Barata, J., da Cunha, P.R. (2014). ISO2: A New Breath for the Joint Development of IS and ISO 9001 Management Systems. In: José Escalona, M., Aragón, G., Linger, H., Lang, M., Barry, C., Schneider, C. (eds) Information System Development. Springer, Cham. The final authenticated publication is available online at https://doi.org/10.1007/978-3-319-07215-9_40.

ISO_2: A New Breath for the Joint Development of IS and ISO 9001 Management Systems

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Abstract We present ISO_2, an approach for the joint development of information systems (IS) and ISO 9001 quality management systems (QMS). ISO_2 was outlined from 14 retrospective case studies, occurred between 2008 and 2012. We then validated and refined the approach through action research. We support the idea that IS and QMS synergies are more important than the perspective of one system merely supporting the other. The ISO_2 combines iterative development steps with a layered and incremental design framework, the O_2. The O_2 metaphor can provide a common abstraction level for the joint design. Over one million companies struggle with IS and QMS disintegration. Our findings offer new insights for the joint development of organizational systems.

1 Introduction

"If you want to change the world, you change the metaphor" is an inspiring quote from Joseph Campbell [1]. There is a need to change the development of information systems (IS) and ISO 9001 quality management systems (QMS). The two endeavors are conducted as separate projects, which are handled by distinct teams, using disconnected methodologies [2]. However, the development of both systems has synergies and often depends on each other [2]. We gathered indications during our research that an approach common to both can individually improve them, as

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well as the organizational outcome of their integration. How can we change the metaphor?

ISO 9001 is a standard for quality management, adopted by more than one million companies worldwide [3]. ISO 9001 requires the internal development of management procedures, work instructions, improvement plans and a demanding measurement system [4]. The external information flows are just as important. In addition, a company certified by ISO 9001 should assign a high priority to the customer relationship activities, create suppliers partnerships, and be prepared for external audits. Therefore, the QMS becomes a tool to manage the relations between the organization and its environment [5].

The information system development (ISD) must consider the influence of the business environment and internal characteristics of the company, such as its politics and procedures [6, 7]. Moreover, the IS has a significant impact in quality management and performance [8–10]. The IS becomes vital for "collecting, storing, analyzing and reporting information on quality to assist decision makers at all levels" [11]. The lack of involvement between the IS and the QMS is well known [12] and the IS and quality departments do not usually leverage the synergistic potential in combining their efforts [2]. Grounded on narrow perspectives, quality experts view IT as mere support, while the IS experts view the QMS as mere compliance. A joint development approach could reduce the pitfalls of the ISO 9001 QMS and the possibility of decreasing its benefits over time [13]. It also may provide simple collaboration tools that the IS and the QMS teams need.

Section 2 presents the background of our research, concerning ISO 9001, ISD and the potential synergies of the IS and the QMS. We then present the dual methodology used for the research. Section 4 presents the ISO_2 approach. Section 5 reports the results of ISO_2 adoption and the O_2 design framework. We particularly stress the IS and QMS design steps. The last section presents the conclusions and directions for future research.

2 Background

ISO 9001:2008 is a world-recognized standard for developing quality management systems. ISO 9001 [4] was published in 1987, and later revised in 1994, 2000 and 2008. ISO 9001 guides companies to improve business quality and adopt continuous improvement as a strategy [14]. The ISO 9001 comprise a model by which organizations of any type and sector of activity can establish, document, implement and optionally certify their QMS. As noted by [15], a "document" means information in any form or type of medium. The standard establishes requirements that each company must fulfill with the systems and approaches that it choose. ISO 9001 recommend a process approach to management and a continuous improvement using the "Plan-Do-Check-Act" cycle [4]. According to [16], the development of a documented ISO 9001 QMS has the following steps : (1) gain-

ing 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.

The methodologies used to develop an IS are still a key research area. They include more technical perspectives such as the SDLC - Systems Development Life Cycle or the "waterfall model". Other methodologies consider both technical and managerial perspectives, such as RUP - Rational's Unified Process [17] or the ISO/IEC 12207 [18] . In contrast with the sequential waterfall model, the agile approaches advise a more iterative and incremental perspective in software development [19, 20]. The ISD research has also followed sociological perspectives, with its foundations in Checkland's SSM [21] and socio-technical approaches. An example of such approaches is the Multiview [22]. There are several ISD methodologies, but problems still exist. For instance, some methodologies may be too complex and inflexible, unfitting to all the possible situations [23]. Although adhoc and informal developments are observed in a number of cases, methodologies are essential for ISD and can be adapted or combined into specific situations [24]. The analysis, design and implementation of the IS consider the technology and the nature of the strategic and operational activities involved [14]. The 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 [6, 7].

A number of authors has suggested synergies between the IS and the QMS [2]. For example, [25] suggest that quality and IT plans should be simultaneously developed at the strategic level. Others like [26] claim that the IS and the QMS are capable of being combined into an integrated approach. [27] propose that the integration can occur at early stages of the design, while [28] identify the gaps between quality and the IS after the design. The lack of IS and QMS integration leads to inefficiency, week correspondence between procedures and practice [2]. The IS and the QMS teams must be involved in the improvement initiatives. [29] and [30] suggest that IS techniques and skills can improve process improvement actions and, conversely, the QMS can benefit the ISD. The development of the IS and the QMS considers organizational, social, and technological aspects that interact and support each other [31]. The IS and the QMS also require similar organizational cultures [32] and may be combined for a cultural change [33]. An example of the IS and QMS mutual benefits is presented by [34], in the company purchasing process. Other authors have found the mutual benefits of QMS and ERP implementations [9, 35]. Despite the several advantages, a joint development approach is absent from the literature. In fact, several barriers may be identified: the QMS does not provide a complete set of requirements for the IS; the level of detail and the distinct vocabulary between quality and IS practitioners are examples of the potential obstacles; continuous change and the internal politics developed in a QMS requires IS support, but may create difficulties for the IS implementation and management [29, 36].

3 Methods

This research adopts a dual methodology. In the first stage, we have used case studies, that are best suited when the frontiers between the phenomena and the context are not evident [37]. The retrospective case studies allows the identification of patterns indicative of dynamic processes [38, 39]. The data gathering techniques were the document collection and 28 semi structured interviews [40], carried out with the IS and the QMS manager of each company. The document analysis and observations have focused the documental structure of ISO 9001 and the IS that supports quality directly (e.g. document management systems) or indirectly, as a source of information for quality (e.g. complaints provided by a CRM or quality costs from an ERP system). Two distinct teams have developed the QMS and the IS. We also acted as consultants in 13 cases. The first version of the approach was designed from the retrospective case studies, as presented in table 1.

Table 1 Retrospective case studies between 2008 and 2012

Sector	Company size	IT scope (average duration: 1 year)
Ceramics #1	Large (>250 employees)	Development of QMS software(a); CRM acquisition(b)
Ceramics	Large (>250)	Dev. of QMS software
Ceramics	Medium (50-250)	Dev. of QMS software
Batteries	Large (>250)	Dev. of QMS software; acquisition of a process modeling software and statistical software
Agro food	Medium (50-250)	Dev. of QMS, production control software and computerized maintenance management system (CMMS)
Metal	Large (50-250)	Dev. of QMS software; CRM acquisition
Metal	Small (<50)	Dev. of QMS software
Paper	Medium (50-250)	Dev. of QMS software; dev. of B2B platform
Institute	Medium (50-250)	Dev. of QMS software
Institute	Large (>250)	Dev. of QMS software; dev. of B2B platform
Environment	Large (>250)	Dev. of QMS software; CMMS acquisition
Printer	Large (>250)	Dev. of QMS software; CMMS acquisition
Automotive	Large (>250)	Dev. of QMS software; dev. of CMMS
Plastics #14	Large (>250)	Dev. of QMS and production software; ERP acquisition

(a) The development of software applications for ISO 9001 requirements, such as document management, complaints and non conformity, action plans and others. 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.

In the second stage, we have selected action research to test and refine the approach. Adopting a cyclic process of theory building and refinement, this approach is suitable for increasing the understanding of an immediate social situation, with emphasis on its complex and multivariate nature [41–43]. Action

research simultaneously aims to improve scientific knowledge and assist a practical problem, by joint collaboration [44]. We have followed the canonical action research, characterized by the five phases of *Diagnosing, Action planning, Action taking, Evaluating and Specifying learning* [45]. To evaluate our research, we have relied on the principles proposed by [46].

4 Retrospective Case Studies and the ISO$_2$ Approach

An overview of the findings is provided in table 2, (I) before, (II) during and (III) after the separated IS and QMS development.

Table 2 Findings from the retrospective case studies

(I) before	The ISO 9001 certification was a top management decision, motivated by a combination of factors such as the 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 documents 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 IT investments. We found that the IS team was not completely aware of ISO 9001 (13 cases), the standard was not used as an input for the ISD requirements – only the users and quality experts point of view. In the same cases, the IS team reported that wasn't well informed about the QMS processes or documents development. 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 participates in the 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 audit). 10 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 validation (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, parallel records) than waiting for IS changes. The IS managers complains that QMS is a burocratic system (14) that does not correspond to practice (8). Additionally, part of the problem was precisely the parallel documents that QMS team develops (3).

The lack of integration in these cases occurs from the beginning, continues during the development and propagates the problems afterwards. The interaction of IS and QMS teams should be replaced by a partnership. The disconnected approach may compromise the ISD results and QMS benefits. Even worse, when the integration fails, each system may become superfluous to the other. All the interviewees agreed that a joint development approach could bring significant advantages. Regarding the benefits of that new approach, we highlight four statements that support "improving the communication process [tactical level by the QMS and ISD]", "encouraging the involvement of the top managers", "accomplishment of the project calendar" and "avoiding duplicated tasks that damage our [IS] internal image, creates systems that are more permissive to errors and harder to manage". As a result, we shaped a clear-cut version of ISO_2, represented in the figure 1.

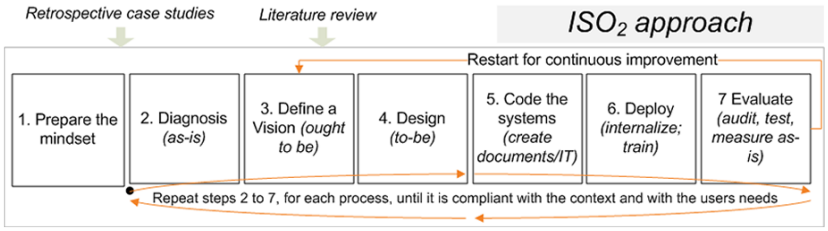

Fig. 1 The steps of ISO_2 approach

ISO_2 consider the iterative nature of the development [21, 45], as proposed by the PDCA. Our frame of reference for action research is outlined in table 3.

Table 3 ISO_2 steps

Step	Description
1	***Prepare the mindset:*** A common approach must be presented to all the stakeholders. We have learned from the retrospective cases that both systems must be aligned from the start and the decisions shared by IS and QMS developers. Three training actions of two hours each are proposed for (1) presenting the approach; (2) the QMS team presents the main cultural aspects of the standard, principles and requirements; and (3) the IS team presents the IS methods, the IT options and guidance for requirements analysis. This step may contribute for the team coordination, management commitment and an awareness campaign [4, 16];
2	***Diagnosis (as-is):*** Identify current quality and IS practices, ISO 9001, and other contextual requirements [17, 18]. Define and assess the current processes by the users perspective [47];
3	***Define a Vision (ought-to-be):*** Define quality and IS politics, create the quality manual [16]. Create a desired process map [4];
4	***Design (to-be):*** Detail each process and indicators [4]. Establish the plan and objectives for each development [17, 18];
5	***Code the systems:*** Develop the IT artifacts [48] and the QMS documents [16];
6	***Deploy:*** Implement the systems, train, internalize, becoming daily practice [16–18];
7	***Evaluate:*** Audit, test, validation and user acceptance [16–18, 47]. Restart to improve [4].

5. ISO_2 Action Research and the O_2 Framework

We have conducted action research in a private technological institute. The company wanted to certify the QMS and to develop quality modules integrated with their ERP. The modules included complaints management, non conformance and actions, audit, product design and development. Due to the complexity of the project, we have decided to focus our intervention on the first 4 steps of ISO_2, leading to the systems design. The lessons learned are summarized in table 4.

Table 4 Findings from the action research

Step	Description
1	***Preparing the mindset - focusing on the awareness of synergies.*** Due to the use of a common approach, the ISD and the QMS development could start simultaneously. The presence of the top manager and the mere existence of an approach successfully transmitted an idea of the relevance of the development to the participants. It was decided that both the IS and QMS teams would develop the same processes and "documents" at the same time, in the type of medium they prefer. 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 their environment.
2	***Diagnosis (as-is) - focusing on the team designers and process users.*** We have started by designing a global process map and then, for each process, carried out the diagnosis by observing the current practice and measuring the process acceptance by the users with a questionnaire [47]. We expected that the QMS team raised problems in sharing their "power" in information management. Surprisingly, they liked the idea because they could now focus on the principles of the standard: improvement and customer satisfaction.
3	***Define a Vision (ought-to-be) - focusing on the organization.*** This step was faster than we expected. We involved the top manager in a brainstorming, with IS/QMS teams and the process owners. Due to 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 the new process map was then communicated to all the organization.
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, are 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 were going to develop "documents", the challenge was to define an ISO_2 "shared document". We also found that the "process approach", by itself, was not sufficient, as we already suspected from the cases and the literature review [49, 50]. The QMS processes were too general to be used by the IS. A common abstraction level was necessary or the joint design would simply not work. Considering the ISO definition of "document" and the inclusion of IT in our approach, we have conceptualized the ISO_2 document as an IT artifact [48]: an application of IT that enables some processes in a human structure that itself is embedded within a context. We have named it O_2 artifact and its framework is presented in figure 2.

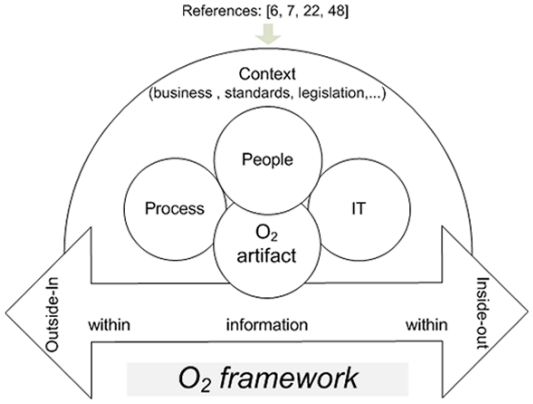

Fig. 2 The O_2 framework. Represents the proposed level of abstraction for the IS and QMS teams. Each O_2 artifact is the practical result of the design cycles. Each O_2 may be linked with a structure of other N O_2 and N processes.

An example is provided for the product design and development (D&D). The process and the O_2 artifacts were jointly designed, as exemplified in figure 3.

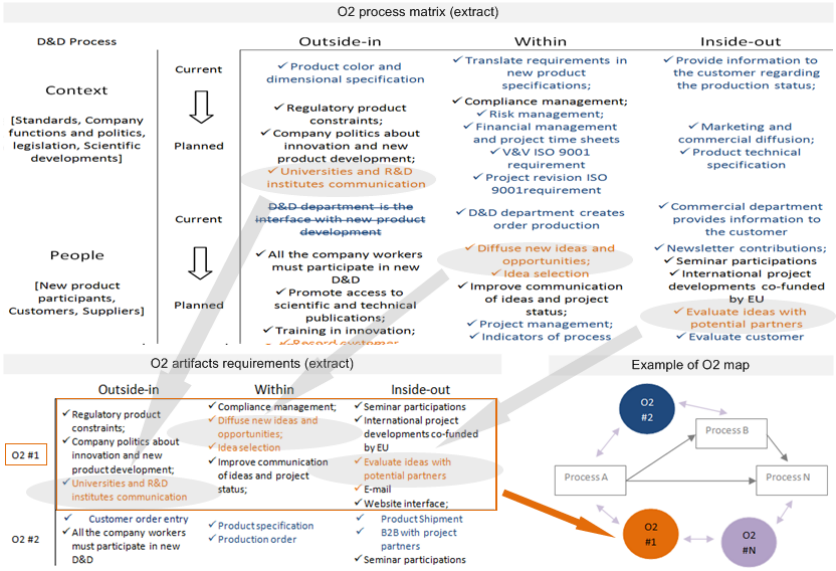

Fig. 3 The O_2 matrix (on top), the O_2 artifacts (bottom-left) and an O_2 map (bottom-right).

The figure illustrates the 3 main views of the O_2 framework. For the D&D process, two IT applications are identified: Innovation management (orange) and a Cloud project management platform (blue). The O_2 design is executed by:

1. For each process, identify the requirements according with the components 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 perspective (matrix columns) of the process;
2. Group the requirements by colors (color black represent a shared requirement), each one representing an O_2 artifact. Each one is a development project. It may be a new IT platform, a paper document, a part of an already existing system such as an ERP, or any other mean to allow the information (*oxygen*) flow, providing to each end user (*system cell*) the vital process information (*breathe)*;
3. Repeat 2 to each process until an ecosystem of O_2 artifacts are designed;
4. Connect all the O_2 artifacts with the processes (*breathing system*).

The introduction of the O_2 artifact has completely changed our intervention. The action research progression is now presented in table 5.

Table 5 Findings from the action research using a metaphor for collaboration

Step	Description
4	***Design (to-be) - focusing on the organization.***
	The teams acted as partners, understood that they could help each other and simplified the IS and the QMS. Interestingly, the QMS team found that when designing the O_2 artifacts, the process activities were easier to identify. Even more interesting, the process map has changed after the O_2 design. The joint IS and 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.
5	***Code the systems - focusing on each O_2 artifact.***
	The coding and implementation was carried on by refining the O_2 concept and understanding its impact in the ISO_2 approach. Both the IS and the QMS developers have stated that the O_2 artifacts were simple to use and provided a proper guide for the development. The language was familiar to both teams and the metaphor had the desired effect, 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 O_2 artifact was not helpful for the training to end users. The O_2 was best fit for the step 5. Nevertheless, the platforms that were developed also incorporated the QMS procedures and rules, contributing to internalize the QMS practices.
7	***Evaluate - focusing on people satisfaction with the O_2 artifact.***
	We have launched the same questionnaire of step 2 for each developed process. The process pain points were eliminated [47]. The auditors have recorded the integration as strong point of the QMS. One auditor 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 O_2 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 O_2 artifact shows the organizational interfaces and the evolution from a plan to the real. The company achieved the ISO 9001 certification and the IS and QMS development was completed on schedule. After five months, 85% of the quality preventive and improvement actions aim the IS or are achieved through IS joint developments. We did not yet started a new cycle to understand how both systems can now evolve combined.

6 Conclusions and Future Work

From our knowledge, ISO_2 is the first approach meant for the joint development of IS and ISO 9001 QMS. According to the auditors and the developers, ISO_2 improves the results when compared with the practice of developing both systems independently. We combined IS and QMS methodologies in a new approach, coping with the ISD problems of diversity, knowledge, and structure [7]. A common abstraction level is determinant for the teams' communication and, eventually for the success of a joint development. The O_2 artifact is that construct. A process approach was followed by both teams. However, it was not sufficient for a joint development. ISO_2 was designed from practice, with a common and simple message. 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 matrixes are also a tool for the ISO 9001 auditors to connect requirements, processes, and IT. The study of a joint IS/QMS may contribute for the ISO 9001 revision, to be published in 2016.

In spite of the obtained insights, several limitations can be identified in this study. The ISO_2 approach is still under development and it requires a higher detail for the coding and implementation parts; the O_2 framework creates a structure of several O_2 artifacts, which are not yet reflected at this stage of the research; we have considered cases with the existence of internal IS and QMS departments and the majority were medium or large companies but the positive effect that we found may not be replicable in distinct client settings.

Several issues remain open. For instance, how both IS and QMS teams can deal with a stronger dependence of both systems and manage two integrated systems. The number of companies that adopt multiple standards, creating a system of systems with ISO 9001 in its core, has been increasing [3]. The auditors have pointed that ISO_2 could 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 may be adapted or extended to include requirements and politics related with the environment management, health and safety, social responsibility, or other standards integration [51]. These are the challenges for the next action research cycle, in an aeronautical supplier with four certified management systems.

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