovation, were more likely to be open to new ideas and ways of working, which is a potential advantage in our effort to improve it.

We used a top-down approach to prepare the mindset, because there are benefits in securing top management support in a synergistic development of the IS and the QMS (Briscoe et al., 2005; Cragg, Caldeira, & Ward, 2011; ISO, 2008b; Ivanova et al., 2014; Lin, 2010; Sroufe & Curkovic, 2008; Wang, 1998). Top management was enthusiastic to support our research, similarly to the top managers of our other CAR cycles. There are several possibilities to explain this apparent unanimous interest: (1) the opportunity to introduce a new dynamic in their QMSs, which, as we found in some cases, did not match reality, leading to a low perceived value, (2) the improvement of collaboration between IS and QMS, and (3) creating improvement evidences rather than reacting to problems. The early involvement of top managers can contribute to overcome some of the difficulties that may occur at the tactical level of management (IS/QMS managers, process managers), by (1) focusing the team on the organization and not on individual departmental interests; (2) establishing priorities that allow ISO_2 to be executed in daily practices; and (3) including the approach in the quality improvement meetings, that are common in ISO 9001-certified organizations.

After an initial presentation of ISO_2 to the top manager, a meeting was scheduled with the IS and QMS managers, to hoist their understanding of the shared view of the development. The managers' commitment to use ISO_2 in D&D process appeared easily in our case. We should note, however, that generally some difficulties may rise at this stage of the project. There is a risk of the QMS manager being used to present requests to the IS and then just wait for an answer (the customer viewpoint). Conversely, the IS manager may not be used to initiate change in business processes besides the technological aspects (the supplier viewpoint). Both managers face challenges, however, their lead by example in working as a team may be important for the sequent involvement of process participants.

After involving top and middle managers, we address the D&D process participants, which represent our third level of team engagement, ending the top-down track. Our experience working with CAR is that process participants generally want to express their opinion, interfering in process improvement with their suggestions. From this point forward, top manager, middle managers, process participants, and, eventually, external elements such as customers, should work as ISO_2 team members. To achieve this objective we use a set of slide presentations that explain the ISO_2 approach and the five dimensions in analysis: Context, People, Process, IT, and

Information/Data. Each participant must be aware of the different ISO_2 steps and its artifacts. They will need to know who the other participants are and their role in the business process, they must understand the process sequence (as-is), the adopted tools, and understand situational information from standards, laws, and policies. The slideshow that we prepared to train the ISO_2 team members had the following sequence of topics: 1-The current D&D process; 2-The D&D process 2020; 3-ISO_2 Approach; and 4-O_2 artifacts. We started to present the process as-is and, according to top management decision, specific aspects to highlight. For example, the process was critical for a five-year strategic plan approved by their administration board. The institute had the purpose to increase their participation in European projects (Horizon 2020). After that, we presented the approach and the artifacts to use. We made it clear that the template artifacts could benefit from improvement suggestions, rather than being rigid prescriptions. We learned in our CAR cases that there are two important aspects to consider at the presentation with users: showing that (1) O_2 artifacts are simple tools (e.g., matrices, tables) that aim to bring a new breath to their process development (the users could present resistances if they do not understand the artifacts and how to use them), and (2) those artifacts will in fact be used in practical improvement actions, rather than being merely descriptive tools, as sometimes happens with quality procedures (otherwise it would become a burden with no use to process participants). The presentation ended by explaining the implications of the approach, stating that it is a starting point for improvement, not an end. After preparing the mindset comes diagnosing.

6.4 Diagnosis (as-is)

To understand existing process friction from the perspective of its users, we deployed a questionnaire as suggested by the MUVE – Motivation, Understanding, Value, and Effort approach (Antunes & Cunha, 2013). The result of the diagnosis for the D&D process is presented in Figure 6-2.

Figure 6-2. The D&D process blueprint with MUVE

The MUVE questionnaire is a field tool with four main groups of questions to access Motivation, Understanding, Value, and Effort, as represented in Figure 6-2. In each cell we can find a set of bars, each representing a question, indicating the average result, across all respondents, for that question. We can see that in the top left cell for Motivation, there is one question with a low result, presented in red (the last line). The green color is used when a question does not reveal problems from the point of view of process participants, yellow is used if the issue deserves attention (even if it is not critical), and red if it is a process problem. The use of colors facilitates the analysis, for example regarding Value (bottom – left cell, all green) we can see that all the Value questions had acceptable answers that do not indicate problems to be solved.

The process participants recognize the Value of the D&D process and the importance of new product developments for the future of the organization. However, we may observe in Figure 6-2 that the Effort (bottom – right cell) is classified with yellow, meaning that participants think that the process requires a significant effort. Again, although process participants recognize the Value of the process for their organization (green), the majority of the Understanding and Motivation bars are yellow, suggesting opportunities to improve. Figure 6-3 presents the evaluation drill-down for each D&D process activity, its inputs, and its outputs.
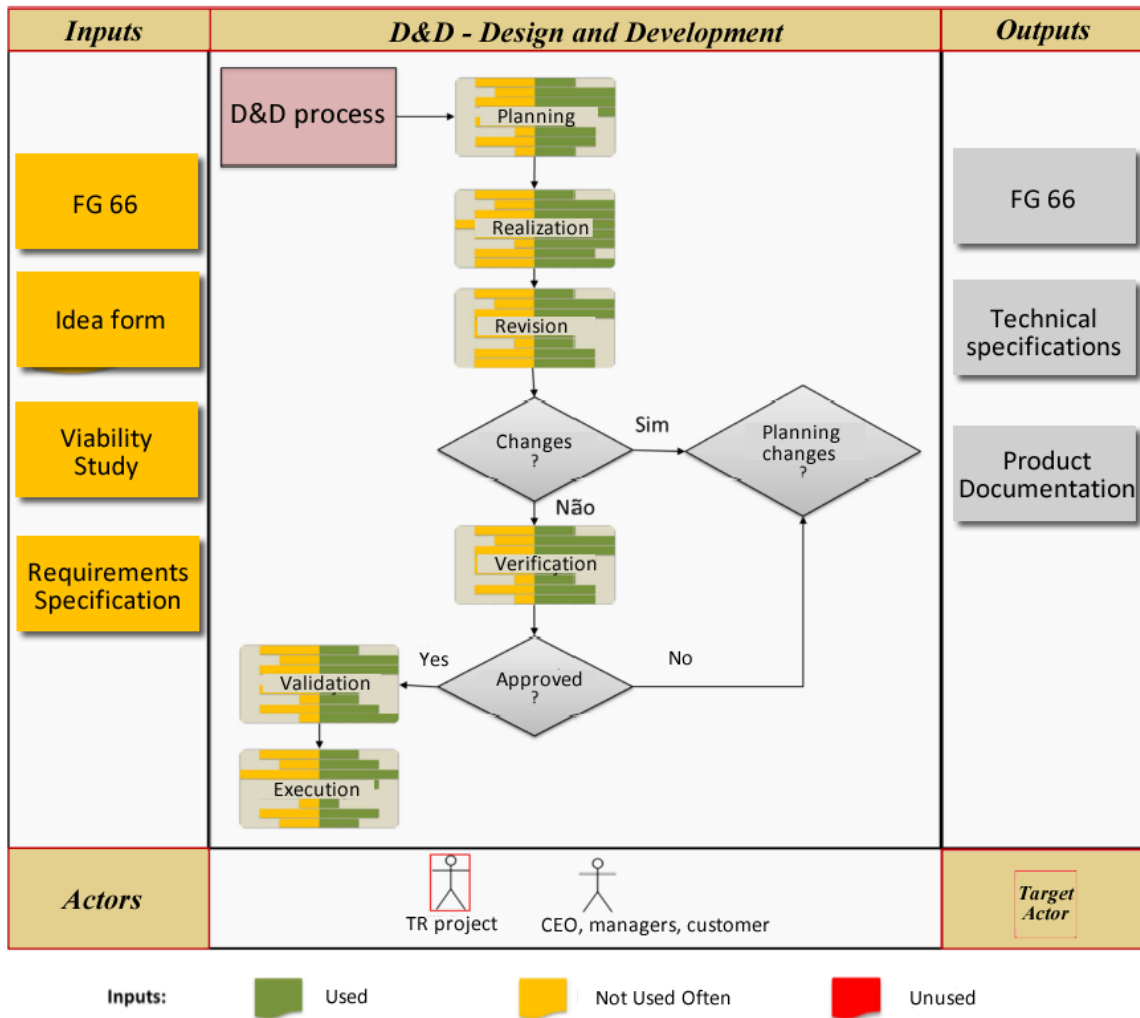
Figure 6-3. The D&D process detailed evaluation with MUVE

The leftmost column of Figure 6-3 presents the process inputs and the rightmost column shows the process outputs. In the middle we have the process flowchart, with an indication of the questionnaire results for value-effort balance for the various activities in each process activity. At the bottom, the process actors are represented. As per the legend key, colors are used to represent the actual level of use of the official process inputs during process execution. In our case they are all yellow, meaning that process participants do not use the D&D process inputs often. The D&D process documentation was composed by spreadsheets and written procedures to define the process steps. The "FG 66" – represented as input and output – is an example of one of those spreadsheets that includes the plan for the project proposal, revisions records, and the checklist for verification and validation.

The motivation to comply with the process rules is problematic in this case. Our questionnaire identified that one of the problems was, precisely, the cumbersome spreadsheets that were used to support the D&D process. Those files were not user-friendly and did not help the users in accomplishing the requirements. The main elicited problems were:

1. The process documentation was not used in practice. No one regularly reads the procedure for D&D; as a consequence (according to the quality manager), the audits frequently found nonconformities in the process;

2. The spreadsheets did not protect the users from mistakes; for instance, the cells were not protected (e.g., erase/change data by error; leave important fields blank);

3. The users needed to fill different templates: one for the project identification (in their ERP system) and another for the project plan;

4. Each project required a paper archive to deal with project communication, for example legislation and external reports;

5. The users stated that the process was executed differently from its design. Moreover, process participants told us that their input was not considered when the process was designed. For example, the D&D manager was not included in the initial meetings that aimed at defining process documentation: it seemed to be a quality manager's problem, not shared with IS and process participants, as it should.

After this diagnosing step, we have moved to the definition of a vision for the process.

6.5 Define a vision (ought-to-be)

The top manager aimed at a business process compliant with ISO 9001. Additionally, D&D is a priority for the organizational strategy towards 2020. The process is critical and had to be improved. It was essential to remove process frictions, including the ones found during our previous ISO_2 step, namely:

1. The process documentation was not used in practice: We had insights from the MUVE questionnaire that the documentation to assist the process participants in daily tasks required redesign;

2. The spreadsheets did not protect the users from mistakes: A D&D process, supported by IT, must guide the users on what they should do, but also protect them from doing what they should not do. IT can provide data validation functionalities, for instance, ensuring that specific fields are filled in an electronic form. To achieve a process that is user friendly, the D&D process workflow and rules must be incorporated in the organizational IT solutions;

3. The users needed to fill different templates: Nonprofit organizations must ensure regulatory compliance. Some quality templates can be automated with IT, reducing the number of forms and even allowing the process simplification. At this stage of ISO_2, we did not know if all the existing D&D templates are really needed to execute D&D and ensure compliance to regulations. The next ISO_2 steps will identify the information requirements and then, how to implement them in daily practice;

4. Each project required a paper archive: IT can reduce paper use, with known advantages for information archiving, such as physical space optimization, improving information search, and data confidentiality (e.g., adopt data encryption techniques, ensuring that sensitive data are only accessible to the authorized users);

5. The users stated that the process was executed differently from its design: Our intervention must involve all the users in the D&D process, at design-time and at run-time. Compliance with ISO 9001 does not allow gaps between design and operation: what is documented must fit practice (Cunha & Figueiredo, 2005).

As presented in Chapter 5, the O₂ framework suggests that we must consider the five interrelated dimensions of Context, People, Process, IT, and Information/Data. It is necessary to identify the information entering the system (outside-in), processed by the system (within), and provided by the system (inside-out). These three perspectives are essential when dealing with external information that shapes the IS and QMS requirements, expressed by goals and rules (outside-in), must be internalized in daily practice (within), and finally, evidence must be provided to external entities (inside-out).

The artifact in Figure 6-4 is used to evaluate the business process quality culture. The first column identifies the principles adopted by the organization (they are the same for all business processes). As we presented in the previous chapter, the principles may include specific high-level policies, such as sustainability, as stated in the organizational quality policy. The technological institute decided to restrict the list of principles to the eight from ISO 9001 dealing with quality (ISO, 2008b). Figure 6-4 presents the *O₂ principles evaluation*.

Main Principle (ISO, 2008b)	General Description (ISO, 2008b)	Business Process Quality Culture
Customer focus	Organizations depend on their customers and therefore must understand the present and future customer needs, satisfy the requirements of the customers and make an effort to exceed customer expectations.	External customers expect that D&D addresses the core business of the institute, namely in materials development. External customers expect that D&D results may be transferred to the market (project utility). Internal customers want to obtain complete information for the D&D: funding opportunities, ongoing projects (internal communication), possibility of allocation of expenses, past and current project outcomes (e.g., publications, public presentations, guides), and the new products developed with D&D.

Main Principle (ISO, 2008b)	General Description (ISO, 2008b)	Business Process Quality Culture
Leadership	Leaders establish the unity of purpose and orientation of the organization. They must create and maintain an internal atmosphere in which the people can become fully involved in the achievement of the organization objectives.	Process participants must regard the D&D process as an opportunity to develop their own business units' processes and products. Company principles must be entwined with organizational practices, at all levels (we are coherent to the principles that we defend).
Involvement of people	People, at all levels, are the essence of the organization and their total commitment enables their skills to be used for the benefit of the organization.	External organizations must be listened to periodically, regarding their D&D needs and ideas (customers, suppliers, potential partners). There is a need to create an environment that facilitates new ideas and their merits recognized. D&D projects must involve participation of all the units of the institute (every unit should participate, at least, in one D&D project).
Process approach	A result is achieved more effectively when the related activities and resources are managed as a process.	D&D process must be defined and documented, supported by IT (100% is the target).
System approach to management	Identifying, understanding, and managing interrelated processes as a system, contributes to the effectiveness and efficiency of an organization in the achievement of its objectives.	D&D process must be evaluated by its outcomes to the market (new product success), but also by the internal processes development, namely consulting and laboratorial. D&D process has interfaces with marketing process, provisioning process, production (laboratorial and consulting), and human resources management (includes training). These interfaces must be included in D&D project plans.
Continual improvement	Continual improvement of the organization's overall performance must be a permanent objective.	At least 50% of the D&D projects must be internally focused: internal process improvements or new product development. This means that for each externally contracted D&D, the organization must deploy an internal D&D project. Adopt ISO_2 for synergistic development of the IS and the QMS.

Main Principle (ISO, 2008b)	General Description (ISO, 2008b)	Business Process Quality Culture
Factual approach to decision-making	Effective decisions are based on data analysis and information.	The scientific advances must justify D&D projects and market needs (combine knowledge and practice). IS quality must be evaluated and continuously improved; to ensure trust in the institute business processes and that decisions are well founded.
Mutually beneficial supplier relationships	An organization and its suppliers are interdependent and a mutually beneficial relationship increases the capability of both for creating value.	Suppliers should be involved in the D&D projects from the beginning (including idea generation).

Figure 6-4. *O₂ principles evaluation* for the D&D process

As we can observe in Figure 6-4, the artifact contributes to improve the process participants awareness of the organization's quality principles (the identification provided in column 1 and 2) and reflection about their practical adoption in the process (column 3 is a result of process participants perspective). A high-level vision emerges for D&D, inspired in the ISO 9001 structure and quality culture (ISO, 2008b, 2012a; Kanji & Yui, 1997; Philip & McKeown, 2004), nevertheless, we may already identify key goals and rules that the users can consider in sequent O_2 artifacts. The next step in the application of ISO_2 increases the level of detail of social, technological, and informational issues to the joint development of the IS and the QMS (Delić et al., 2014; Lee et al., 2015; Paul, 2007). From vision we move to design.

6.6 Design (to-be)

The design team in the technological institute involves the IS manager and the QMS manager, but other process participants can also contribute. The ISO_2 approach suggests a joint development, as a partnership, trusting the top manager to decide unsolved issues among the team members. One of the difficulties of managing joint design is the different backgrounds of the project participants.

To make design more effective, the ISO_2 uses matrices to identify development requirements (goals and rules). The *O₂ matrix* for the D&D process is presented in Figure 6-5.

D&D Process		Outside-in	Within	Inside-out
Context [Standards, company functions and policies, legislation, scientific developments]	Current		✓ Translate requirements into new product specifications ✓ Compliance management;	✓ Provide information to the customer regarding the project status
		✓ Project calls; ✓ Partner search		
	Planned	✓ Regulatory product constraints; ✓ Company policies about innovation and new product development; ✓ Universities and R&D institutes communication	✓ Risk management; ✓ Financial management and project timesheets; ✓ Verification and validation requirements of ISO 9001; ✓ Project revisions (ISO 9001 requirement)	✓ Marketing and commercial diffusion; ✓ Develop technical specifications (product documentation)
People [New product participants, customers, suppliers]	Current	~~D&D department is the interface with new product development*~~	✓ D&D department creates order production	✓ Commercial department provides information to the customer ✓ Newsletter contributions;
	Planned	✓ All the company workers must participate in new D&D; ✓ Promote access to scientific and technical publications; ✓ Training in innovation; ✓ Record customer suggestions	✓ Diffuse new ideas and innovation opportunities; ✓ Idea selections (create rankings, priorities); ✓ Improve communication of ideas and project status; ✓ Project management (e.g., Gantt charts); ✓ Indicators of process success	✓ Seminar participations; ✓ International project developments co-funded by European projects; ✓ Evaluate ideas with potential partners; ✓ Evaluate customer satisfaction for new products

D&D Process		Outside-in	Within	Inside-out
IT [Network, software]	Current ⇩	✓ Web portals to obtain information about technological developments; ✓ Newsletters input	~~Excel*;~~ ~~Production records (paper)*~~	✓ E-mail
	Planned	✓ Monitor competitors use of IT	✓ Innovation management platform; ✓ Project management solution with B2B functionalities	✓ Website interface; ✓ B2B with project partners
Process [Tasks, responsible and performance indicators]	Current ⇩	✓ Customer order entry	✓ Product specification; ✓ Production order ✓ Idea management (record – evaluate – decide to implement /discard);	✓ Product Shipment
	Planned	✓ Knowledge management about product, process, and marketing innovation	✓ Project management (Record project, define teams and plan, define objectives – develop – training – evaluate)	✓ Project report to external entities; ✓ Product catalog / commercial presentation; ✓ Financial and quality indicators: % success, profit margin, detailed costs

* eliminated in the improved process

Figure 6-5. *O₂ matrix*: the goals and rules for the D&D process

The matrix includes goals and rules that the design team considers more relevant for the D&D process. There are lines for the goals and rules currently implemented (as-is, step 3) and the planned goals and rules (to-be). The next step is to group goals and rules by colors. Each color represents a development project, and the black color represents a shared requirement, that is not specific to a project but must be considered for all the development projects in the D&D process.

In the example presented above (Figure 6-5), there are two colors: blue and orange. The orange color represents an innovation management platform, while the blue color represents a

project management solution with B2B functionalities. When we combine the goals and rules of the same color in a unique table, we have the requirements for that solution to be sourced, as presented in Figure 6-6. To exemplify, we will detail the innovation management platform.

D&D Process	Outside-in	Within	Inside-out
New IT solution (O₂): Innovation Management Platform	✓ Web portals to obtain information about technological developments; ✓ Newsletters input; ✓ Regulatory product constraints; ✓ Company policies about innovation and new product development; ✓ Universities and R&D institutes communication; ✓ All the company workers must participate in new D&D; ✓ Promote access to scientific and technical publications; ✓ Training in innovation (in this case represented by manuals and definitions included in the platform); ✓ Record customer suggestions; ✓ Monitor competitors use of IT; ✓ Knowledge management about product, process and, marketing innovation	✓ Compliance management; ✓ Diffuse new ideas and opportunities; ✓ Idea selection; ✓ Platform for managing ideas; ✓ Idea management (record – evaluate – decide to implement/discard)	✓ E-mail; ✓ Seminar participations; ✓ International project developments co-funded by European projects; ✓ Evaluate ideas with potential partners; ✓ Website interface; ✓ Product catalog / commercial presentation; ✓ Financial and quality indicators: % success, profit margin, detailed costs

Figure 6-6. *O₂ list*: the innovation management platform: main goals and rules

The artifact provides a guide of requirements for the new solution, which may be more detailed over time (it is suggested to create versions of the artifact). Figure 6-7 presents the *O₂ 5W* to detail each goal/rule of the previous *O₂ matrix*. We present the case of two requirements presented in Figure 6-6: outside-in column, line 1 and line 3.

O_2 goal/rule	Type	Why	Who	When	Where	What
Web portals to obtain information about technological developments	Outside-in	✓ Innovation requires information from several sources; It is a requirement of ISO 9001 (decisions based in facts)	✓ Any user of the process can obtain external information	✓ Notification by external stakeholders; It is also possible to obtain internally by research	✓ IT menu for knowledge management – technological vigilance web form	✓ Websites, papers, articles, notes about ideas
Regulatory product constraints	Outside-in	✓ New products (and related services) must comply with regulations	✓ Project manager	✓ Product specification phase; risk analysis	✓ IT menu for project identification: grid view of project objectives; product restrictions field	✓ Standards laws, customer requirements

Figure 6-7. The O_2 *5W*: detailing goals and rules for the innovation management platform (2 examples for the outside-in column in Figure 6-6)

The O_2 *5W* artifact provides finer grained information about each goal/rule and identifies its reasons (why), the persons involved (who), when the goal/rule occurs / events that trigger it (when), where we can obtain evidence of its implementation (where), and the type of information that is needed (what). After this level of abstraction, each participant may detail even further as needed, for instance, the IT developer may create specific use cases or database diagrams (if one is developed), the purchasing manager can create the terms of reference for a market acquisition.

The ISO$_2$ and the O$_2$ framework address a level of detail that may fit a joint development (the main purpose is not individual development by each expert), however, collaboration is suggested even in tasks that may be of the exclusive responsibility of one team, respecting the goals and rules previously identified. The artifacts were created in a way that supports ISO 9001 clause 7.3 compliance (ISO, 2008b), regarding planning, execution, inputs, and outputs of D&D.

In this case, we had the purpose of reducing the D&D process documentation (procedures, form templates, and instructions) to a single smaller, friendlier document. It was possible to: remove rules included in document and include it in IT platforms; include process definitions in IT (tooltips, glossary); and removing all the references to external documents. The process documentation changes are illustrated in Figure 6-8.
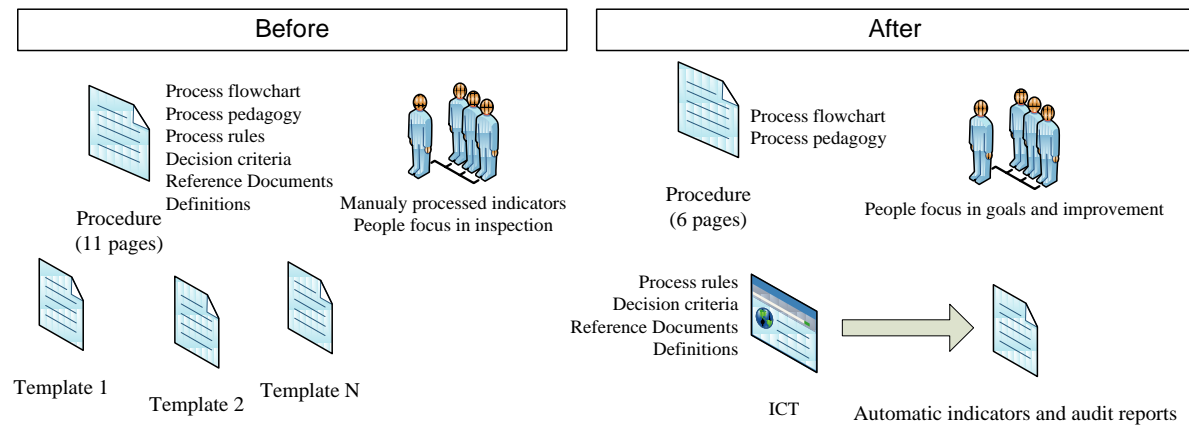
Figure 6-8. Process documentation changes with ISO_2 (Barata et al., 2014)

After the design, comes the sourcing of the systems.

6.7 Source the systems (documents/IT support)

With ISO_2, the teams create or buy the tools (O_2) with the methods and technologies they prefer, according to the guidelines that are established in the organization. There are several methodologies to source systems, for example, coding of IT systems (Larman & Basili, 2003) and buying or assembling IT solutions (van der Aalst, ter Hofstede, & Weske, 2003b); however, the ISO_2 approach does not suggest any one in particular. Nevertheless, we did not ignore this step because it is important to assist IS and QMS teams in their daily practice, especially to avoid duplications (e.g., the same information in procedures and IT user manuals) and inconsistencies (e.g., procedures indicating some rule ignored by the supporting IT).

In this specific case an web-based system was developed in-house, according to the institute's technology guidelines. The application requirements included the ones previously identified in the institute's general policies (e.g., technology, database, security…), and the new ones identified with the O_2 artifacts for the D&D process. This phase had a duration of nearly three months, involving regular meetings between the IS and QMS teams. One of the resulting IT applications that emerged from the requirements in Figure 6-5, Figure 6-6, and Figure 6-7 (orange color) is represented by the print screen in Figure 6-9.
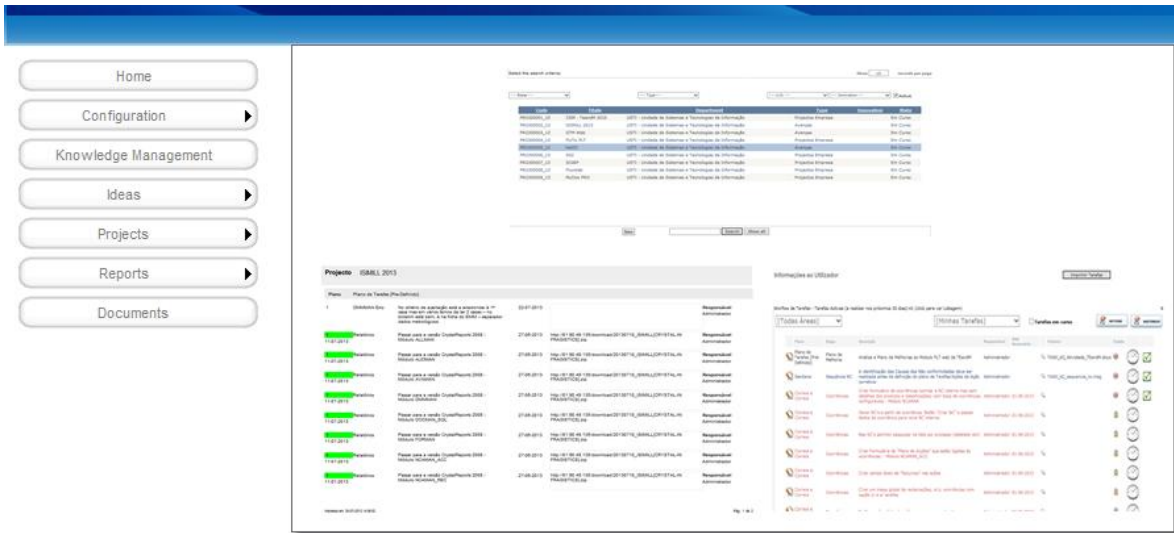
Figure 6-9. IT support for the D&D process

During the creation of the new process documentation and of the supporting web tool, there were several meetings of about 45 minutes each. The purpose was to evaluate the integration between the tools and the O_2 goals and rules previously identified. The O_2 artifacts are not static elements, so they may change as the implementation evolves. New goals were added to the matrices as new functionalities were included in the tool; for example the (inside-out) goals "To obtain Gantt charts reports or by exporting data for Microsoft Project" and "Financial execution report".

Updating the matrices as the tools evolve is important for the ISO_2 success, because O_2 artifacts can be used to support the audits, similarly to checklists that auditors follow to (1) check compliance and (2) propose improvements. An additional benefit of the O_2 artifacts is to make improvement actions more precise, as suggested by a member of the institute IS team:

> "The audit report usually has vague suggestions or nonconformities that represent problems found during the audit. However, we need to present solutions to those sentences the auditor writes. If the O_2 artifacts are complete, we can ask the auditor where exactly is the problem, to help us in the identification of the O_2 artifact that requires changes (nonconformity) or can be further developed"

The idea expressed in this sentence is to assist the identification of improvement actions and their follow up. We suppose that this is a possibility, however, we could not test if, in practice, this aspect is helpful to the organization. Nevertheless, we had the opportunity to gather important feedback from the external auditor, who said that our ISO_2 approach had the benefit of providing process "meta data". We agree with this observation because ISO_2 proposes a different form of process representation (documented information), as we have seen, that are useful for both the design-time and run-time phases.

Throughout our research, we constantly inquired if the overhead introduced by the O_2 artifacts was justified by their benefits. For the D&D process, in our joint interpretation with the organizational managers, we agreed in the following foremost benefits:

1. New forms of information representation (a typical representation in ISO 9001 is a procedure or a work instruction), based in matrices that describe different dimensions of the IS/QMS, adopting to a process approach as suggested by ISO 9001;

2. The ISO_2 adoption, just by itself, is a potential improvement action to include in ISO 9001 audits: clause 8.5 for improvement (ISO, 2008b);

3. ISO_2 can guide the assessment and improvement of IS quality, in the context of ISO 9001, potentially increasing user satisfaction with the process and its supporting systems.

4. The variety of process documentation increases with the O_2 artifacts, but may decrease in length and complexity of the written procedures. The improvement of process documentation have the potential to reduce *"ceremonial conformity"* (Biazzoa, 2005) if the documents are more useful for practice.

Regarding the first benefit, as we have seen in our case studies, ISO 9001 process documentation is not comprehensive enough for IS development. In our cases, we found a cumbersome situation of process documentation changes and IT changes with no relation between them, leading to the lack of adherence among the formal process, the supporting tools (IT), and daily practice. The second benefit of ISO_2 adoption was recognized by the internal and external auditors, as an improvement to the production of evidences (ISO, 2011). The third benefit was observed by the possibility to evaluate the conformity of tools that support the goals and rules. The collaboration between IS and QMS teams is expected to decrease the risk of late requirements for the IS, but also minimize the problems of lack of IT support for business processes. Finally, we could witness the fourth benefit in practice by integrating IT and the process documentation, thus decreasing document length and improving readability. All the rules were removed from the process documentation and included in the IT platform. Bellow we provide examples of sentences that were removed from the D&D procedure to be enforced by the IT support system:

- *"The responsibilities regarding this procedure are presented in the next section"*: IT permissions allow knowing who does what in the process. The IT platform knows the users and their respective permissions (e.g., who can add new projects, who validates the project, who is the administrator);

- *"When a new project is created, the manager must develop a plan using form XYZ"*: This type of sentence can be removed from the documentation of the procedure if IT and the process are synergistically developed. First, the project plan form XYZ must be a part of the IT system. Second, if necessary, the platform will require the user to fill the plan (required fields). In the present case, "form XYZ" is a web form;

- *"When an idea for a new product is identified, the relevance of creating a new project of D&D must be evaluated. The criteria to evaluate an idea are... [criteria 1], [criteria 2], (...)"*: The functionality and the criteria should be included in the IT system, not in a written description of the procedure. Otherwise, there is the risk of changing one (the process procedure or the IT) without changing the other. Additionally, it is not adequate that the user needs to read a procedure to know the criteria to evaluate new ideas, those should be presented directly in the IT platform;

- *"The identification of the D&D project risks must be done by"*: This is another example of what something that should be handled by the workflows configured in the IT system. Furthermore, proper validation of data entry truly helps the users of the process;

- *"Definitions; Innovation means the implementation of new (...)"*: Definitions should be present where needed, as contextual information. IT-enabled systems have means to provide definitions (e.g., tooltips, videos, and user manuals) directly accessible during operation.

In spite of the promising feedback, we still believe that there is a need to balance the level of detail that users require for their O_2 artifacts. If it is less than needed for system implementation and sequent auditing, then the O_2 artifacts run the risk of becoming useless, and consequently, a part of the *"ceremonial conformity"*. If the O_2 artifacts include too many details, there is an overwork with the approach; it becomes more difficult to keep the O_2 artifacts updated, and the audits may not see these artifacts as proper checklists for guidance due to their length. Conciseness is key, since ISO 9001 quality audits last just a few days during which several areas of the organization must be addresses. We suggest that ISO_2 users should decide when to stop detailing their information and that this decision may depend on each case, according to the company size, the type of process, the IT development capacity (internal vs. external), or even the level of demand of their customer audits (requiring more or less detail).

Our option during this research was to reach the minimum level of detail in O_2 artifacts that, according to process participants, was simultaneously useful and sufficient for ISO 9001-based QMS compliance. A joint development shall aim at coherence and collaboration among the practitioners. How the organization decides to create the tools is their own decision. This is especially critical when standards such as ISO 9001 may be adopted by multinational organizations (eventually with internal IT development), or by very small organizations with minimum IT support (eventually acquired from external suppliers).

After the sourcing step of ISO_2, comes the deployment.

6.8 Deploy (internalize/train)

This step represents the moment when the various O_2 become available to the organizational users. These may be spreadsheets, web applications (as presented in our case), or

any other media accepted by ISO 9001 (ISO, 2008a, 2008b). These tools should be according to the requirements expressed in our O_2 artifacts and the process participants can use them with minimal friction (Antunes et al., 2014; Antunes & Cunha, 2013). In the present case, at the technological institute, we selected a pilot D&D project to launch the new platform and train the users with real data.

Training is an opportunity to identify improvement opportunities and to assess if the O_2 are according to the requirements. One suggestion regarding this phase is that training to end users should include the process owner or, alternatively, elements of the ISO_2 team. In ISO_2, the IS and the QMS emerge from the users practice, with the benefits of a socially constructed process. The second suggestion is that training recalls the background of goals and rules behind the implemented tools. In this way, we also train the users in the quality principles and policies that the organization defends.

Having the solutions deployed, they should be evaluated.

6.9   Evaluate (audit/test/measure as-is)

This step is similar to the "C – check" phase of PDCA (Shewhart, 1939). It is always possible to improve the IS and the QMS, but priorities must be established. This step of ISO_2 uses artifacts in the form of checklists. Complementarily, it is possible to gather inputs from complaints or nonconformities, questionnaires or any other evaluation source that the organization uses to measure processes.

Regarding the checklists that we developed (*checklist for auditing IS quality culture*, *O_2 principles development checklist*), we reinforce their non-prescriptive nature. They provide guidance for the principles that the organization chooses to follow. Then, for each case, or even for different processes, the checklists may be adapted. In this section we present the checklists used for the D&D process of the technological institute.

Figure 6-10 presents the IS quality culture evaluation. The artifact was initially developed for the organizational level (not to specific processes), as discussed in Chapter 5, but we made changes to its use at process level. One adaptation was to include the viewpoint of the process owner, while the auditor may be internal or external to the organization. Although we only considered the feedback of one auditor for this process, additional columns can be added if there are additional relevant viewpoints; for example, if it is possible to obtain a richer picture provided by both, an IS auditor and a quality auditor. There were other minor changes; for example, the first checklist item has been changed from "plans of the IS department", as presented in the first line of Figure 5-12, to "plans of the organization". We also excluded the service quality group of questions, at the process level, because the organization decided to integrate that evaluation aspect in their processes as a whole. We omitted the information regarding the action stage (rightmost column) because it is not relevant, being represented in the same way of Figure 5-13, which include the correspondent PDCA stage (Shewhart, 1939).

P	Administrative Quality Checklist	Process Owner*	Auditor*	Action
CF	(1) The feedback of process participants is registered (e.g., with questionnaires) and considered for budgets and plans of the organization	4	4	
CF	(2) The IS management directly interacts with end customers, to understand needs and opportunities	4	2	(A0) Monthly meetings for continuous improvement (these meetings occurred annually) (A1) The IS team shall visit one external customer each trimester
LE	The IS has a defined strategy that aligns business and IT	4	3	
IP	Distinct business departments are involved in establishing IS plans and acquisitions in D&D; for example, the process participants are involved in evaluating requirements for new IT initiatives	4	3	(A2) Organize brainstorming sessions with distinct business departments
PA	Processes are defined	4	5	
SA	(1) There is an established procedure that defines the IS in all its dimensions of people, process, information, IT, and quality context	4	4	
SA	(2) The potential of IS standards is known and used as a guidance for the organization	4	4	Note: Top management decided not to adopt specific standards for security management (ISO 27001) – an option under consideration
CI	The projects and budgets are monitored and evaluated at the end. Preventive and improvement actions are established (e.g., risks are identified before each project and actions planned)	5	3	(A3) ISO_2 approach
FA	The plans and budgets are evaluated and lessons are used in future projects	4	3	(A3) ISO_2 approach
SR	Authorized suppliers have documented quality procedures and adopt standards for their key service/product	1	2	(A4) Develop a template for supplier evaluation checklist. It should involve action plans (for the suppliers) of key products and services

	Information/Data Quality Checklist	Process Owner*	Auditor*	Action
CF	(1) Process participants are inquired on the quality of input data and actions are taken to improve information processing	2	3	(A3) ISO_2 approach
CF	(2) Incomplete information/data is identified and treated as nonconformity. Actions are taken to solve the identified problems	3	2	(A5) Create a functionality to check and report data quality problems in the D&D innovation management platform (A6) Create explanation labels (or tooltips) in specific fields of the D&D innovation management platform
LE	Information quality is recognized as an essential aspect of quality, similar to any other resource	5	3	Note: not so developed when compared to the laboratorial sectors
IP	(1) Users are aware of the need to protect access to sensitive data	4	4	
IP	(2) Users participate in data validation tasks (e.g., validate calculations of a specific software or spreadsheet) and consider information/data quality as an issue concerning all the stakeholders of the organization	1	2	(A3) ISO_2 approach
PA	The information requirements are identified for all the process activities	4	5	(A3) ISO_2 approach
SA	There are no "islands" in the IS: the users have the required information to develop their work and consider that information reliable	5	4	
CI	Process participants are motivated to improve the quality of information, such as accuracy, objectivity, believability, access, security, value-added, timeliness, completeness, interpretability, and ease of understanding	5	3	
FA	Records allow traceability, for instance, to know by whom and when important records are created, changed, or deleted	4	3	(A7) Implement a web service (identified as a new O_2) to record deletions in a central database: the current logs do not identify the deleted records – only record creation and changes)
SR	Information provided by suppliers can be validated (evidences of quality, such as digital signature, test reports)	1	3	Note: During this work we found that supplier management process requires improvements

	Software Quality Checklist	Process Owner*	Auditor*	Action
CF	(1) D&D software requirements are identified by the end users	4	4	
CF	(2) Users requests are recorded and appropriate actions taken to improve the software	5	4	
LE	(1) Business-IT alignment is a permanent concern of management and evidenced in corporate reports and business plans	5	5	
LE	(2) There is a D&D process improvement plan that includes IT	5	5	
IP	User satisfaction is monitored concerning D&D software solutions	5	4	
PA	The organization is able to identify the business processes supported by each software application	5	5	
SA	There is an integrated perspective of software applications (enterprise application integration issues)	5	3	(A8) Renegotiate the ERP contract to include more development time. Current contract does not include integrations or development requests
CI	(1) There are external maintenance contracts for the most relevant software (if applicable)	N/A; Not applicable – internally developed	4	(A9) Define service requirements for IT – new field in the D&D project form
CI	(2) There is a plan for the evolution and update of internally developed software (if applicable)	5	2	(A3) ISO$_2$ approach
FA	There is evidence of software testing, software validation, and acceptance (not only for clause 7.6)	2	2	(A3) ISO$_2$ approach
SR	(1) Suppliers provide validation evidences for software products	N/A**	1	
SR	(2) Improvements are suggested to the suppliers	N/A**	2	
	Infrastructure Quality Checklist	Process Owner*	Auditor*	Action
CF	(1) The network performance is adequate for internal and external access (see users feedback)	3	4	(A11) Evaluate VPN problems reported by process owner
CF	(2) It is possible to identify infrastructure requirements for each organizational function	4	4	

LE	The organization considers IT requirements when planning process changes and new organizational investments	4	4	
IP	There is feedback concerning infrastructure performance (e.g., workers satisfaction inquiries include items concerning computers or network compliance with their functions)	5	4	
PA	IT infrastructure can be connected with the process map. IT requirements are identified for specific activities and responsibilities (for instance, process X, developed by function Y, requires operating system Z, and internet access G)	3	4	
SA	(1) Organizational infrastructure is identified (e.g., IT network map)	4	5	
SA	(2) Backups of data/information and software applications are identified and there are recovery plans (and a contingency plan)	4	5	
CI	Organization updates IT according with the needs of the processes and technological innovations	4	5	
FA	The selection of IT includes criteria other than price, for instance, process requirements, performance requirements, specific applications for the D&D function	4	5	
SR	(1) IT suppliers provide timely information concerning new IT in the market	N/A**	2	(A12) Establish IT provisioning requirements for each D&D project (an input) – new field in the D&D project form
SR	(2) IT interventions (e.g., repair) is recorded by the suppliers	N/A**	2	(A9) Define service requirements for IT management, if applicable – new field in the D&D project form

evaluate from 1(inexistent), 2(weak), 3(satisfactory), 4(good), and 5(very good)

** *The process owner and the auditor had divergent interpretation of the item*

Legend of column 1: [QP] Quality Principle; [CF] Customer focus; [LE] Leadership; [IP] Involvement of people; [PA] Process approach; [SA] System approach to management; [CI] Continual improvement; [FA] Factual approach to decision-making; [SR] Mutually beneficial supplier relationships.

Figure 6-10. *Checklist for auditing IS quality culture*: D&D process

There are advantages in including a column for the evaluation of the process owner; for example, to overcome potential difficulties in getting access to auditor with the required skills to access that process in particular. The process owner may gather insights from process participants and contrast their evaluation with the auditor's viewpoint. The original checklist has two additional columns (on the right of the evaluation score) that we do not present here, to report the comments and evidences for each evaluator. It is similar to a notes field and allows the evaluators to explain their viewpoint and eventually propose actions. We can also observe, in Figure 6-10, that one action may attend to more than one goal/rule. For example, A3, regarding the ISO_2 adoption, appears in distinct lines.

An interesting aspect that occurred in this process was annotated with ** (regarding IT suppliers) because the process owner and the auditor answered with a different interpretations. While the process owner considered IT for the strict support of D&D process, the auditor interpreted IT suppliers more broadly, including IT that could be supplied for specific D&D project outputs (e.g., IT in support of a new equipment that was developed trough D&D). After the first evaluation, the team separated those questions, including two additional lines to distinguish IT in support of their D&D process and IT in support of their D&D projects.

Next, we present the *O₂ principles development checklist* for the D&D process. To ensure that all principles are addressed in our development, the second column should have at least one goal/rule regarding the D&D process, as presented in Figure 6-11. We omitted the action stage and notes columns (on the right of the process owner/auditor score) to simplify the presentation.

P	Goal/Rule Checklist	Process Owner*	Auditor*	Action
CF	External customers expect that D&D addresses the core business of the institute, namely in materials development	4	3	(ACF1) Create protocols with universities (non-metallic materials)
				(ACF2) Include a new section in the activity plan to present: (1) emerging issues in non-metallic materials and (2) distinguish D&D for materials and other type of D&D
CF	External customers expect that D&D may be transferred to the market (project utility)	3	4	(ACF3) Create a new field in the D&D project form to describe the initiatives taken to ensure technology transfer of the project outcomes
CF	Internal customers want to obtain complete information for the D&D: funds opportunity, ongoing projects (internal communication), possibility of expenses allocation, past and current project outcomes (e.g., publications, public presentations,	4	3	(ACF4) Suggest a D&D section in the internal newsletter

	guides), and the new products developed with D&D			
LE	The D&D process must be regarded as an opportunity, by process participants, to develop their own business units' processes and products	4	2	(ALE1) Create an indicator that measures the formal D&D projects and the informal ones (ALE2) Provide short training course in project management
LE	Company principles must be entwined with organizational practices, at all levels: coherent to the principles that the organization adopts	3	4	Note: The process owner and the auditor considered ISO$_2$ as an action with potential to address this principle
IP	External organizations must be periodically listened regarding their D&D needs and innovation ideas (customers, suppliers, and potential partners)	4	2	(AIP1) Change the workshop participant questionnaire to include D&D suggestions (AIP2) Promote focus groups for each strategic area of the institute, involving external organizations (AIP3) Suggest the creation of an online forum for H2020/P2020 ideas with the institute associates
IP	There is a need to create a D&D environment that facilitates the proposal of new ideas and ensure that their merits are recognized	5	3	(AIP4) Include the new product success indicator in the balanced scorecard
IP	D&D projects must involve participation of all the units of the institute (try that every unit participates, at least, in one D&D project)	4	3	(AIP5) Monitor the involvement of multiple units in D&D projects
PA	D&D process must be defined, documented, and adequately supported by IT (100% is the target)	4	4	(APA1) Adopt NP 4457 standard as a guide for D&D project documentation Note: There are improvements that can be done regarding external communication. [to study in improvement group meeting]
SA	D&D process must be evaluated by their outcomes to the market (new product success), but also to the internal processes development, namely consulting and laboratorial	4	5	
SA	D&D process have interfaces with marketing process, provisioning process, production (laboratorial and consulting), and human resources management (includes training). These interfaces must be included in D&D project plans.	3	4	(ASA1) Change D&D project form to include required fields for: marketing analysis, planned resources, required laboratorial analysis, and project responsibilities
CI	At least 50% of the D&D projects must be internally focused: internal process improvements or new product development. This means that for each externally contracted	3	2	(ACI1) Promote regular meetings in each business unit to promote D&D (ACI2) One new internal project must start, for each external

CI	D&D, the organization must deploy an internal D&D project			project approved
	Adopt ISO_2 for synergistic development of the IS and the QMS	5	4	(ACI3) Adopt ISO_2 to other processes of the organization
FA	D&D projects must be justified by the scientific advances and the market needs	4	5	
FA	IS quality must be evaluated and continuously improved.	4	4	
SR	Suppliers should be involved in the D&D projects, from early stages of the process (including idea generation).	4	5	

evaluate from 1(inexistent), 2(weak), 3(satisfactory), 4(good), and 5(very good)

Legend of column 1: [QP] Quality Principle; [CF] Customer focus; [LE] Leadership; [IP] Involvement of people; [PA] Process approach; [SA] System approach to management; [CI] Continual improvement; [FA] Factual approach to decision-making; [SR] Mutually beneficial supplier relationships.

Figure 6-11. D&D *O_2 principles development checklist*

The organization can always improve a goal/rule, but this does not mean that an action must always exist if the evaluation is less than 5/5. For example, some actions may involve investments that may not be easy to approve, and it depends on the priorities that the top management of the organization establishes. Our suggestion in ISO_2 is to record the proposed actions, identifying the ones that were discarded/postponed by the top management. This identification allows picking those actions in the future, if and when appropriate, simultaneously providing evidence to external auditors about the organization transparency in their decisions. The ISO_2 approach suggests top management involvement (at least) in the initial phases of preparing the establishing a mind set, and in the final stages of evaluating improvement and validating actions. In our research, we could observe different levels of top management participation, from mere approval and incentive, to active participation in action identification and planning. We found the latter commitment more positive to ISO_2, if it is possible to achieve.

The gap between the evaluation of the process owner and the evaluation of the auditor can be represented graphically, as illustrated in Figure 6-12.
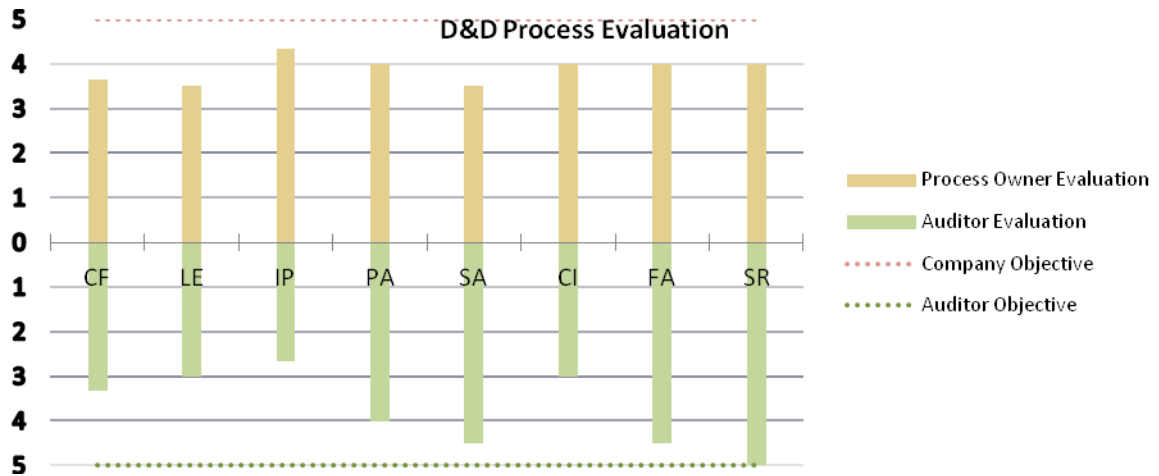
Figure 6-12. Graphical representation of the principles evaluation for D&D

Figure 6-12 compares the grade assigned by the process owner and the grade assigned by the auditor for each principle of the selected process. The eight columns refer to the quality principles presented in ISO 9001 (ISO, 2008b), namely Customer focus (CF); Leadership (LE); Involvement of people (IP); Process approach (PA); System approach (SA); Continual improvement (CI); Factual approach to decision-making (FA); and Mutually beneficial supplier relationships (SR). Another representation is offered in Figure 6-13.
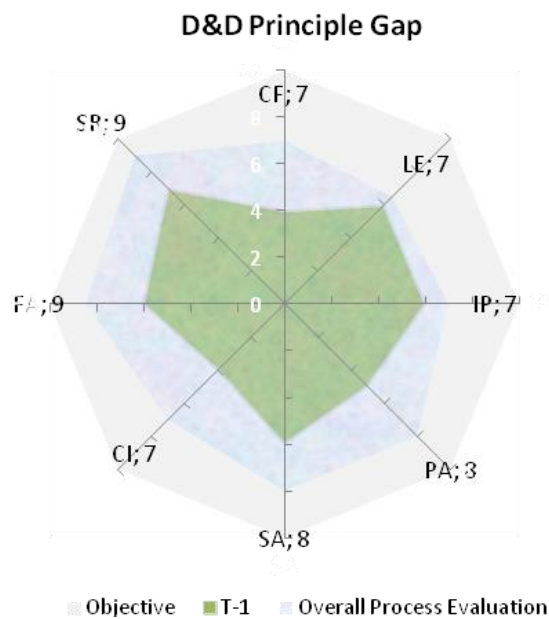
Figure 6-13. Graphical representation of the D&D principle gap

Figure 6-13 presents a different perspective of the principle gap when compared to Figure 6-12. It is accomplished by summing the evaluation of the process owner and the auditor (maximum of 5 each), for each quality principle (maximum of grade 10 each). This graph highlights the principles that require more attention from the organization in the D&D process. For example, CI – Continuous improvement (grade 7) is more problematic when compared to SR

– Mutually beneficial supplier relationships (grade 9). This form of evaluating quality principles was not accessible to the organizations that were studied (in our case studies and action research). The series T-1 represents the prior evaluation period, allowing us to see if there were changes (comparing the evaluation at T-1 and the present) or the sustainable achievement of grades, according to the perspective of the process owner and the auditor.

We can evaluate D&D process changes with the adoption of ISO_2. The first consequence is the integration of compliance by design (Abdullah et al., 2010a, 2010b; Sadiq et al., 2007). "*The fundamental feature of the compliance by design approach is the ability to capture compliance requirements through a generic requirements modeling framework, and subsequently facilitate the propagation of these requirements into business process models and enterprise applications*" (Abdullah et al., 2010b, p. 548). Second, according to the process participants, the D&D process documentation became more friendly and accurate, decreasing the risk of inconsistencies between process documentation and IT. A third relevant aspect was that the process participants found the improved IT-enabled D&D process simpler. The developed tool has functionalities such as notifying the users about their actions, managing all the project documents, and providing D&D process indicators automatically. Table 6-1 presents a synthesis of the major changes that we found in the D&D process at design-time.

Table 6-1. What changed within design-time at the D&D process?

Before	After
Regulatory goals and rules used as a basis for developing process documentation	Regulatory goals and rules embedded in the IT supporting system
Semi-structured documents are the main tools in support of business processes, difficult to maintain	Semi-structured documents and IT are the main tools in support of business processes, developed in coherence with each other
Quality manager is responsible for developing and ensuring process compliance	Teamwork for developing and ensuring process compliance, including managers and process participants
Lack of coherence between procedures and practice	Practice is executed with IT support which, in turn, is aligned with the procedures
User complaints: the process procedure is complex, leads to errors	The process procedure is simpler. Users acknowledge that IT prevents errors
Impossible to connect regulations with the process	Regulations, processes, people, IT, and information are interrelated in the O_2 artifacts
Difficult to audit compliance	The O_2 artifacts provide an improved and transparent support for audit (and promotes process owner involvement)

The D&D process owner told us that the users seemed more demanding about "their" process, suggesting more improvement actions than before. We found this positive, even if both

the managers and process participants recognize the difficulties in implementing some actions (especially when involving bigger investments). This is a contribution to a "shared view" that our vision for a synergistic approach had in the first place.

Another advance found for the D&D process was the inclusion of process rules, process definitions, and documental references directly in the IT systems. One of the process participants told us: "*now the IT has the burden of nonconformities, not us! If some field is not filled and is required, if some step of the process is not executed, that is because the tool does not protect the users from error. Previously, we had the entire responsibility concerning process problems. The procedure said one thing, the practice another. Now we can combine both advantages of going digital: efficiency and effectiveness*". Nevertheless, we argue that incorporating rules in IT does not make the process participants less responsible for problems, because they participate in the evaluation and decisions about the process and IT support. The difference is that once again we aim at a "shared view" of the joint development and some burden is removed.

Although we have created one *O₂ matrix* for the entire D&D process, it is also possible to create the matrices for activities or even tasks, in complex processes. Nevertheless, the checklist also had shortcomings that were raised at this ISO$_2$ stage by the users. First, the initial checklist did not provide enough support to draw the action plan; for example, in defining the responsible for the action, the type of measurement to evaluate the action impact, and the periodicity of that measurement. We recognized that limitation and included the responsible person in the most recent version of the checklist (we do not represent the column in Figure 6-11 because it was only included after). Yet, additional research is needed to improve action support, including additional items or studying ISO$_2$ integration with other approaches, for example the balanced score card (Kaplan & Norton, 1996). It was not our purpose to establish a direct association between actions taken and their consequences; for example, stating that a specific action A contributed to improve the principle X. That type of evaluation must be a result of the process participants' interpretation (for example with the support of MUVE). Additionally, we can see from the checklists that the type of actions is dissimilar. Some are closer to intentions, whether others are more specific such as the changes in the IT platform. Again, we state our interest in guiding the initial stages for the joint development of the IS and the QMS, so there is opportunity to improve in this aspect, for example, differentiating actions, and including some of them (the ones that seem intentions) as new lines in the checklist. In spite of these limitations, the process participants confirmed that the artifacts are simple to use and argued that improvement is not only a matter of numbers and averages; it is also a *personal perception* of the people involved. While adopting ISO$_2$, the users are invited to discuss their *personal perception* with numbers and comments. That discussion will lead to actions that, in turn, may focus the process participants in the principle that those actions wants to promote.

The next step after evaluation is to use the obtained insights for improvement.

6.10 Improve (repeat steps 2 to 7)

Neither the IS nor the QMS can become stale, or the problems that they solved will soon reappear. In our cases we witnessed situations in which the change of organizational processes, if not properly managed, can create inconsistencies between IT, process documentation, and practice. It is necessary to identify those changes and the required actions. Therefore, the organization needs to have outside-in information to be aware of the context changes, within information to address those changes in daily practice, and inside-out information to provide evidences of compliance to the new situation. Improvement is an enduring organizational effort materialized by actions (as the ones that we identify in the previous ISO_2 step) and its support is included in several O_2 artifacts presented in Chapter 5. To illustrate change in the D&D process run-time we will present the *O_2 map* in this section and provide some considerations about its use. With the *O_2 map*, when a change occurs in one of the systems dimensions (Context, People, Process, IT, and Information/Data), managers know which IT systems are affected, who uses those systems, the affected processes, and the required information. This representation can be made for specific processes or for the entire process architecture. We illustrate this part in Figure 6-14 including three processes related to D&D: human resources; provisioning; and quality management.
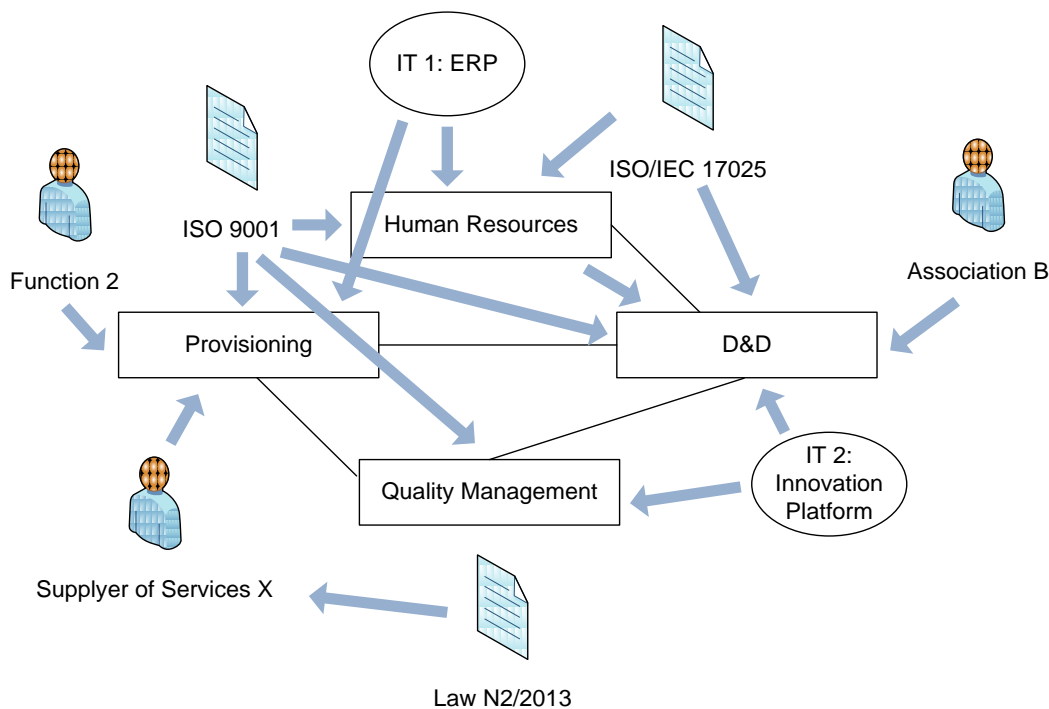

Figure 6-14. The D&D *O_2 map* (the excerpt omits legal aspects and persons/functions names)

The map provides a better understanding of the impact that a change in one element can have in other elements. For instance, if a new person assumes Function 2, we know which regulations and IT are applicable, and can provide proper training. If a regulation changes, we can

quickly find affected processes and IT systems; then we can use the O_2 *matrix* to check details and plan the necessary changes. Each element of the map has metadata provided by the O_2 matrices. For instance, an arrow points from the IT 2: Innovation Platform to the D&D process. If a user drills down on that arrow he can access the goals and rules presented in Figure 6-6.

The O_2 *map* provides guidance for the run-time phase, however, a complete solution for such a complex problem is not yet achieved. The main problem with the map is that we cannot see details easily. For instance, which requirements of ISO 9001 affect provisioning? Which functionalities of IT2 are related with the D&D process and which ones are related with the quality management process? To answer such questions we must look at the O_2 matrices with the details. This task can be automatic with the help of a software tool, available as a prototype as we presented in Chapter 5. Nevertheless, important advances for run-time could be found with this map, listed in Table 6-2.

Table 6-2. What changed within run-time at the D&D process?

Before	After
Regulations are a burden to IS and QMS users, available in spreadsheets' lists, unrelated to business processes, not useful for practice	Regulations shape the context of the organization and provide goals/rules to be used in a synergistic approach for the joint development of the IS and the QMS
Ad-hoc management of regulatory requirements, without involving IT as a critical dimension	IT is one of the five dimensions considered for a joint development of the IS and QMS
Difficult to identify the impact of changes in business processes	The O_2 *map* allows the identification of the main elements that are affected by changes
Regulations seen as a problem of others, not directly of the IS management	Regulatory compliance, minimizing errors, and avoiding nonconformities is a responsibility of IS management and all process participants
Difficult to gather evidences of compliance in audit	The O_2 artifacts can provide evidences of compliance

A typical ISO 9001 process map complemented by written procedures, as the ones that are commonly found in organizations, cannot represent the interrelated connections between the IS and the QMS. We confirmed the situation in our various cases presented in Chapter 4. From our experience, the organizations do not possess a simple way of identifying these relations; the O_2 *map* is one option. An internal or external audit (ISO, 2009a) may use the O_2 *map* to see which persons to interview, which IT systems to address for process indicators, and how the organizational context is defined by the applicable regulations.

6.11 Conclusions

This chapter provides an example of the application of ISO_2 to a real business process, with the aim of synergistically developing the underlying IS and QMS. A practical case is provided, to exemplify how organizations can jointly develop the IS and QMS, across their lifecycle. We complemented the case presentation with insights that emerged during action research, regarding the benefits and pitfalls of ISO_2. The approach proposes a change on how information is documented in the context of ISO 9001. We gathered evidences that ISO_2 can be used to shift from "documented procedures and records" in ISO 9001:2008 (ISO, 2008b) to the need of a documented information in the next ISO 9001 revision (due in late 2015), including the "requirement to define the boundaries of the QMS", an "increased emphasis on organizational context", and "a greater emphasis on achieving desired outcomes to improve customer satisfaction" (IAF, 2014, p. 5).

This case also highlights some limitations. First, the approach was successfully applied to the D&D process and in other processes of the organizations that we studied, but the positive results may not occur in all the possible organizational settings. Second, the approach focuses on ISO 9001 and it was applied in organizations with in-house IS and QMS teams. We did not test ISO_2 in a case that involved more complex cases of IT acquisition regarding multiple processes, for example ERP systems. A software tool can assist the practitioners in this task, and we already developed a prototype. Such an application would create a multi-layered network of IS and QMS entwining, with the possibility of multiple visualizations (for instance, only seeing the links of a specific law and hiding other links and dimensions). These are some of the issues that we will address in the conclusion chapter.

Chapter 7

Conclusions

There are potential synergies to explore throughout the lifecycle of the IS and the QMS. In this thesis we have proposed an approach called ISO_2 to assist in that endeavor, both at design-time and at run-time, in cases where quality management is based on the ISO 9001 standard. Our research program evolved as follows:

- First, we conducted a systematic literature review (Kitchenham, 2004; Okoli & Schabram, 2010; Tranfield et al., 2003; Webster & Watson, 2002) to identify potential synergies between the IS and the QMS, in the context of ISO 9001 and TQM principles (Zhu & Scheuermann, 1999). On the one hand, the design-time stage involves the identification of business processes and the requirements that the organization desires to implement in daily practice. On the other hand, when the IS and the QMS are operating, there is a need to evaluate and improve them, according to high-level quality principles (ISO, 2008b). We found that the majority of authors studied the viewpoint of one system in support of the other. Other researchers suggest that a synergistic development has advantages (Cunha & Figueiredo, 2005; Dahlberg & Jarvinen, 1997; Hemsworth et al., 2008; Perez-Arostegui et al., 2012; Pérez-Aróstegui et al., 2015; Ravichandran & Rai, 2000a; Worthington, 2000), however, we could not find approaches to assist practitioners in this endeavor.

- Second, in spite of the multiple claims offered by the literature about the mutual impact of the IS and QMS (Delić et al., 2014; Forza, 1995b; Heston & Phifer, 2011; Wai et al., 2011), we did not find studies which reported that practice across the lifecycle of those two systems. To address this gap we conducted interviews (Myers & Newman, 2007; Turner, 2010) with ISO 9001 auditors and fourteen case studies in different organizations (Darke et al., 1998; Walsham, 1995a; Yin, 1994). We have addressed five interrelated dimensions that we found in the IS literature (Alter, 2008; Carvalho, 2000), namely: Context, People, Process, IT, and Information/Data.

- Third, action research (Susman & Evered, 1978) was selected to refine our ISO_2 approach, whose initial draft resulted from the actions above. We conducted three action research projects (Davison et al., 2004; Lindgren et al., 2004; Susman & Evered, 1978), each one with a specific focal point. The first project consisted of a single cycle and provided a sequence of steps (routines) and a small set of artifacts (Pentland & Feldman, 2008) to assist in the synergistic development of the IS and the QMS. The second project

concentrated our attentions in the design-time, with three complete CAR cycles that included the modeling of regulations, in the context of ISO 9001 (ISO, 2008b). Finally, our third action research project aimed at refining the run-time support of ISO_2, fostering an IS quality culture and a business process quality culture (Barata et al., 2013a, 2013b; Barata & Cunha, 2014b).

ISO_2 is available to assist companies in the synergistic development of the IS and the QMS, in the context of ISO 9001. Moreover, its field tools can also be of use to auditors, to assess requirements compliance, the need for improvement actions, and quality culture (Hildebrandt et al., 1991; Kanji & Yui, 1997). Our contribution is for a *shared organizational view* (Chen et al., 2010) of the IS and the QMS, where systems managers and process participants cooperate for organizational improvement. By cooperation we mean the concept of interdependence of the work by different people to produce a product or service, as presented by Schmidt and Bannon (1992). The work practices can evolve with the help of artifacts "*to mediate and organize communication*" (Perry & Sanderson, 1998). Those artifacts are named O_2 artifacts in our approach, built to guide and support practitioners in the different steps of ISO_2.

As we stated in the introduction of this thesis, our main research purpose was to:

> *"Propose a synergistic approach for the joint development of the Information System and the Quality Management System, in the context of ISO 9001"*

To achieve this purpose we identified a set of research objectives. In the next section we offer a synopsis of those objectives, which together forms a final reflection and draws conclusions about the research purpose presented above. Subsequently, the limitations and also the opportunities for future research are discussed.

7.1 Recap of the research objectives and reflection

RO1. Compile relevant literature about IS and QMS synergies by means of a systematic literature review.

The development of the QMS and of the IS have been researched for decades, but problems for their joint development still exist. We performed a systematic literature review to understand how deep the problems were and which solutions had been proposed. Three main perspectives were found, namely: (1) the use of IS to support the QMS; (2) the use of QMS as principles to adopt in IS function and activities, and (3), the IS and QMS shared view. The latter perspective offered the highest potential for our research, in the context of ISO 9001. While the first two represent the contribution that one system can give in support of the other, the third represents a joint development, where the result is *more than the sum of the parts* (Cunha & Figueiredo, 2005).

We also found differences when comparing the design-time, while both systems are being created, and the run-time, when both systems are run, audited, and continuously improved. In the first stage, both the IS and the QMS teams are involved in creating tools that process participants can adopt in daily practice. There is a need to identify requirements in the form of goals and rules for the systems design. Then, after both systems are in use, they need to evolve as the context changes. Both stages, the design-time and the run-time, are continuously iterating between each other across the IS and the QMS lifecycle. They need to be addressed in a way that allows cooperation between the development teams and process participants, involving different experts.

Several researchers have studied both systems in terms of the combined effect of IT and quality management on organizational performance (Delić et al., 2014; Sánchez-Rodríguez & Martínez-Lorente, 2011) or in specific processes such as purchasing (Hemsworth et al., 2008); yet, a joint development approach was absent from the literature. Moreover, the opportunity to develop such an approach had been suggested before (Cunha & Figueiredo, 2005).

RO2. Understand the IS and QMS potential synergies from the perspective of quality auditors.

The opinions of ISO 9001 quality auditors that we have collected are formed by their audit experience, in different companies, in distinct sectors of activity. Moreover, we have inquired auditors with consulting background, allowing us to explore their perspective regarding the development of the quality management system. The results were important to create a frame of reference for action research (Checkland & Holwell, 1998b; Lau, 1999; Shrivastava & Mitroff, 1984), and to balance the researcher interpretation of the phenomena. A group of auditors were interviewed in three different stages of our research. First, we conducted five interviews to identify opportunities for the research proposal. It was an opportunity to focus our research objectives in the development of a lightweight approach accessible to different experts from the IS and QMS fields. It was also one of the first occasions to confirm the practical relevance of our research purpose.

The auditors were interviewed again one year later. In this case we used a semi-structured format that we prepared before our case studies, providing additional inputs to our research:

1. In the auditors opinion, the IS has an important influence in quality management, confirming the literature review. They highlight aspects such as document management and evidences for the audit. The interviewees strengthened our idea that an approach for the joint develop the IS and the QMS should improve daily practice of the organization, not only for (or prepared in the previous days of) the audit.

2. It is possible to improve the audit practices in the scope of ISO 9001. The auditors consider that their IS knowledge is at the user level and a guide could help.

3. The ISO 9001 auditors that we interviewed believe that they are prepared to audit any ISO 9001-certified organization, independently of the QMS maturity and the degree of IT support. The auditors believe that they do not need specific IS training, but there are problems: the ISO 9001 audits are not fully explored as an opportunity to improve the IS and adopt quality principles in IS.

4. In the auditors opinion, it is not necessary to create a new IS standard to complement ISO 9001. However, they acknowledge the interest of complementing ISO 9001 with guidelines regarding an integrated development of the IS and the QMS.

Finally, we interviewed eight ISO 9001 auditors when we were proposing a *checklist for auditing IS quality culture*. These interviews occurred after our second CAR project. The answers of the interviewees' allowed us to understand potential problems with ISO 9001 audits regarding quality culture, especially the lack of guidance to the auditors and process participants for system evaluation and continuous improvement efforts (Barata et al., 2013a, 2013b).

RO3. Identify the IS and QMS potential synergies from the perspective of IS and QMS managers in ISO 9001-certified organizations.

To address this objective, we conducted fourteen case studies in ISO 9001-certified organizations. We studied the potential of synergies from the perspective of IS and QMS managers, regarding five dimensions: Context, People, Process, IT, and Information/Data (Barata & Cunha, 2013a). We asked them to retrospectively report the experiences before, during, and after their IS/QMS development (Barata & Cunha, 2014a).

The lack of integration between the IS and the QMS occurs before, during, and continues after both systems are in operation. In 12 cases the IS development was planned only subsequently to the QMS project, creating planning difficulties for IS and missing tight integration opportunities between IT and process procedures. The IS and QMS teams typically assume a customer-supplier role, where the QMS establishes requirements (a customer) and the IS provides tools (a supplier) to support them. On the one hand, the IS team skills in process modeling and requirements elicitation were not used. On the other hand, the QMS team skills were not applied to IS development as they could, for example to improve a holistic IS quality (Stylianou & Kumar, 2000) in the scope of ISO 9001 (ISO, 2008b) and to create a quality culture at process level. The lack of effective communication between the IS team and the QMS team was noted as a cause for project delays and misfit between procedures and practice. Moreover, the problems continue after the IS and QMS implementation, creating risks for continuous improvement, for example (1) the IS does not correspond to the organizational needs so the users start to develop their own tools (generating parallel records) and unofficial applications (Handel & Poltrock, 2011); (2) the QMS is seen as a bureaucratic system that is not useful to practice, therefore it is only considered before the audit; and (3) the IS team is not involved in continuous improvement as they should be.

Our purpose is to turn these problems into opportunities for a joint development. IS and QMS managers agree that they would benefit from a synergistic approach, and that organizational benefits would be substantial. Removing duplications, avoiding potential errors in information and quality, and overcoming the gap between the systems and practice are examples of the benefits.

RO4. Outline the main steps of the synergistic approach for the phases of design-time and run-time in the joint development of the IS and the QMS.

We suggested a series of steps that IS and QMS teams can follow to jointly develop tightly integrated quality management and information systems. Those steps suggest patterns of action (Pentland & Feldman, 2008). The result should follow a process approach as recommended by the ISO 9001 quality standard (ISO, 2008b). We found support in the IS/QMS literature to propose those steps (offered in Figure 7-1), in an approach that we named ISO_2.
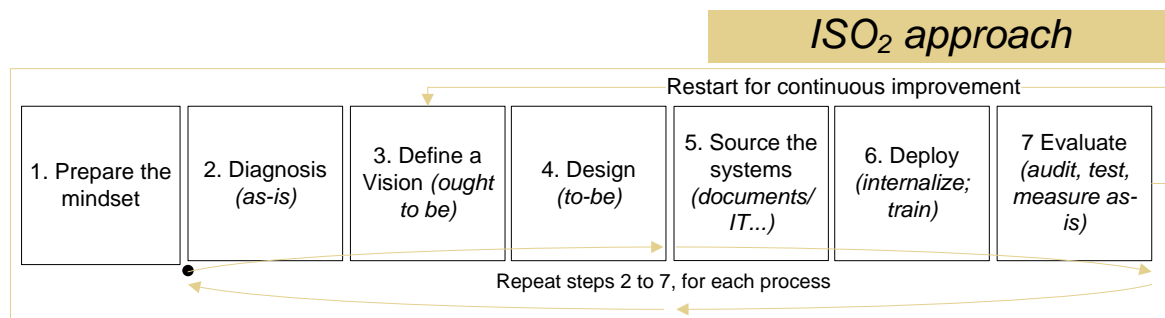
Figure 7-1. The steps of ISO_2 approach (Barata et al., 2014; Barata & Cunha, 2014a)

Action research (Susman & Evered, 1978) was selected to evolve and refine ISO_2, which contains a set of artifacts (Lee et al., 2015; Zhang et al., 2011) to support each step. The artifacts were designed according to a framework that we named O_2, representing the five interrelated dimensions that must be jointly developed: Context, People, Process, IT, and Information/Data. The IS and the QMS teams, including organizational managers and process participants, are challenged to identify the information flows, outside-in, within, and inside-out their systems, as illustrated in Figure 7-2.
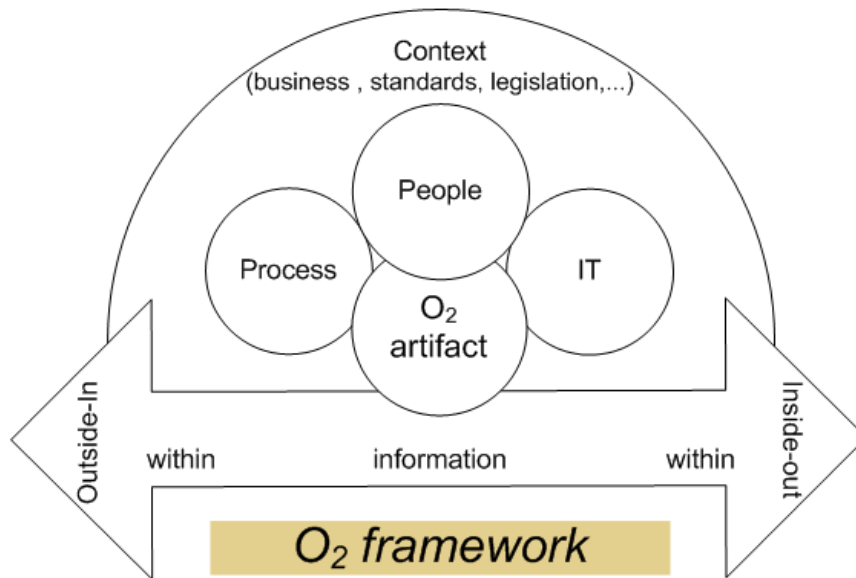
Figure 7-2. The O_2 framework (Barata & Cunha, 2013b, 2014a)

The O_2 framework representation, in Figure 7-2, suggests that the IS and QMS teams are not going to merely create documents and write out procedures (a usual output of QMS teams) or create IT solutions (a usual output of IS teams); they need to design and operate a combination of dimensions, all requiring their attention in information processing activities. Helping people to deal with information is a common purpose of the IS and the QMS, according to the principles selected by the organizations. In ISO 9001-based QMSs those principles are known in advance (ISO, 2008b), but others may be added according to the organizational vision for the future (e.g., safety, sustainability, among others).

> *"Action research facilitates the development of techniques which we will call 'practics' (to distinguish from positivist techniques). Practics would provide the action researcher with know-how such as how to create settings for organizational learning, how to act in unprescribed nonprogrammed situations, how to generate organizational self-help, how to establish action guides where none exist, how to review, revise, redefine the system of which we are part, how to formulate fruitful metaphors, constructs, and images for articulating a more desirable future"* (Susman & Evered, 1978, p. 599)

As research evolved, we found problems and opportunities that led us to identify the additional research objectives:

> **RO5.** Clarify the concept of quality information system in the selected organizations and propose a definition for our work.

The literature did not provide a common holistic definition for quality information system, as stated by Gerber, Dietzsch, and Althaus (2004). Therefore, we proposed one for our research purpose that is based on the dimensions of Context, People, Process, IT, and Information/Data. Then, we used that conception to study the QIS from the perspective of IS and QMS managers within our case studies. We propose a conception of the QIS that is inseparable from the organizational IS. In our research, the QIS should not be seen as a mere IT system "owned" by quality departments to support quality needs, nor the mere adoption of TQM principles by the IS. We argue that a QIS is socially constructed by their users, and requires considering the different interrelated dimensions that have we found. The context is shaped by a quality culture: quality principles must be put into practice through the processes of the organization. Different people participate in the QIS development, including the IS and QMS managers, other managers, the process participants, and external entities such as the auditors, regulators, or customers. The process approach suggested by ISO 9001 is a common theme for the IS and QMS (Antunes et al., 2014). In turn, those processes may be supported by IT, *"heterogeneous solutions, of different ages, supplied by different vendors, at dissimilar stages of technological evolution"* (Cunha & Figueiredo, 2006, p. 521). Our QIS definition emerges from the literature review and from our case studies:

> *"A system that intertwines **people** and **IT**, in a **context** that is influenced by quality policies, procedures, standards, the organizational infrastructure, and its external environment, processing **information** in cycles of planning, execution, monitoring, measurement, and improvement of the organizational **processes"** (Barata & Cunha, 2013a, p. 8)

RO6. Contribute for the development of an IS quality culture in the selected organizations, in the context of ISO 9001 principles.

How to deal with the run-time of the synergistic approach for a joint development? What to evaluate and improve that could bridge both systems interests? The relevance of quality culture (Gallear & Ghobadian, 2004; Hildebrandt et al., 1991) became visible when we were seeking answers to these questions. And one of the answers is to foster an IS quality culture (Barata et al., 2013a, 2013b). We started at the organizational level, inspired by the holistic IS quality proposal by Stylianou and Kumar (2000), proposing a comprehensive checklist and an artifact to assist in improvement actions, suitable for ISO 9001-based QMSs. The checklist was included in ISO_2 for assisting the run-time of the IS and QMS integrated lifecycle. For each quality principle, we proposed a set of configurable items to address in the audits, accessible to people without specific IT training. Moreover, we have created an artifact to support improvement actions that can include multidisciplinary teams from the fields of IS and QMS.

RO7. Contribute to the development of a business process quality culture in the selected organizations, in the context of organizational policies and ISO 9001 principles.

There are cultural aspects involved in the design-time and run-time of the IS and the QMS. They are "*way of working*" (Gallear & Ghobadian, 2004), and those aspects can be developed and learned (Schein, 1990). Cultural principles that emerge from people use of the tools that support business processes, formally or informally defined in a specific context (Handel & Poltrock, 2011; Paul, 2007). This is the vision that we propose and it is inspired by both IS and QMS literature. This is a shared view (Chen et al., 2010) of the IS and the QMS in the organizational daily practice.

Business processes are a central element in our research. Process diagnosing and improving must consider the insights from process participants, guiding them in the adoption of the overall principles that the organization decides to implement (Antunes et al., 2014). To address this objective we have proposed a set of artifacts that complemented the ISO_2 approach with quality culture integration in business processes. Cultural aspects in business processes are a current research topic (Schmiedel et al., 2014), and an approach to promote a quality culture at process level was absent in the literature (Barata & Cunha, 2014b).

The research objectives that we present were systematically integrated during our research, refining ISO_2 approach through action research, allowing to:

1. Use a step-by-step guide to assist the synergistic development of the IS and QMS.;

2. Facilitate a common understanding by the IS and QMS professionals about the interdependence between their systems, in different phases of their lifecycle;

3. Define important goals and rules for the systems development, considering five main dimensions: Context, People, Process, IT, and Information/Data. Those goals and rules are in the form of O_2 artifacts that can be designed by experts in different areas;

4. Integrate regulations in the joint development of the IS and the QMS;

5. Create maps that link each of the five dimensions of the QIS, the *O_2 maps*. For example, identify which IT supports each process, which user participates in which process, or which user must use which IT solution. This association is simple and was considered important by auditors and managers, but it was not previously available;

6. Assess and improve IS quality culture;

7. Assess and improve the business processes quality culture.

In spite of what was achieved, it is natural that this research has limitations that we must be aware of, as presented in the next section.

7.2 Limitations

The first limitation is that ISO_2 does not offer a total and single solution for the synergistic development of and IS and a certifiable ISO 9001-based QMS. ISO_2 does not replace specific QMS approaches such as the PDCA (Shewhart, 1939); neither does it replaced specific BPM or IS development approaches. ISO_2 fills a gap in the joint development of the IS and the QMS in the context of ISO 9001.

Second, we have restricted the QMS to a specific standard that is ISO 9001, and the regulations that organizations need to comply during that process. Standards change over time and ISO 9001 is no exception, with a new version due sometime during 2015. As far as we know from the available publications about the ISO 9001 transition (IAF, 2015), ISO_2 should not require modifications specifically for the new version of ISO 9001. This does not mean that ISO_2 cannot be improved and adapted; it only means that to the specific changes that ISO 9001:2015 publication anticipates, the ISO_2 approach seems to be useful as it is presented in this thesis.

Third, our research has considered cases where an IS team and a QMS team existed in the organization. In some cases, for example small organizations, the systems implementation can be achieved by external consultants, eventually buying IT packages in the market. Our results suggest that ISO_2 can be useful even in such cases, to assist the integration of the IT portfolio and the quality requirements through the matrices and maps. However, we did not have a case to test such a setting.

Forth, when we included regulations such as laws in our second action research project, the number of goals and rules dramatically increased, when compared to the requirements explicitly included in ISO 9001. To deal with regulations was not an initial objective of our research but we could not ignore the needs that organizations express. ISO_2 increased its relevance for top managers by including laws and contract agreements; however, the complexity of goals and rules was amplified and could benefit from the existence of a support tool to our approach. We created a prototype for a support tool but it is still under development and lacks the 3D support to the *O_2 maps* that we propose.

Fifth, the simple structure of the O_2 artifacts that we proposed and the intuitive steps of the ISO_2 approach facilitate its use in daily practice, by different stakeholders. This aspect is relevant for the small and medium size companies that adopt ISO 9001, but the use of artifacts such as the *O_2 matrix* may become more complex as the number of goals and rules increases. Therefore, there are risks of decreasing its usefulness, for example, in ISO 9001 audits. This potential limitation is related to the previous one, which makes it suitable to be addressed with a support tool.

Sixth, the use of a new approach requires additional time for the QMS and IS development, which is consumed with the ISO_2 meetings and the O_2 artifacts development. The feedback of quality auditors, IS and QMS managers, top managers, and process participants is that the extra time allows improvements to their previous practice and it is worth it. Additionally, the time spent in ISO_2 would be probably spent in meetings to make the IS and the QMS compatible, and

perhaps much more time wasted in future changes, solving their incompatibilities. Furthermore, there are potential inefficiencies if the IS and/or the QMS are not implemented in (and according to) daily practice. Our research does not enable the quantification of some of the reported benefits by organizational users, for example how many nonconformities are avoided, or how much the users satisfaction improved with one or both of the systems, when compared to the traditional approach of developing the IS and the QMS separately or ad-hoc. Nevertheless, the evidences collected in our research allow us to argue that ISO_2 brings a *new breath* to the joint development of the IS and the QMS, at design-time and at run-time, in the context of ISO 9001.

7.3   Opportunities for future research

Our research program addressed the research objectives, but, simultaneously, raised new question that we could not attend to in the limited time of a Ph.D. In this section of the dissertation, we discuss the opportunities for future research.

> *"Nuggets of knowledge from earlier work may integrate into a unified understanding of the problem domain. Further applied research may draw on these new understandings to produce a system that delivers the potential value of the technology in a form that users can accept and use"* (Briggs et al., 2011)

First, there is an opportunity to go beyond ISO 9001. Nowadays, ISO 9001 is at the core of other different certification standards, such as ISO 14001 (Ivanova et al., 2014). Those standards include different requirements and possibly different cultural principles (e.g., social responsibility). They also bring additional complexity, for example regarding regulations in environmental and safety management. There is an opportunity to test ISO_2 for different standards, adapting, and extending the existing artifacts to different needs, in different settings.

Second, we focused on specific aspects within the lifecycle stages of design-time and run-time that we considered more important as a result of the literature review, interviews, and case studies. Additional aspects can be explored; for example, how to integrate ISO_2 with approaches such as the balanced scorecard that aims at the creation of strategic maps of the organization (Kaplan & Norton, 1996). Furthermore, the study of how to integrate and improve ISO_2 with other approaches such as the QuEF (Domínguez-Mayo et al., 2012a) in the field of model-driven web engineering, the MLEARN method in BPM (Coelho, 2005, 2010), improvement approaches such as the Six Sigma and frameworks such as CMMI and ITIL (Heston & Phifer, 2011).

Third, there is an opportunity to combine ISO_2 with methods that proposed for formal modeling of regulations (Ingolfo et al., 2011, 2013), participative modeling (Stirna, Persson, & Sandkuhl, 2007) and other frameworks that are suitable for the tasks of detailed modeling, coding, and implementation (Kharbili, 2012). ISO_2 can be integrated with existing models in compliance (Abdullah et al., 2012), goal modeling (Cardoso & Santos Jr, 2010; Giorgini & Mylopoulos,

2003), and ISO 9001 (H. M. Kim, Fox, & Sengupta, 2007; H. M. Kim, 1999). Modeling is one possible view to understand IS (Böll, 2012) and there is a need to keep the end-users models accessible to different stakeholders, therefore, future studies in this area can precede the development of support tools and the potential integration of ISO_2 in commercial modeling tools.

Fourth, we did not fully explore the potential of integrating ISO_2 with IT development or acquisition (if and when it occurs in the joint development of the IS and the QMS), more specifically in the phase that we named sourcing. During our research in the technological institute, we found interest in a deeper relation between the goals and rules and the supporting IT that we developed, for example, when a goal or rule changed we wanted to identify immediately in which parts of the code or interface to intervene. This is possible by looking at the matrices lines of IT, and more generally seeing by the *O_2 map* which processes was related with that goal / rule and which IT was connected to those projects, but an IT development team would prefer to have that analysis integrated in their development framework. Therefore, there is an opportunity to integrate our approach with development environments to assist IT developers.

Fifth, we built a prototype of a tool to support ISO_2, but it has limited functionality. There is an opportunity to evolve it further or to integrate O_2 artifacts into existing modeling tools (Mertins & Jochem, 2005). Our contribution provides the foundations that future researchers can use to that effect, with an opportunity to refine even more the approach and adapt it to specific development frameworks that was not in the scope of our research.

Sixth, our proposal suggests the metaphor of a *new breath* for the joint development of IS and QMS (Barata & Cunha, 2014a). Although the metaphor is intentional for inspiring the teams about the dynamics of information between the organizational processes and the context, we did not explore the full potential of the metaphorical thinking (Lakoff & Johnson, 1980; Lakoff, 1986; Steen, 2008) in our research. A metaphor is a figure of speech, "*giving to one thing a name or description that belongs by convention to something else, on the grounds of some similarity between the two*" (Leary, 1994). A metaphor is also a form of thought and action (Lakoff & Johnson, 1980; Lakoff, 1986), either individual or collective, allowing the research and understanding of one thing by the viewpoint of another (Leary, 1994; Schmitt, 2005). According to Steen (2008) metaphors can be used to (1) fill lexical gaps in the language system (naming), (2) offer conceptual frameworks for concepts that require at least partial indirect understanding (framing), and (3) produce an alternative perspective on a particular referent or topic in a message (changing). Metaphors can not only be used to describe the reality but they can also be used to design the future (Tsoukas, 1991). Nonetheless, there are also problems in the use of metaphors, because each participant can interpret them differently. But now there is an opportunity to research the metaphor effect in the ISO_2 approach, because "*metaphor analysis cannot work without previous socialization in the language and environment in general and, in particular, without field experience gained prior to or during the course of research*" (Schmitt, 2005, p. 383).

Seventh, a maturity model could be developed to assess the synergies between the IS and the QMS. Maturity models are increasingly studied in different areas of the IS and the QMS (Hammer, 2007; Paulk, Curtis, Chrissis, & Weber, 1993; Röglinger, Pöppelbuß, and Becker,

2012). There are also studies that address both fields of quality and IS (Lin et al., 2012; Paulk, 1993) and provide guidelines for maturity models design (Becker, Knackstedt, & Pöppelbuß, 2009; de Bruin, Freeze, Kaulkarni, & Rosemann, 2005). A maturity model could provide additional synergistic tools and information about the stage of the joint development in the organizational IS/QMS.

Eight, the new ISO 9001:2015 is due in September 2015, and, as far as we can anticipate (ISO/TC176/SC2/WG23N063, 2013), it reinforces the quality principles, includes a clause for the organizational context that must be defined, and increases the visibility of other interested parties of the organization besides customers and suppliers, for example, regulators (IAF, 2015). The process approach is more explicit and includes a clause for it (4.4.2). Additionally, top management is suggested to promote awareness of the process approach in the organization, regulations appear directly in the standard, and the organization must identify risks and opportunities for the QMS and propose related actions (IAF, 2015). Changes must be planned and the objectives must include references to why, who, when, where, and what. These are examples of changes that increase the relevance of approaches such as ISO_2, guiding organizations in their ISO 9001:2015 transition or in new implementations from scratch. The use of ISO_2 in the context of ISO 9001:2015 and its improvement are key subjects to study in the forthcoming years.

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