Regulatory Compliance and Quality Programs: Constraints and Opportunities for Integration

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Abstract

Management systems for regulatory compliance and quality programs are examined in this paper from the standpoint of their potential integration and in terms of the concept of a process. The paper identifies five common drags on management system optimization and outlines a scoring system that organizations may use to evaluate their management systems for potential adoption of an integrated process-based program.

Key Words: Management system; implementation; integration; ISO; regulatory compliance

1. Introduction

This paper argues that by examining the costs and benefits of implementing process-based integrated management systems, organizations may gain insight into the potential value of merging regulatory compliance with quality programs. In this paper, we define regulatory compliance as all government requirements, exclusive of accounting, facing an organization and the activities an organization takes to conform to these requirements. Quality programs are defined as customer, international and national standards, and other requirements where an organization is obligated to show conformance. According to ReVelle (2003), a process is "a series of sequentially oriented, repeatable events that have both a beginning and an end, and which result in either a product or a service." Research by Carvalho et al. (2015) makes a strong case for integrating multiple standards (e.g., quality, environmental, safety) into a single management system. Their research findings are outlined further below. They define an integrated management system as "a set of interrelated processes that share human resources, information, materials, infrastructure, (sic) financial resources" (Carvalho et al. 2015). However, their research focuses exclusively on international standards, setting aside questions concerning regulatory compliance. Fiene (2019, 2022) has recently made the case that regulatory compliance programs may be enhanced by incorporating measurement and continual improvement—hallmarks of quality initiatives—into regulatory compliance programs. Our focus here is on the challenges and potential efficiencies that organizations may experience through implementing a management system

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designed to merge regulatory compliance and quality into an integrated process-based management system.

Scholars have identified a lack of research on the topic of the relationship between quality programs and regulatory compliance (Doyle 2007; Doyle et al. 2014). Furthermore, researchers have noted that relatively few studies of implementation in regulatory compliance have been published to guide research (Panitz et al. 2011). Recent actions by the US Food and Drug Administration (FDA) presents an opportunity to highlight the relationship between regulatory compliance and quality programs in organizations.

On February 23, 2022, the FDA issued a proposed rule to align 21 CFR 820 (known as the Quality System Regulation) with ISO 13485: 2016. ISO 13485 is an international standard for medical device quality. The FDA's proposed rule intends to achieve this alignment by "incorporating by reference" ISO 13485 into 21 CFR 820. FDA's proposed rule to align its Quality System Regulation with ISO 13485 provides a catalyst to examine the relationship between regulatory compliance and quality with specific reference to implementation because of the process-based orientation of ISO 13485 and other ISO quality standards. Organizations looking to take advantage of the alignment of 21 CFR 820 with ISO 13485, and companies planning to explore management system integration of other regulations and standards, may not have process-based systems in-place to manage conformance. It is with these points in mind that this paper puts forth a basic framework that organizations may consider when assessing the costs and benefits of adopting an integrated process-based system.

This alignment of ISO 13485 and 21 CFR 820 is atypical and not yet conventionally found elsewhere when considering regulations and standards, however, organizations may take the initiative to create a process-based management system that integrates other regulatory compliance requirements with quality program standards. For example, the food processing industry is regulated by FDA's 21 CFR 117 known as Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (CGMP). An international standard in food processing quality is Safe Quality Food (SQF). An organization in this sector may face the dual requirements of FDA's CGMP and SQF's quality requirements (SQF Code Edition 9) and choose to integrate their programs to conform to both in a single management system. CGMP is not aligned with SQF by the regulator or standards publisher, respectively. However, an organization may utilize cross-reference matrices to integrate them into their management system. A cross-reference matrix shows shared requirements between two standards or regulations. A cross-reference matrix also lists requirements that are not shared, yet still required from one of the two standards or regulations under consideration.

Considering the background sketched out above, this move by the FDA to align a regulation with a process-based standard is unique because regulations are not typically written in a process framework, let alone aligned with a standard. To the contrary, regulations tend to be written in a policy narrative format listing requirements and end-state outcomes organizations must achieve. Process-based standards, on the other hand, are organized around the idea of allowing an organization the latitude to set their own metrics while requiring companies to show their reasoning for these targets while engaged in continual improvement, among other systematically related activities. At the other end of the spectrum,

a regulation is conventionally a set of inflexible rules that a government agency imposes on an organization. International, national, and industry standards differ from regulations in that they are not promulgated by government agencies, rather they are a set of technical specifications developed by an international body (e.g., International Organization for Standardization - ISO), a national standards entity (e.g., American National Standards Institute - ANSI) or an industry standard (e.g., American Institute of Steel Construction - AISC). Standards are typically adopted by organizations voluntarily, however organizations sometimes encounter customer requirements that stipulate conformance with a standard.

2. Common Problems Encountered by Organizations in Management System Implementation

Organizations inevitably encounter through external audits, executive reviews, and operations, inter-relationships between regulatory compliance and quality programs. However, research suggests that organizations do not generally prioritize investment in the design and implementation of management systems focused on controlling and optimizing this inter-relationship (Doyle 2007). Thus, outside of the realm of operations the relationship between compliance and quality in organizations is more often reacted to in a haphazard manner as opposed to intentionally integrating the two in a management system. As Doyle (2007) has pointed out, one reason for this predicament is that it is inherently difficult for organizations to coordinate legal and supra-legal requirements. Supra-legal refers to binding requirements faced by an organization in addition to government rules. Supra-legal requirements may include national association standards and customer specifications. Additionally, research has identified other roadblocks that deter organizations from integrating quality programs with regulatory compliance, including limited resources, lack of top management support, and inherent complexity (Doyle et al 2014). Scholars, with the notable exceptions cited above, generally treat the two topics separately. Government agencies and standards registrars, for their part, have historically avoided prescribing structural/organizational requirements concerning documents and their information format in management systems. In part due to this, government and certifying body auditors encounter a myriad of information management schemes in stand-alone and integrated management systems.

As seasoned management consultants can attest through their experiences encountering legacy management systems in organizations, it is common to find a set of characteristics that constrain organizational effectiveness in the pursuits of quality programs and regulatory compliance. Here we identify five constraints, based on decades of practice in the implementation of management systems for organizations through consulting. Each of these constraints are drags on the optimization of management system implementation.

First, organizations often react passively to externally generated regulatory compliance targets and accept them at face value as published by government agencies. When organizations accept targets at face value, the wider context and purpose of collecting and reporting data on a given topic may be ignored by an organization. Accepting compliance targets as-is may decrease the chances an organization has to undertake initiatives to explore data collection and reporting that are of value to the organization, beyond just satisfying regulatory compliance.

Second, as a reaction to agency generated compliance targets, organizations may develop policies, procedures, forms and reports that are binary yes/no in format (e.g., was the target met?). Implementing a management system based on binary values stymies measurement.

Third, facing an array of compliance targets imposed externally, organizations may then decide to maintain two separate management systems, one for regulatory compliance and the other for their quality program. As a result of this, management systems can fall prey to becoming centralized silos of information. For the regulatory compliance system, but also encountered in quality programs, organizations may adopt an information management approach based on the sequence, numbering arrangement, and official language of the regulation and/or standard (i.e., an elements-based system). Adopting the language of an outside entity wholesale increases the chances that an organization will silo regulatory compliance information, thereby disconnecting this knowledge from the wider organization. Government agencies promulgate regulations, does it make sense for an organization with a unique culture and practices to follow a structure imposed from outside?

Fourth, organizations may create a narrative structure (text rather than process flowcharts and process maps) to carry out an elements-based system. Best practices in industry have moved away from narrative-based procedures in management systems because dense text is hard to follow; text-based policies are less likely to be linked to other activities in regular workflows than other graphical devices.

Best practices now utilize process flowcharts and process maps. Products such as Visio, along with an evolving world of web-based flowcharting tools, exist as resources. ISO 5807, the standard for flowchart symbols and methodology, is a helpful reference. ISO 5807 (1985: 1-2) identifies five types of flowcharts: data flowchart, program flowchart, system flowchart, program network chart, and system resource chart (see Figures 1 and 2 below).

ReVelle's (2003) definition of process flowchart is useful for the purposes of management system implementation explored in this paper. According to ReVelle (2003) a process flowchart is a graphical representation of a single process, using symbols to show the sequence of steps, typically moving left to right. Although the idea of a process map is not referenced in ISO 5807 because it came into use in industry after the standard was originally published in 1985, the marketplace adopted the concept because it nicely illustrates how processes are linked to one another. As ReVelle (2003) notes, a process map is "a two-dimensional version of a process flowchart that also portrays handoffs and receipts of products and/or services from one person, organization and/or location to another. A process map shows process inputs and outputs moving left to right but then connects to other processes sequentially by linking to subsequent processes in a top to bottom arrangement.

Fifth, by default narrative-based management systems are commonly structured on departmental organizational charts, rather than being based on individual process-ownership. Responsibility in the departmental organizational chart method rests with the department. This method means it is not clear who is responsible for implementation and execution of a specific area. Additionally, with an organizationally based approach it is expensive and time

consuming to change the structure of a management system every time an org chart changes. Allocating responsibility and authority at the individual level through process-ownership avoids the wasted effort of re-designing the management system when an organization changes structure. Furthermore, vesting process-ownership at an individual level makes it easy to locate the person responsible for a given process to obtain information and discuss improvements.

3. Characterizing Management System Attributes in an Organization

An organization may wish to evaluate its existing management system or explore options concerning implementing a new management system. This section, also based on practice in management consulting, applies to an organization seeking to better understand its current management system. This section, also based on practice in management consulting, applies to an organization seeking to better understand its current management system. A management system is defined as an information management framework that describes how an organization conforms to legal and supra-legal requirements concerning quality, environmental, and other aspects.

Organizations can undertake two activities that will provide a basis to outline the pros and cons of changing the structure of a management system or improving components of a management system. The first step is to identify all legal and supra-legal requirements facing an organization. Second, an organization's management system is categorized into the following types: elements-based or organized using an independent system; composed primarily with narrative, text-based procedures or process oriented with process flowcharts and process maps.

To identify legal requirements facing an organization, a table is generated containing rows of all known regulations that apply to the company within the scope the organization wishes to control. Next, all compliance points are detailed in a column adjacent to each regulation, including any required training along with written plans and/or procedures. Finally, the required records and reports are identified in an additional column. The same steps are undertaken by the company to identify supra-legal requirements. In the case of supra-legal requirements, an organization should identify international standards, national standards, contractual customer requirements, corporate policies, insurance requirements, and trade association standards.

With the legal and supra-legal requirements in a table, the organization may proceed to characterize the format of its existing management system. This step begins with an understanding of the typical components of a management system. Management systems often contain a brief manual at the front that spells out the scope of the management system by listing the regulations and standards that the system covers along with a related scope of operations. Procedures and work instructions, the how-to of the management system, typically follow the manual. Finally, forms and records round out the management system. To assess the current state of the management system an organization should know the overall structure of the information and the type of format it is using for procedures and work instructions. There are two common types of general information management structures organizations use in management systems:

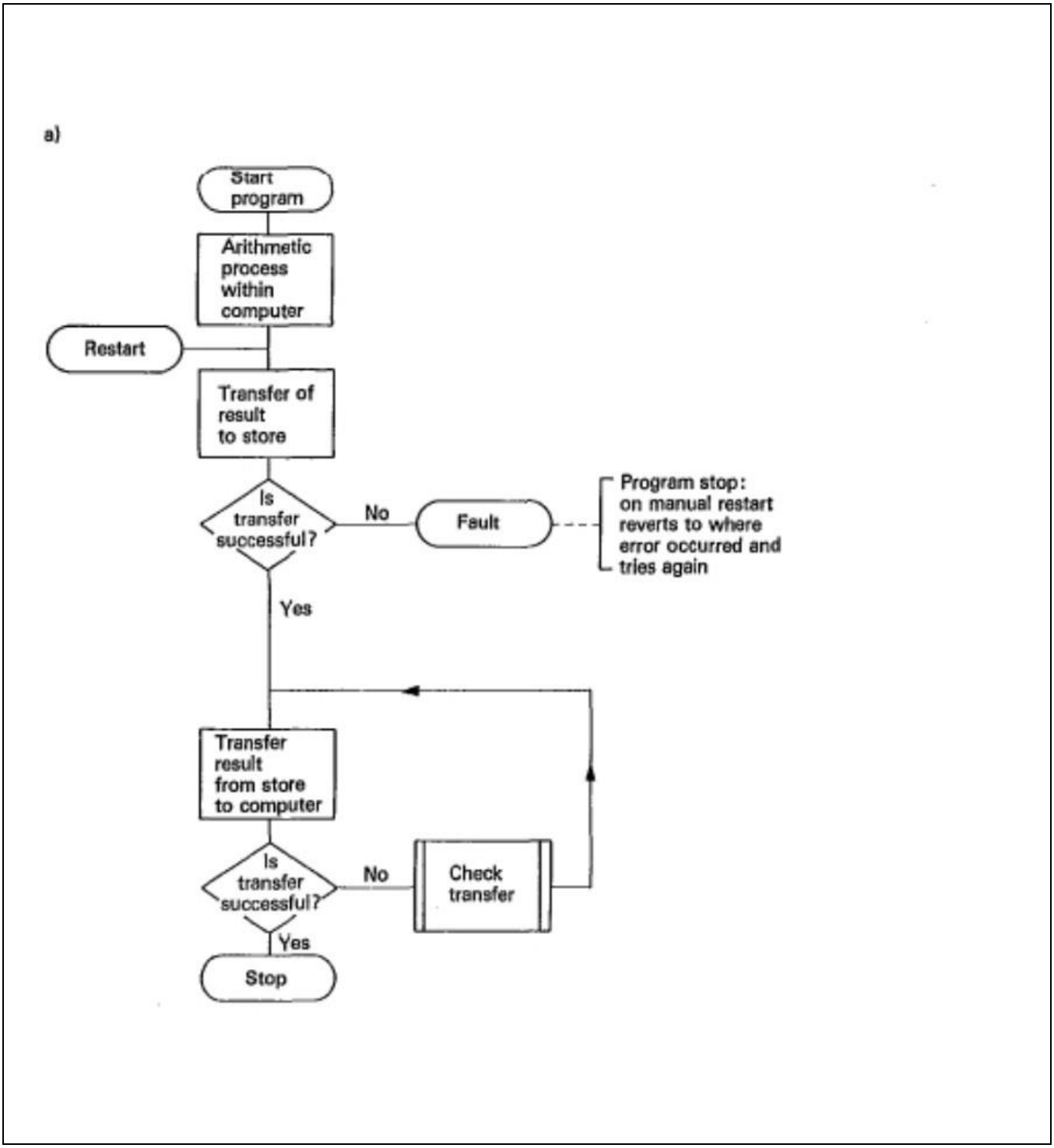

Figure 1: Program Flowchart, from ISO 5087 Annex B

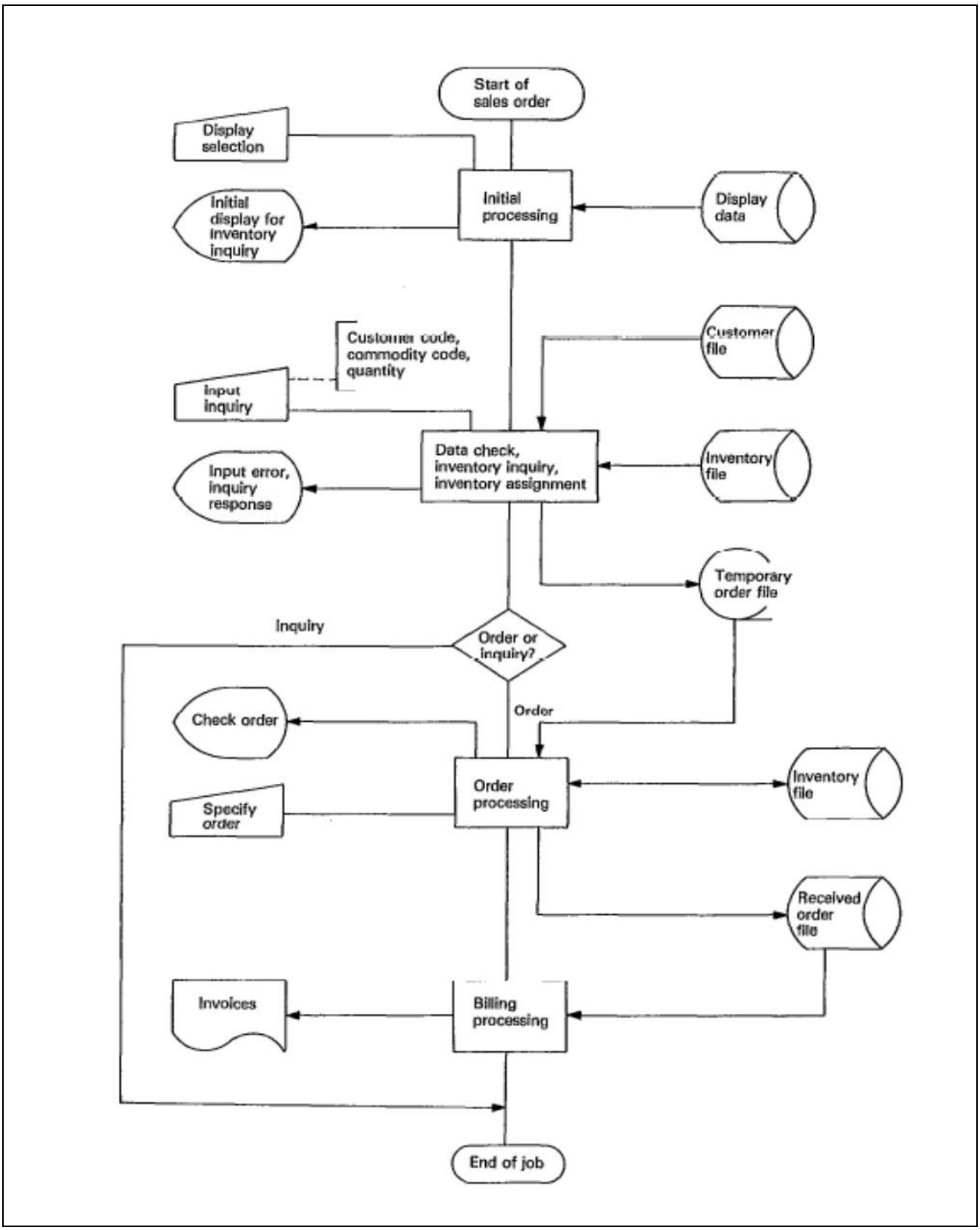

Figure 2: System Flowchart, from ISO 5087, Annex C

elements-based and independently structured. An elements-based system follows the numbering and order of the regulation and/or standard. An independently structured system is based on a generic ordering using language common to the organization.

To characterize the format of procedures, begin by selecting three procedures from separate areas of the management system. Read the procedure and look for one of two common possibilities: narrative sentences organized in statements or graphical depictions of the steps of an activity (process flowcharts and process maps). If no process flowcharts or process maps are encountered, the organization has a narrative management system. If the organization's management system contains process flowcharts and process maps, the possibility exists that the management system is process-based.

With the table of legal and supra-legal requirements in hand along with the findings of the assessment of the management system format, an organization can next score their findings. To score the findings, begin by reviewing the table of requirements. If the table contains many requirements and the majority of these are complicated, then issue a score of High/Complex. The table's listings may be scored Medium/Standard if the organization is not in a highly regulated sector. Finally, a score of Low/Simple may be assigned to companies that are lightly regulated.

To score the overall structure of the management system, assign a label of Elements for systems that follow the sequence and nomenclature of the regulation and/or standard. If the system is based on the organization's own approach, label it independent. For procedures, assign a value of Primarily Narrative for management systems where most of the information in the procedures and work instructions is in sentences of text without graphical flowcharts. If an organization encounters a management system where the procedures and work instruction are mainly composed of flowcharts and maps, assign a value of Primarily Process.

Organizations with a combined score of High/Complex, Elements, and Primarily Narrative may find value in considering a transition to a process-based management system.

4. Challenges and Advantages to Implementing a Process Oriented Management System Integrating Compliance and Quality in an Organization

This paper concludes by briefly identifying some challenges and advantages organizations may encounter in the transition to a process-based integrated management system.

There are two primary challenges to an organization seeking to transition to a process-based approach to its management system. First, looking at each area of an organization as a series of activities characterized by an input and an output may be new to employees. A process-based approach also requires a shift in mindset for team members with no previous experience with a process-based system. Second, an organization moving to a process-based management system should plan for an activity that often requires six months to a year to accomplish. The transition to a process-based management system, the implementation phase, can be time consuming.

There are three main advantages of adopting a process-based management system. First, this approach facilitates the establishment of a baseline. Second, with a process baseline established, a company may then expend

less effort to set metrics and measure against a baseline. Third, the activity of continual improvement is enhanced through a process approach because an organization has established benchmarks for each process.

In their study of management system integration, Carvalho et al. (2015) found that the primary barrier to integration is a lack of collaboration between managers in the different areas (e.g., quality, environmental, safety). In the case of the integration of quality programs and regulatory compliance the nature of the relationship between managers in these areas would likely be a key factor in project implementation.

Among the benefits of integration outlined by Carvalho et al. (2015), six findings may be useful for organizations to consider. First, an integrated system uses a shared resources approach so there is only one procedure for auditing, purchasing, and corrective-action, for example. Second, team members found that it was easier to manage a single system. Third, it took less time to audit the system. Fourth, the organization experienced less time spent in meetings. Fifth, there was increased understanding of the entire system. Sixth, the organization may experience reduced costs.

In summary, the case for process-based management system integration is organizational efficiency, elimination of redundancy, along with compliance improvement through enhanced knowledge and measurement brought about by feedback from quality initiatives.

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