An ArchiMate-Based Approach to ISO 9001:2015 Quality Management: Shifting to IT-Enabled Documented Information

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Abstract— This paper presents an approach to document ISO 9001:2015 quality management systems (QMS) using ArchiMate. The research is done in cooperation with a research and technology development institute developing ISO 9001:2015-compliant information systems. The models and the steps needed to adopt an enterprise architecture approach to ISO 9001:2015 are demonstrated for the aeronautical setting. ISO 9001:2015 suggests a process approach to management. However, the increasing digitalization of organizational practices raises difficulties for auditing and calls for a deeper alignment between processes, strategy, applications, technologies, and physical infrastructure. Shifting to an Enterprise Architecture (EA) approach to ISO 9001:2015 documented information can contribute to a unified view of quality management and digital transformation.

Keywords—ISO 9001:2015, documented information, enterprise architecture, ArchiMate.

I. INTRODUCTION

Quality management systems (QMS) can offer significant benefits to organizations [1]. Usually supported by quality standards like ISO 9001:2015 [2] published by the International Organization for Standardization (ISO), companies implement quality procedures and devise policies aiming to increase customer satisfaction and ensure the consistency of their practices. ISO 9001:2015 suggested a process approach to management and documented information (e.g., process models, procedures, evidence of quality practices) [3], creating an important tool for communication, establishing links between management and employees [4].

Enterprise architecture (EA) unites two crucial concepts: an *enterprise* that is "*any collection of organizations that has a common set of goals or purpose*" [5], such as a company, a business, or a partnership; and *architecture* that refers to a system's organization "*embodied in its components, their relationships to each other, and to the environment and the principle guiding its design and evolution*" [6], such as a framework, a building, or a design. EA also has relevant standards. For example, The Open Group Architectural Framework (TOGAF) framework [5] recommending steps to design and manage EA, and ArchiMate language [7] used to create EA models according to the layers of strategy, business, application, technology/physical, and implementation and

migration. ArchiMate was selected for this research because it is an open standard that integrates different enterprise layers and incorporates motivation components necessary to understand the different stakeholders [7] of a QMS.

The QMS and EA have synergies [8], [9], but there are still important challenges in the adoption of process approaches in quality systems, and many "*investments in quality systems have not resulted in process management*" [10]. On the one hand, both approaches need to identify and document business processes, progressively more supported by digital technologies. On the other hand, different teams using separate standards and approaches frequently work independently, documenting the same processes and organizational goals. Moreover, the communication gap between the workforce and designers is well known in the literature [11], requiring new approaches to align quality management and Information Technology (IT). Aiming to create synergies between EA and ISO QMS, the following research question was formulated: *Propose an EA modeling approach based in ArchiMate to document ISO 9001:2015 quality management systems*.

The rest of this paper is structured as follows. Section II presents foundational concepts on ISO 9001:2015 and EA. Next, the research approach is explained. Section IV details the EA modeling in an ISO 9001:2015 compliant process for document management. Section V discusses the main findings of this work. Finally, we close the paper by stating the main conclusions, limitations, and opportunities for future research.

II. BACKGROUND

A. ISO 9001:2015 Quality Management Systems

Quality can be defined in terms of stakeholders' satisfaction with the products and services [12]. In some markets, the existence of an ISO 9001:2015 certified QMS is a crucial requirement to compete, revealing to third-party entities that the organization controls its processes and adopts continuous improvement practices [2]. Quality control is achieved through established quality policies and rules or procedures to ensure consistency in organizational practices.

ISO 9001:2015 is one of the most popular standards to adopt a quality management system. The latest ISO report shows that over one million sites are certified by the standard, and the number is still increasing [13]. The standard was last revised in 2015, and more requirements were added to support business development. The main principles include customer

focus, relationship management, evidence-based decision making, improvement, people's engagement, leadership, and process approach [14].

ISO 9001:2015 entails documented information and a process approach to management [2], [3]. Information is crucial to provide evidence of compliance. Therefore, it must be documented "*in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS*" [14]. The process approach is based on the *Plan-Do-Check-Act (PDCA) cycle*. Therefore, companies must define the most relevant processes and interactions, the users' roles, the inputs, and the outputs. Additionally, it is necessary to plan actions (P), execute them according to the requirements (D), evaluate the results (C), and continuously improve (A).

Nevertheless, some studies reveal that ISO 9001:2015 certified companies have difficulties adopting process management [10]. There is a lack of solutions to document processes that are increasingly digitalized and integrated with the organizational strategy. Moreover, documented information and a process approach to management are not detailed in ISO 9001:2015, and each organization may choose their approach.

B. Enterprise Architecture, ISO 9001:2015, and Archimate: Establishing the Link

EA models can be helpful to provide a perspective of the current and future situation, evaluate the transition from an "as is" to a "to be" architecture [15], and model regulations [16]. To map, identify, and address the weaknesses of the enterprise while fulfilling its mission and looking to their processes and its interactions, there are several well-known EA Frameworks. For example, the pioneer Zachman Framework, TOGAF, Department of Defense Architecture Framework (DoDAF), Treasury Enterprise Architecture Framework (TEAF), Federal Enterprise Architecture Framework (FEAF), and Gartner Enterprise Architecture Framework (GEAF) [17]. Each framework addresses specific issues depending on the stakeholder's concern. Since an organization comprises a set of stakeholders with their language and terminology, it is vital to develop a way to communicate and induce understanding among all of them [18]. A modeling language can fit that purpose, showing the main elements (e.g., roles, processes, data) and interdependencies of the enterprise.

ArchiMate establishes a metamodel assisting EA professionals in representing organizational layers in specific views to visualize models with information requirements [7]. It covers different layers of the organization, including business processes at the core of ISO 9001:2015. Moreover, an EA language can help understand which applications, technologies, and infrastructures are implemented and how digital solutions support the business.

Several authors looked for synergies between EA and the ISO 9001:2015 standard. A search using the keyword combination "enterprise architecture" + "ISO 9001" + ArchiMate" in Google Scholar returns 117 results. For example, [19] mapped ISO 9001 concepts in EA through the definition of an ISO 9001 Reference Architecture. According to [19], "*an ISO 9001 ArchiMate representation can lead to further alignments with other EA represented frameworks and help obtain better results while avoiding costs and efforts duplication when implementing quality*". More recently, [20] proposed an approach to model the EA based on business process models available in the organization. ISO 9001 is one of the standards mentioned by the authors. ISO 9001:2015 is unquestionably an essential context for EA approaches since the foundational proposals of ArchiMate, because "[a] *well-designed and documented enterprise architecture helps an organization to conform to the ISO 9001 requirements on process identification and documentation*" [21]. However, it is surprising that a search using ArchiMate + "ISO 9001:2015" in the same database only shows 15 results, and there is a lack of studies detailing ISO 9001:2015 documented information of a complete process with this EA language.

III. RESEARCH APPROACH

Design science research (DSR) is an essential and distinctive research activity in the information systems field [22]. DSR projects aim to create artifacts in the form of "*constructs, models, methods, and instantiations*" [22]. These artifacts also generate design knowledge valuable to real-world problems [23], [24]. First, however, it is necessary to delineate the specific class of problems that DSR aims to contribute, or what [25] name as "*situational artifact construction*".

Our contribution focuses on the context of ISO 9001:2015 information. Therefore, the class of problems is restricted to documenting business processes that are compliant to the standard, comprehensively representing process knowledge. Furthermore, the artifact construction is usually made by the ISO-9001 certified companies or their assessors. Accordingly, our work can be summarized with the DSR grid proposed by [24].

TABLE I.   EA ADOPTION IN ISO 9001:2015 PROCESS DOCUMENTATION (ADAPTED FROM [24]).

Problem	Research Process	Solution
EA languages can be used to represent documented information in ISO 9001:2015, but examples are lacking	Delimitation to the ISO 9001:2015 documented information class of problems; Modeling of a real process; Evaluation	Document management process modeled in ArchiMate; ISO 9001:2015-compliant
Input Knowledge	*Concepts*	*Output Knowledge*
ISO 9001:2015 requirements; Process documentation; ArchiMate specification	ISO 9001:2015 quality management system; Process approach; Business and IT alignment	Examples and recommendations to adopt ArchiMate in ISO 9001:2015-documented information

This study was conducted in cooperation with an ISO 9001:2015 expert and lead auditor and a research and technology institute. They were documenting a document management process of an aeronautical organization investing in document digitalization.

The process must deal with critical information and different document creation, approval, distribution, and retention paths. Moreover, all the classification details, permissions, activities, IT (e.g., file formats, servers, applications) must be documented to (1) support the process users and (2) internal and external audits. The team had access to the process documentation and instantiated it with ArchiMate.

The evaluation was exploratorily aiming to understand the documentation completeness and the capacity of ArchiMate to be incorporated in ISO 9001:2015, shifting from a process approach to management to an EA approach to management.

IV. RESULTS

This section presents the main views created with ArchiMate to document the document management process of the case company. The team decided to start with a top-down approach representing a high-level view of document management requirements. Therefore, the process flow, requirements, and most relevant IT systems needed to be linked in a coherent view. However, both assessors and process users need details for their daily activities that would be missing in a single high-level view. The research continued with a "drill-down" of *how* the process occurs, *what* must be done, *where*, *when*, by *who,* and perhaps even more important to quality systems knowledge: *why* it is essential to the organization. These questions are foundational to EA approaches like the Zachman framework [26] and an inspiration to our DSR.

Fig. 1 shows the overall view of the document management system. The following ArchiMate layers are used: motivation, business, application, and technology. The business layer (yellow) presents the process flow from the early stages. External documents are immediately stored in the IT system (blue element on the top), while the internal follow a different path. On the one hand, if there is a need to develop a new template/form, a set of procedures are needed: setting the template/form reference and preparing or updating an existing template/form capable of responding to current needs. After preparation, the review is carried out, which may or may not be approved. In case of rejection, the cycle is repeated since the preparation stage. Finally, when the template/form is approved, it can be stored. Then, a reference is defined. Afterward, the nature of the document is verified. If it is a

record, it is filled correctly and immediately stored. Otherwise, another cycle of procedures begins with preparing the document, followed by its review and approval. When they are rejected (the review and/or the approval), comments are made so that the process can be appropriately repeated. Finally, the document may be stored (physical archive or electronic format using cloud storage provider – green technology layer). Backup and recovery are periodically performed, ensuring, in principle, the integrity of the documented information (DI) in the Motivation layer (purple elements in Fig. 1).

Fig. 1 answers why DI is necessary (purple elements), how it is done (yellow), the primary IT infrastructure (green), and the supporting application. The team found this model interesting to provide a comprehensive view of their (text processing-based) document management system. However, several parts were still missing.

Fig. 2 presents more detailed information for specific phases of document creation. It is useful when a user needs specific information about document flows (high-level representation in Fig. 1). The same ArchiMate layers are used at this stage, including more specific elements such as roles. This model zooms in the parts of the primary model that require an explanation about its purpose, flow, and digital support. More specific information incorporates, for example, the review procedure: open the document, increment its version, and update the document reference. During the approval, comments and changes to the document are reviewed, and once accepted, they can be stored. Finally, all access is blocked except for the process responsible (PR). Storage is done by checking outdated versions, which will be discarded, and the document is stored according to its format. Backup and recovery are periodically performed.

The next step is to describe specific attributes of the document lifecycle. Fig. 3 depicts how to proceed when
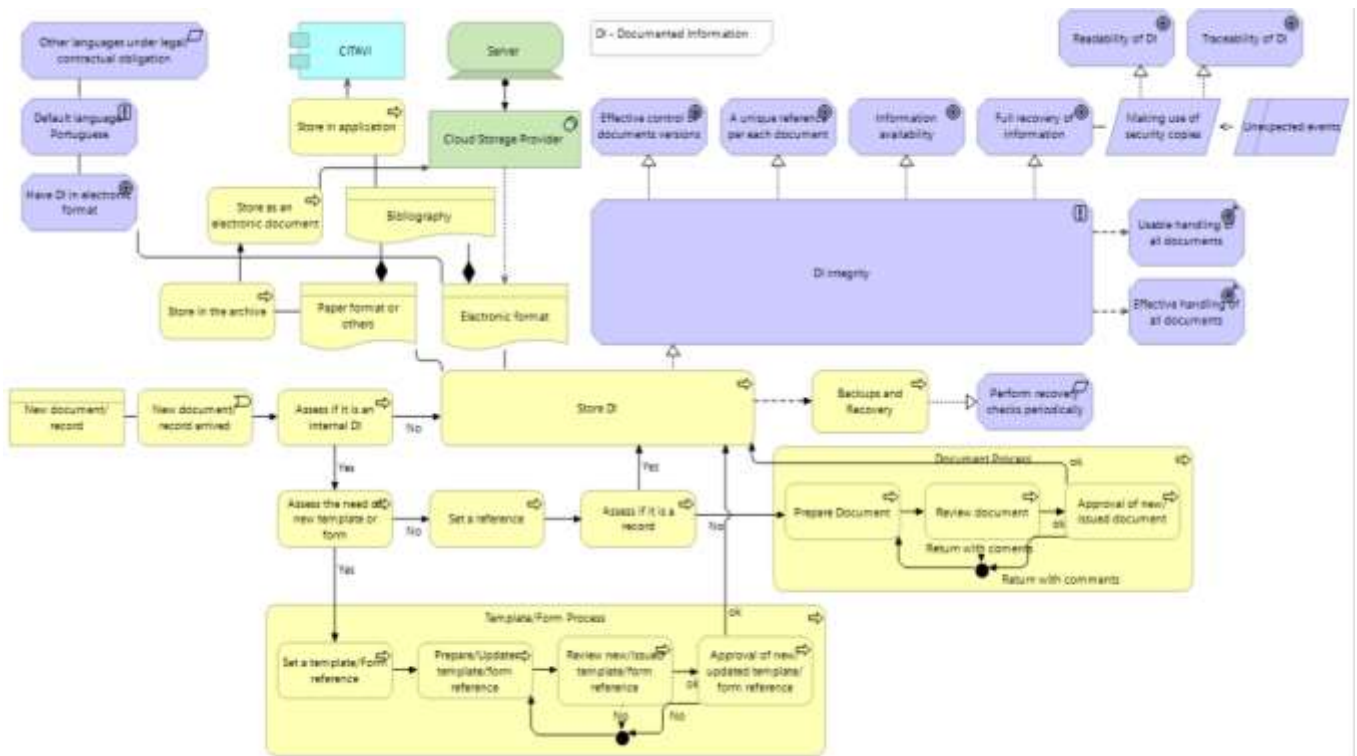

Fig. 1. Documented information flow – main view.

changes occur in document storage (depends on the DI's format), retention period, and versioning.

However, these models were not yet sufficient to thoroughly explain document management. For example, it was necessary to define classification schemas allowed in the organization (e.g., file names). Therefore, this fine-grained description is presented in a separate model included in Fig. 4.After building views presenting the primary process, variants, and classification, the team created a model to describe the regulatory compliance requirements (Fig. 5)
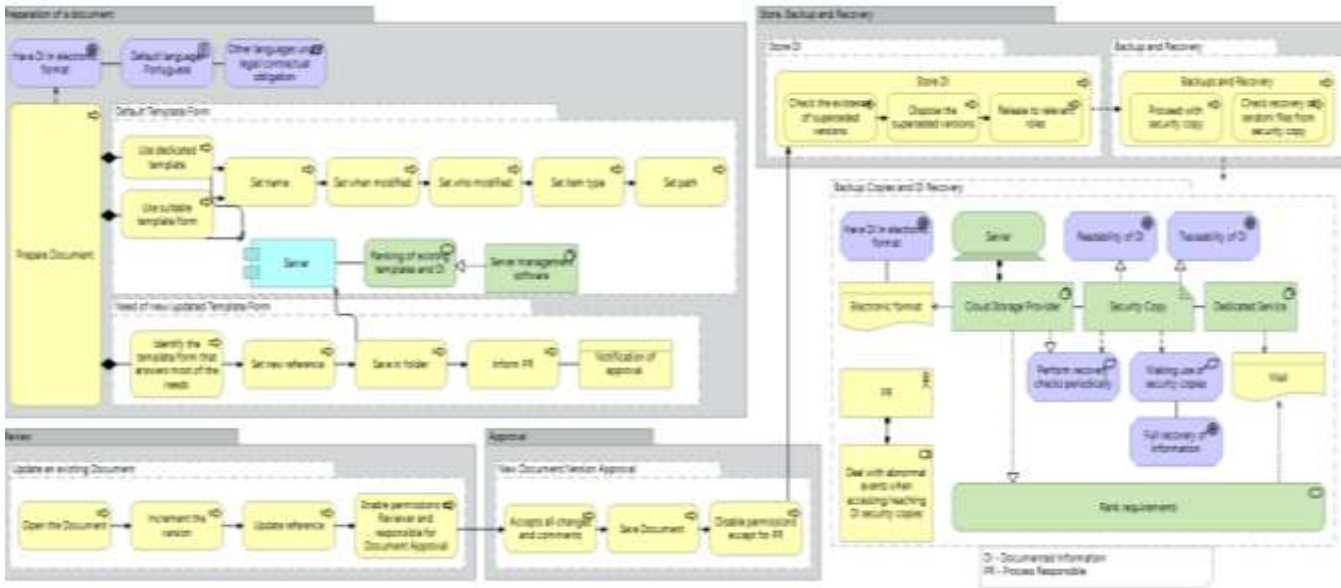

Fig. 2. Detailed model of document preparation, review, acceptance, and storage.
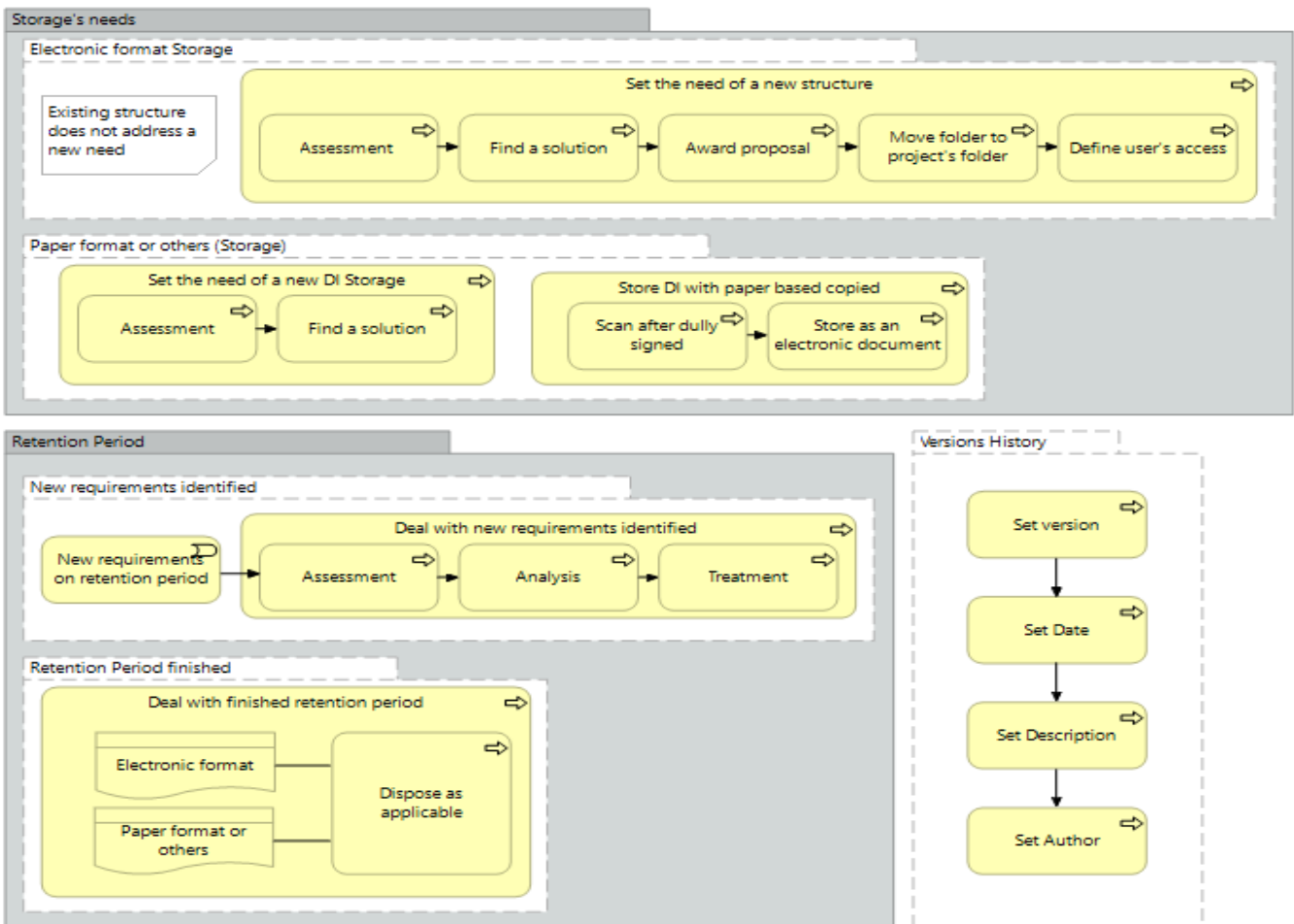

Fig. 3. Document storage, retention period and version history.
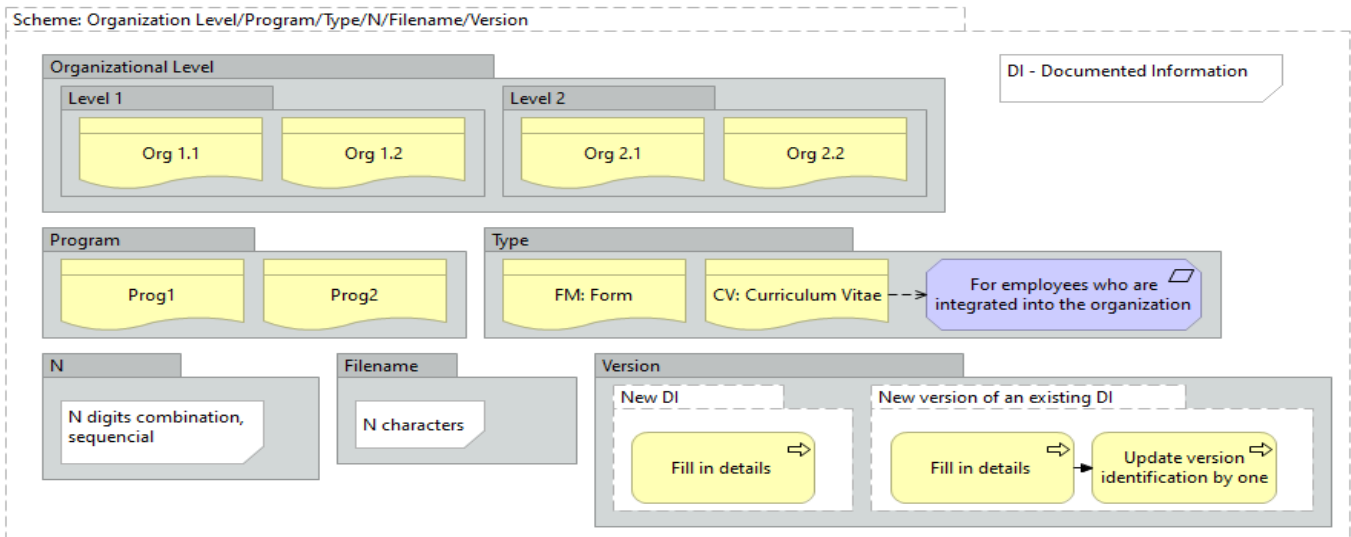
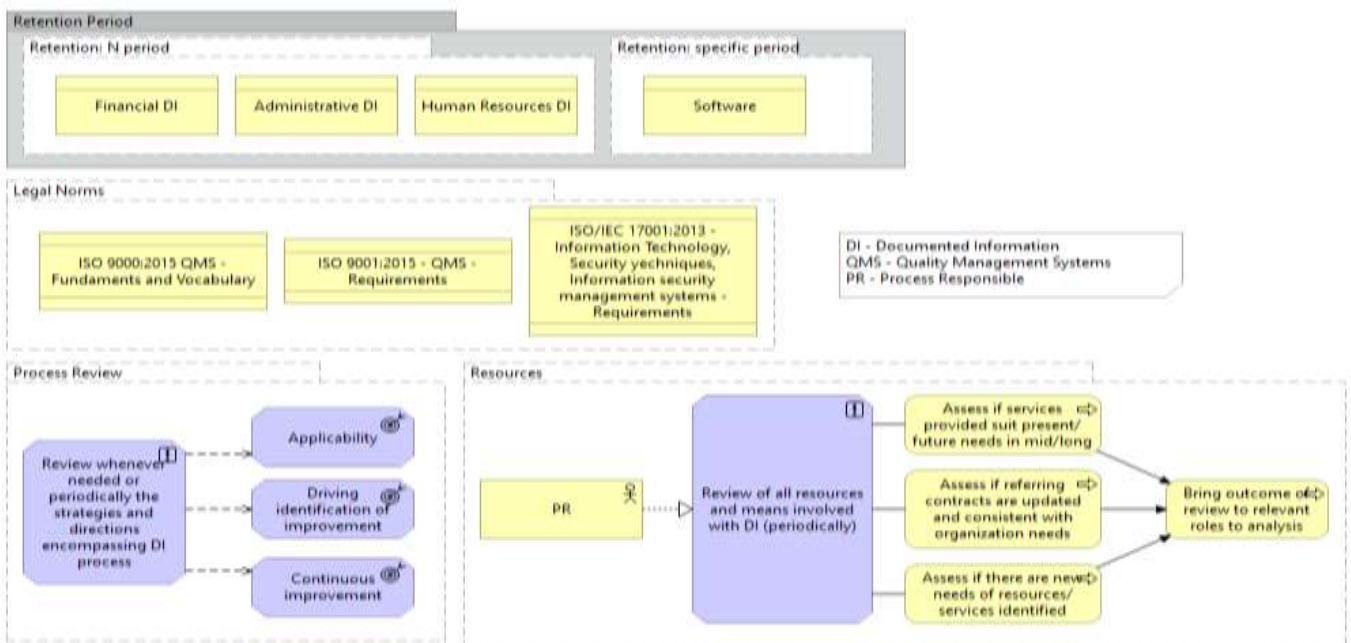Fig. 4. Document attributes and classifications schema.

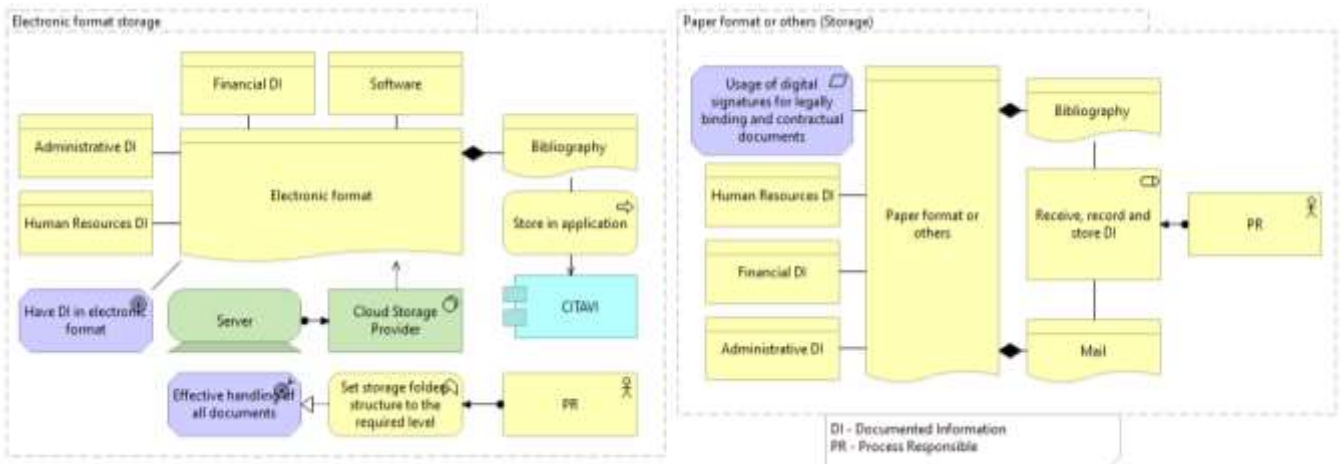Fig. 5. Compliance requirements view.

Fig. 6. Document medium view.

Our EA approach extends the traditional process models. The view included in Fig. 5 presents the document retention period (numbers removed for confidentiality purposes), regulations by which the case company is governed, vocabulary, and core QMS principles. However, the document medium (physical or digital) is also relevant for ISO 9001:2015 compliance.

Fig. 6 represents these differences. While documents in electronic format (e.g., administrative, human resources, financial) are stored according to the representations presented on the server using the Cloud Storage Provider software system, the physical documents are stored in a separate application.

Responsibilities are essential in ISO 9001:2015. Fig. 7 shows the primary stakeholders' responsibility (process responsible on the top). Another example of stakeholder is presented below. Stakeholder 1 approves documents and deals with management duties related to accounts, reports, activity plans, and budgets of both the current and following year.

Next, Fig. 8 presents the main motivations for document management in the target organization. Motivational elements can be found in all the previous ArchiMate views, but the team found interest in representing an additional motivational view, strengthening "why" quality is essential to the company (relevant for training purposes).

The lessons learned and the discussion of the design and development steps are presented in the next section.
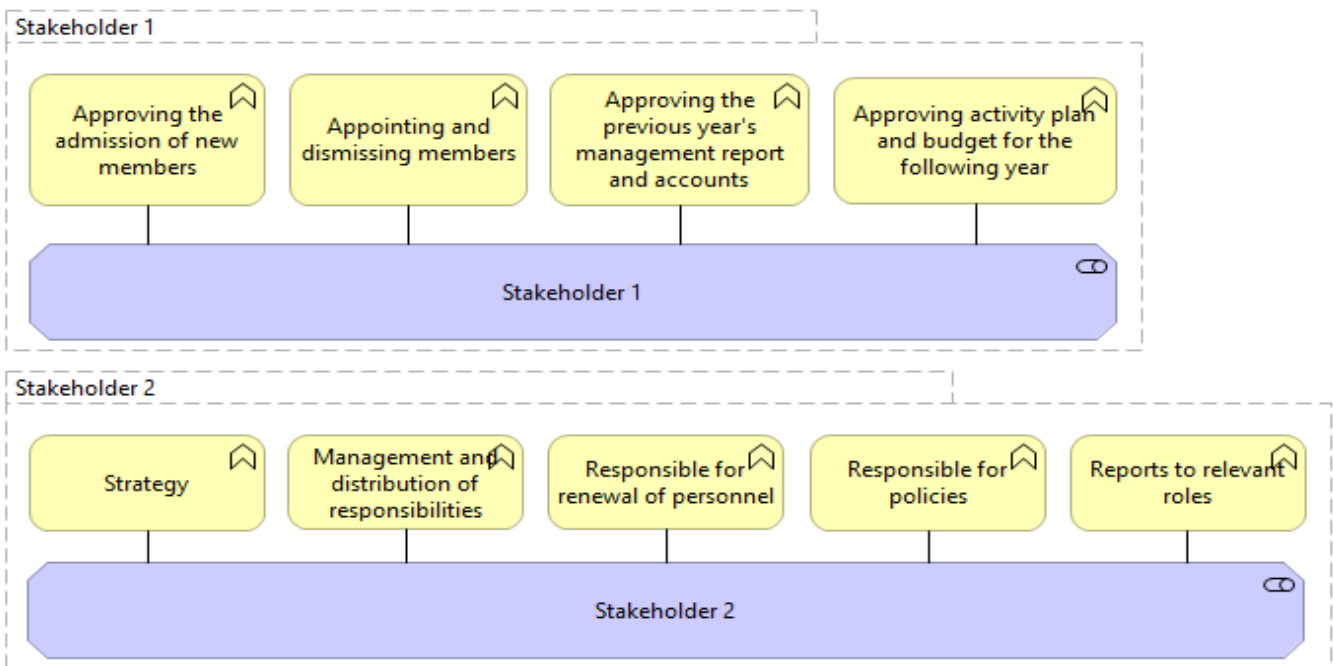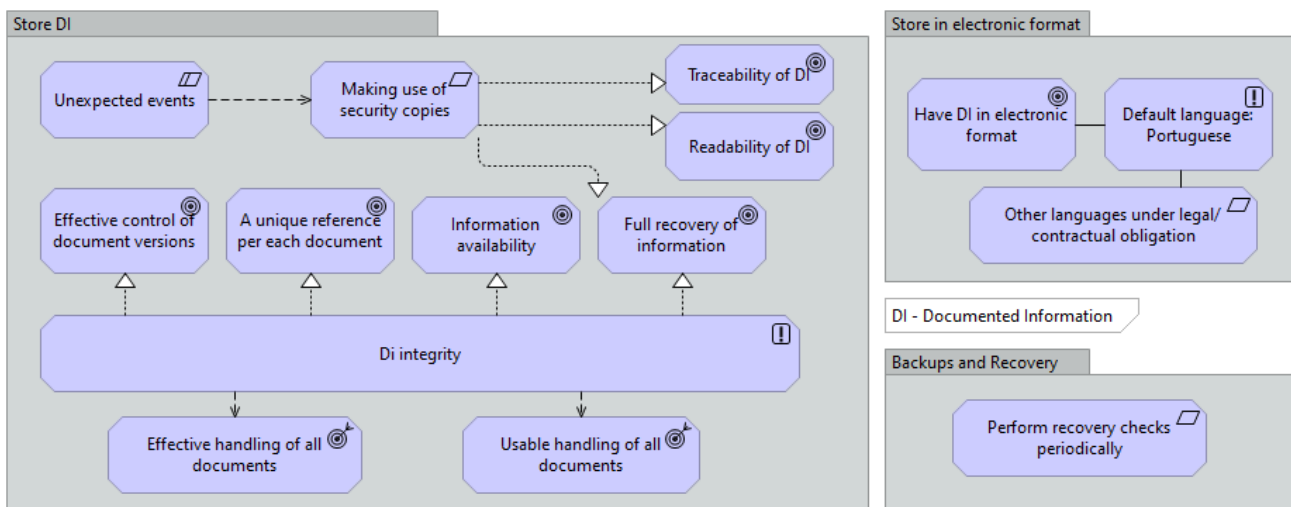

Fig. 7. Responsibility's view.

Fig. 8. Motivation view.

V. DISCUSSION

Our EA modeling approach started with the selection of a modeling language. ArchiMate allows the creation of models in a structured manner, using layers (strategy, business, application, technology & physical, and implementation & migration), which we found necessary in the literature review phase. Along with layers, ArchiMate also encompasses motivational, behavioral, structural, and composite aspects relevant to contextualize the logic of ISO 9001:2015 quality management systems. Next, we collected detailed information in the case company about a specific process: document management systems and documented information requirements.

The third step was to model the relevant information for ISO 9001:2015 compliance and assist the process users: internal (e.g., document creators) or external to the organization (e.g., assessors). A total of eight essential views were identified: (1) main view; (2) document creation and change (according to specific phases that needed detail); (3) document lifecycle management (e.g., storage, retention, disposal); (4) attributes and classification; (5) compliance requirements; (6) medium (physical-digital); (7) responsibilities, and (8) motivation.

At this stage, we needed to capture the design logic of ISO 9001:2015 and apply the Zachman Framework's core questions: Who, What, How, Where, When, and Why. For example, who is responsible for the documented information? Who are the stakeholders of the organization? What are the classifications and attributes related to DI? How is the DI procedure flow (default behavior)? How to deal with new needs in the process (specific behavior)? Where is DI stored? When are the rules and compliance of DI implemented?

Moreover, why is DI relevant? All these questions need to be addressed appropriately in documented information relevant to quality managers and EA professionals. A summary of the proposed approach is represented in Fig. 9.

The approach starts with the analysis of existing information (e.g., flowcharts, text-based procedures, organizational charts). The "big picture" (stage 2) includes business, IT, and motivation elements. Afterward, the detailed views are created according to the needs of the stakeholders and enriched with more specific information about the domain. This is an iterative process that may require several meetings with the process participants. Finally, it will be necessary to integrate the models in the QMS, continuously improving the documented information. Continuous improvement and people engagement are key principles of ISO 9001:2015 that can also be adopted in approaches for IT-enabled documented information.

We iteratively improved the models according to the feedback provided by ISO 9001:2015 experts. A high-level view to summarize document management was considered mandatory. However, this view needed to be simple and accessible to all the document stakeholders. Therefore, additional views were created, depending on the required granularity level. In ISO 9001:2015 settings, models must have sufficient detail to avoid errors and ensure consistency in the procedures. An acronym list was found necessary since not all stakeholders are familiar with the terms and visual elements used in the models. Moreover, we found that it is also vital to provide a short training about ArchiMate modeling to the designers.
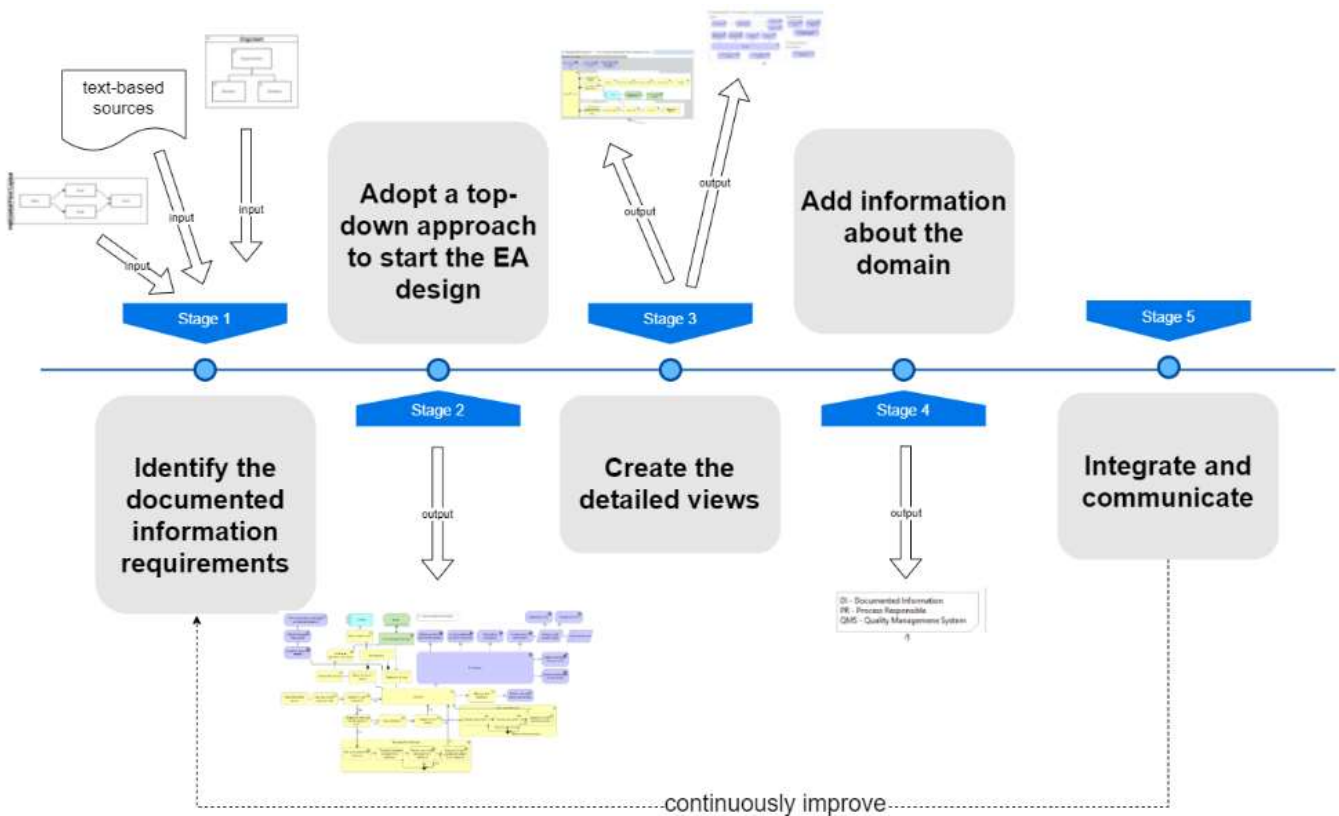

Fig. 9. An ArchiMate-Based Approach to ISO 9001:2015 Quality Management.

The evaluation made by two certified assessors participating in this research was positive, namely: "it is possible to implement", "it is a comprehensive model and allows a fine-grained detail level of analysis", "its use can be complementary to the existing document and flowcharts", providing an "explanatory perspective on the paths to quality", and "it can contribute to business-IT alignment including the digital transformation perspective".

The main advantages of the proposed approach are:

- ISO 9001:2015 documentation can be improved using a visual language that extends the representation capabilities of traditional process models;

- The EA models can be used in quality audits;

- Process documentation do not require a traditional text-based process description;

- It makes possible a joint representation of the QMS requirements and the IT department requirements;

- Clarifies the relationships between different domains of the organization;

- Provides alignment between the quality management system and IT, using a standard notation;

- This EA initiative can be included in the list of improvement actions for ISO 9001:2015-certified organization (e.g., upgrading traditional process representations to EA models);

- Identifies technologies applicable to different parts of the process and the data requirements in each phase;

- Suggests views tailored to the needs of each stakeholder of the QMS.

There are also disadvantages in the EA approach to ISO 9001:2015 documentation. The most relevant are:

- The effort of creating a new representation may be more suitable to complex and digitized processes. For example, some core ISO 9001:2015 requirements like internal audits (that may be supported by mobile technologies, platforms to create preventive actions), training, non-conformance, or the example used in this study focusing document management systems;

- The difficulty in identifying the most appropriate granularity level. Our work evolved in iterations until the final approval by the company expert;

- The need to provide a short training action to quality managers and IT managers not familiar with ArchiMate. Although the main view can be more accessible to the other users, it was necessary to include a list of acronyms and a legend about the elements used in the model.

We put the hypothesis that an EA approach to ISO 9001:2015 will be more valuable to organizations adopting digital transformation strategies [27] (e.g., Industry 4.0). Moreover, quality assessors could also use this approach, improving their service to the customers by documenting information that integrates quality and IT in a unified view.

VI. CONCLUSION

This paper presented an EA approach to ISO 9001:2015quality management systems. The business process of documented information in an aeronautical organization provided the setting. Our research exemplifies how to create new models that capture the complexity of increasingly digitalized processes in ISO 9001:2015certified organizations.

The results were generally positive because an EA approach is potentially more complete to document quality information when compared to the strict use of text-based procedures or flowcharts. Nevertheless, we also found limitations in the artifacts and in the approach that deserve additional work. First, this is our first attempt to represent an ISO 9001:2015 compliant process exclusively using ArchiMate. Therefore, the models need to be evaluated by other stakeholders, and it is possible to improve them for readability. The company may continue developing its models in the future. Second, the results were positively evaluated by two ISO 9001:2015 auditors, but it was not possible to test them in an external audit. Therefore, we need to evaluate the requirements for that phase (e.g., provide sufficient knowledge to the auditor about the documented information models) that is planned to be conducted with a parallel representation of the (text-based) document management procedure. Comparing both models by external auditors can be interesting. Third, ISO 9001:2015 applies to any organization operating in any sector of the economy and is not prescriptive about most processes that need to be documented. Our work focused on a specific process, and we identified the potential transferability of this approach to other processes in the organization (e.g., internal audits). However, it is not possible to state that the approach is helpful to all types of processes (e.g., manufacturing, maintenance) or ISO 9001:2015 requirements (e.g., training).

Significant opportunities for future work are identified. First, the ISO 9001 family of standards is constantly evolving. *The process approach to* management can be upgraded to an *EA approach to management*. This improvement is justifiable in an era of digital transformation but requires additional studies to understand how organizational practices can be represented in a unified and accessible way. Second, ArchiMate is only one of the possible approaches that can be tested to document ISO 9001:2015 information. Third, many other standards could be evaluated [28] with an EA approach for (1) design time, when it is necessary to create the compliant system, and (2) run-time, when it is essential to assess if activities detailed in the model are effectively adopted. Action design research [29] is a promising research approach to focus on the social changes emerging from EA approaches in ISO 9001:2015 certification.

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