ARTICLE
https://doi.org/10.22239/2317-269X.01833

Quality management in public administration: self-evaluation on the application of practices in the National Health Surveillance System

Gestão da qualidade na administração pública: autoavaliação sobre a aplicação de práticas em órgãos do Sistema Nacional de Vigilância Sanitária

Wilma Madeira da Silva[I]
Vera Maria Borralho Bacelar[I]
Artur Iuri Alves de Sousa[II]
Danila Augusta Accioly Varella Barca[I]
Cláudio Medeiros Santos[I]
Bruno Lopes Zanetta[I]

ABSTRACT

Introduction: Quality management is an outstanding mechanism in the managerial context, established as a theoretical and practical space of knowledge production, influencing the execution and control of processes in organizations. **Objective:** Identifying by means of self-evaluation the application of quality management practices in Health Surveillance Agencies. **Method:** Exploratory, descriptive, self-evaluation study using an electronic form for data collection, regarding a set of requirements deemed as initial stage of the Quality Management System model based on the ABNT NBR ISO 9001: 2015 Standard. In order to consult with Health Surveillance Agencies that deal with activities of high sanitary risk, municipalities and states in whose territories there were at least three factories of either medicines or active pharmaceutical ingredients or healthcare products classes of risk III and IV were selected. Thus, the universe of study comprehends seven states and 32 municipalities, with 94.0% and 63.0% of the Brazilian industrial park for these kinds of industry, in 2018. **Results:** In every agency there are quality management practices being performed: practices related to Planning and Support are the most widespread; those relative to Performance Evaluation are the least present. **Conclusions:** Grasping the degree to which Health Surveillance Agencies comply with the starting set of requirements of each section of the Model has contributed to confirm the potential of implementing the principles of the Quality Management System in the entities of the National Health Surveillance System, so they are in line with the demands for management improvement imposed by the national and international regulatory environment.

KEYWORDS: Quality Management; Health Surveillance; ISO 9001

RESUMO

Introdução: A gestão da qualidade é um mecanismo de destaque no contexto gerencial, firmando-se como espaço teórico e prático de produção de conhecimento e influenciando a execução e o controle nos processos de trabalho nas organizações. **Objetivo:** Identificar a aplicação de práticas de gestão da qualidade, por meio de autoavaliação, em órgãos de Vigilância Sanitária. **Método:** Estudo exploratório descritivo, de autoavaliação, com uso de formulário eletrônico para a coleta de dados. Foram selecionados e aplicados requisitos considerados iniciais em um modelo de Sistema de Gestão da Qualidade, a partir da norma ABNT NBR ISO 9001:2015. Com o intuito de consultar órgãos de Vigilância Sanitária que exercessem ações envolvendo atividades de alto risco sanitário, foram considerados municípios e estados em cujos territórios houvesse concentração de, pelo menos, três unidades industriais fabricantes de medicamentos, insumos farmacêuticos ativos e produtos para a saúde classes de risco III e IV. Assim, o universo do estudo compreendeu sete estados e 32 municípios, nos quais estavam instalados, respectivamente, 94,0% e 63,0% do parque industrial brasileiro das referidas indústrias, no ano de 2018. **Resultados:**

[I] Hospital Alemão Oswaldo Cruz, São Paulo, SP, Brasil

[II] Agência Nacional de Vigilância Sanitária (Anvisa), Brasília, DF, Brasil

* **E-mail:** wilma.madeira@gmail.com

Received: 17 Nov 2020
Approved: 28 Apr 2021

Observou-se que, nos órgãos de Vigilância Sanitária estudados, existem práticas de gestão da qualidade sendo executadas, sendo que as práticas de planejamento e apoio são as mais difundidas, enquanto as voltadas à avaliação de desempenho são as menos presentes. **Conclusões:** Conhecer o grau em que os órgãos de Vigilância Sanitária atendem aos requisitos iniciais de cada uma das seções de um modelo de Sistema de Gestão da Qualidade contribui para confirmar o potencial para implantação de princípios da Gestão da Qualidade nos entes que compõem o Sistema Nacional de Vigilância Sanitária, para que esses estejam em sintonia com as exigências de melhoria de gestão impostas pelo ambiente regulatório nacional e internacional.

PALAVRAS-CHAVE: Gestão da Qualidade; Vigilância Sanitária; ISO 9001

INTRODUCTION

Quality management (QM) has a prominent position in the context, establishing itself as a theoretical and practical space for the production of knowledge, influencing the execution and control of work in organizations[1]. A worldwide phenomenon since the 1980s, it is observed that many different organizations have invested efforts in the qualification of their work processes, through the incorporation of practices from Quality Management Systems (QMS)[2].

As a topic of growing importance, more and more organizations around the world have implemented QMS using the ISO 9001 as a normative reference, which, prepared by the International Organization for Standardization (ISO), was developed to serve organizations that seek to improve the quality of their processes, products, and services. ABNT NBR ISO 9001, a standard that establishes the set of requirements for a QMS, can be applied to any branch of activity and aims to provide the implementation of a reliable organizational management system, with the purpose of delivering services and goods to customers according to the defined specifications[3].

Public sector organizations are not oblivious to this phenomenon and make efforts towards the implementation of QMS[4]. In Brazil, as in other countries, the applicability of the precepts of ISO 9001 to public organizations was boosted with the publication of a specific standard: ABNT NBR ISO 18091:2014 – QMS – Guidelines for the application of ABNT NBR ISO 9001:2008 in city halls[5], whose objective is to establish management requirements to obtain reliable results. Organizations in the health area have also been accumulating experiences in the institutionalization of such QMS practices, especially assistance organizations, in view of the constant need to guarantee, maintain, and improve the quality and safety in the provision of health services. In the scope of sanitary regulation of products and services, the global movement led by the World Health Organization (WHO) has been discussing the importance of implementing QMS in National Regulatory Authorities (NRA), aiming to facilitate regulatory convergence, mutual trust, and recognition mechanisms among the Member States[6,7].

In this sense, the WHO published, in 2020, a document of guidelines for the implementation of QMS in NRA[7], in which he points out that effective regulatory systems are an essential component of the healthcare system and that all Member States should have regulatory systems that: (i) address context-related risks and opportunities for continuous improvement; (ii) demonstrate compliance with specific requirements of the QMS; (iii) ensure the quality, safety, and efficacy of medical products; and, finally, (iv) ensure medical products and other health technologies in the market to meet their customer/citizen requirements. The WHO also highlights that a QMS has the potential to ensure that products and services subject to the normative acts of a regulatory agency consistently comply with statutory and regulatory standards, thus meeting the expectations of its customers/citizens.

In Brazil, the Organic Law of the Unified Health System (SUS), Law nº 8.080, of September 19, 1990[8], defines health surveillance as a set of actions capable of eliminating, reducing, or preventing health risks and intervening in health problems arising from the environment, production, circulation of goods, and the provision of services of interest to health. The action of health surveillance in the states, Federal District, and municipalities has been diffuse over time, considering the differences in regulations, the low harmonization and uniformity in the execution of actions, and the differences in the definition of globalized processes of production and commercialization of products subject to sanitary surveillance. Additionally, the need to expand the supply of Brazilian products abroad shows the need for recognition of sanitary equivalence by international health authorities[9].

Qualifying health surveillance actions with the incorporation of instruments that contribute to the improvement of management processes has been the work agenda of the Brazilian Health Regulatory Agency (Anvisa) and other entities of the National Health Surveillance System (SNVS) in recent years Thus, it became an important agenda for the SNVS to qualify health surveillance actions with the incorporation of instruments that contribute to the improvement of management processes, more specifically with regard to QM[4].

In the search for the improvement of national practices, in a context of interfederative partnership, the Resolution of the Collegiate Board (RDC) nº 207, of January 3, 2018[10], by Anvisa, provides for the organization of health surveillance actions and regulates the need to implement a QMS as a condition for the Health Surveillance services of states, Federal District and municipalities to assume responsibility for inspection actions in drug industries, of active pharmaceutical inputs (API), and health products of risk classes III – high risk to the individual and/or medium risk to public health – and IV – high risk to the individual and high risk to public health[11,12]. In this context, this article aimed to identify the application of quality management practices, through self-assessment, in Health Surveillance bodies.

METHOD

This study was developed within the scope of the project *Qualification of Management of Strategic Health Surveillance Actions in the SNVS - IntegraVisa II*, a partnership between Anvisa and Oswaldo Cruz German Hospital (HAOC), through the SUS Institutional Development Support Program (Proadi-SUS). This is an exploratory and descriptive study, referring to the application of QM practices in a Health Surveillance agency in seven states and 32 selected municipalities. This study was conducted in three stages: (i) bibliographic survey; (ii) field research; and (iii) data analysis and discussion of results.

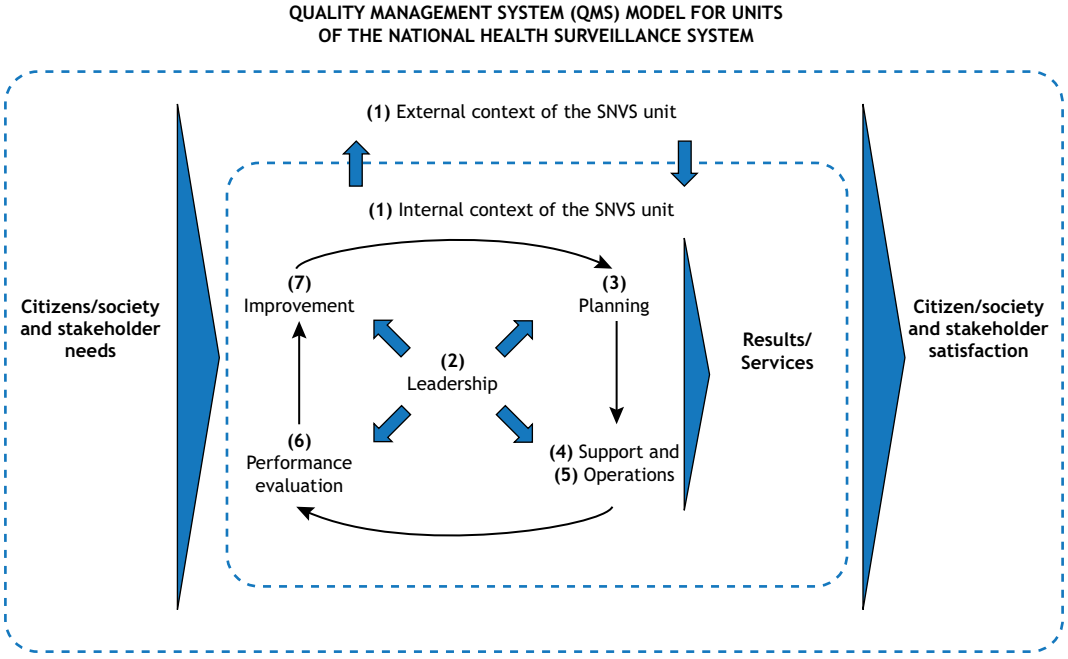
The bibliographic survey (i) enabled the constitution of theoretical references that supported the elaboration of the discussions of results. It was carried out through searches in bibliographic databases related to the theme, with terms validated according to the Health Sciences Descriptors (DeCS)[13], related to the three sets of keywords: (a) quality management system, and/or quality management, and/or quality management in Health, and/or quality; (b) regulatory agency, and/or health surveillance, and/or health service, and/or health area, and/or health; and (c) public service; and/or public sector; and/or government.

In order to carry out the field research (ii), the second stage of the study, were established as a cutout to be studied municipal and state Health Surveillance bodies in whose territories of operation existed, in 2018, at least three industrial units of manufacturers of medicines and/or active pharmaceutical ingredients and/or health products classes risk III and IV. Were identified as members of the universe of this study Health Surveillance bodies from seven states - Goiás, Minas Gerais, Paraná, Rio de Janeiro, Rio Grande do Sul, Santa Catarina, São Paulo - and 32 municipalities - Amparo, Anápolis, Aparecida de Goiânia, Barueri, Bauru, Belo Horizonte, Campinas, Contagem, Cotia, Curitiba, Diadema, Florianópolis, Goiânia, Guarulhos, Hortolândia, Indaiatuba, Juiz de Fora, Lagoa Santa, Maringá, Mogi Mirim, Nova Lima, Pinhais, Porto Alegre, Ribeirão Preto, Rio Claro, Rio de Janeiro, São Carlos, São José do Rio Preto, São José dos Campos, São Paulo, Sorocaba, and Taboão da Serra.

For the data collection stage of the study, it was decided to use a structured electronic form, with questions related to the initial requirements for the implementation of a QMS model in Health Surveillance bodies, based on the ABNT NBR ISO 9001:2015 standard[3]. This standard was considered adequate and adherent to the SNVS entities that seek to implement a QMS, and the proposed model is composed of the following sections: external/internal context, leadership, planning, support, operations, performance evaluation, and improvement, totaling seven sections (Figure 1). The electronic form was sent to the managers of the 39 Health Surveillance agencies, the universe of the study, accompanied by a glossary with definitions of the main terms adopted (Chart 1).

The questions made available in the electronic form were grouped according to the seven sections of the proposed model, in each of which the requirements considered as minimum or fundamental to identify that a Health Surveillance agency has a QMS implemented or being implemented were presented.

To support the answers to the questions of the electronic form, a guideline was prepared, in which the professionals of the selected Health Surveillance agencies were instructed to respond as a team, thus enabling the elaboration of more complete



Source: Adaptation of the authors from the reference of the ABNT NBR ISO 9001:2015 standard, prepared within the scope of the IntegraVisa project[21].

Figure 1. Quality Management System model for units of the National Health Surveillance System, 2019, prepared based on the ABNT NBR ISO 9001:2015 standard.

Chart 1. Description of the sections of the ABNT NBR ISO 9001:2015 standard included in the electronic form of the survey of quality management practices in Health Surveillance bodies.

Section	Description
Organizational context (section 1)	It addresses practices related to the organizational context, allowing the identification of opportunities and obstacles, as well as stakeholder needs.
Leadership (section 2)	It addresses practices related to organizational roles, responsibilities and authorities, customer focus, and QMS policy and communication.
Planning (section 3)	It addresses practices related to the establishment of tools and processes to characterize problems and needs, focusing on risks and opportunities for management.
Support (section 4)	It addresses practices related to the provision of resources, people, infrastructure, and skills necessary for the development of health surveillance actions.
Operations (section 5)	It addresses practices related to operational activities, as well as managing work processes, dealing with non-conformities and evaluating outsourced services.
Performance evaluation (section 6)	It addresses practices related to monitoring, measurement, analysis and evaluation of performance and citizen/society satisfaction, internal auditing, and critical analysis by the organization's management.
Improvement (section 7)	It addresses practices related to continuous improvement practices, such as identification and treatment of non-conformities and corrective actions.

Source: Adapted by the authors from the reference of the ABNT NBR ISO 9001:2015 standard, prepared within the scope of the IntegraVisa project[21].
QMS: Quality Management System

responses that are better anchored in the local contexts of these bodies. A direct channel of communication was also made available with the team that conducted the study, in order to clarify doubts that had not been previously identified. As a complement to the answers, the study participants were asked to send evidence – such as documents, models, work standards, practices, routines, systems, manuals, or regulations – that would allow objective proof of compliance with the requirements.

To identify the existence or execution of practices related to the initial requirements of the sections in the routine of each selected body, managers were asked to carry out a self-assessment exercise on compliance with these requirements, considering the management of Health Surveillance in a global way, from the perspective of two dimensions: if the initial requirement is fulfilled and if the practice to fulfill this requirement is performed only in specific areas or in the entire organization. In the electronic form, a ruler was included, whose strategy was to represent a measurement of these two dimensions, in a graphic, clear, and transparent way, allowing the identification not only of the number of practices related to the initial requirements met, but also the scope of carrying out these practices within the scope of the Health Surveillance agency (Table 2). The electronic form was available on the internet between March 14 and April 29, 2019.

In the results presented, there is no identification of the Health Surveillance bodies that responded to the form. For the presentation of the results in this study, the agencies were identified with the Visa code X.YY, where X indicates the state and YY the municipality. When the identification is Visa X.00, it indicates that the information is from the State Health Surveillance. The results were structured in tables and analyzed according to the results identified in the literature search.

RESULTS AND DISCUSSION

Of the total number of Health Surveillance agencies selected for the study (39), in the period established for data collection, 26 responses were received, being six states and 20 municipalities, or 66.7% of the universe studied. However, when considering separately the responses received from municipal and state Health Surveillance, we have, respectively, 62.5% and 85.7% of adherence to the survey. In this sense, and taking into account that states are responsible for coordinating and supporting municipalities, within their territorial limits, especially in health surveillance actions that involve objects with a higher degree of health risk intrinsic to activities and products, it can be said that the amount of responses received points to the reality of the implementation of QM practices in the SNVS. The study, therefore, allowed the construction of an overview of meeting the initial requirements by section of the QMS, considering the evaluation from the perspective of the two methodological dimensions applied, which refer to the practices related to the initial requirements met, developed in part or in the totality of the organ (Table 1).

Table 1 presents, in percentage values, the distribution of the 26 Health Surveillance agencies that responded to the survey form, regarding the level of compliance with the set of requirements referring to each section of the QMS. Thus, each line of the table represents a section, and its values total 100.0%, which allows you to view, line by line, the percentage of Health Surveillance for each level of compliance with the requirements, according to the ruler described in Table 2.

On the one hand, when analyzing the results of Table 1, it is observed that the requirements related to sections 3 (planning) and 4 (support) can be considered the sets of initial requirements most incorporated into the practices of Health Surveillance services, since, adding up the three highest levels of service on the ruler, we reach, respectively, 61.5% and 57.7% of the Health Surveillance Departments that responded to the form. In these two sections, therefore, most of the Health Surveillance bodies consulted met, at least, "more than half or all of the requirements of the section in part of Visa", as indicated by the rule used.

Table 1. Percentage distribution of Health Surveillance bodies (n = 26), according to compliance with practices from sections 1 to 7, related to the requirements of the Quality Management System, 2019.

Ruler / Model section	Does not meet any of the requirements in the section	Meets less than half of section requirements, in part of Visa	Meets less than half of section requirements, across Visa	Meets more than half or all section requirements, in part of Visa	Meets more than half of section requirements, across Visa	Meets all section requirements, across Visa
Organizational context (section 1)	15.4%	7.7%	30.8%	19.2%	26.9%	0.0%
Leadership (section 2)	15.4%	15.4%	26.9%	7.7%	19.2%	15.4%
Planning (section 3)	11.5%	11.5%	15.4%	11.5%	19.2%	30.8%
Support (section 4)	11.5%	11.5%	19.2%	15.4%	34.6%	7.7%
Operations (section 5)	0.0%	15.4%	50.0%	15.4%	19.2%	0.0%
Performance evaluation (section 6)	26.9%	23.1%	30.8%	15.4%	0.0%	3.8%
Improvement (section 7)	19.2%	26.9%	19.2%	11.5%	15.4%	7.7%

Source: Elaborated by the authors, 2020.
Visa: Health Surveillance.

On the other hand, taking as a reference the three lowest levels of service of the ruler, it is possible to verify that most of the Health Surveillance agencies participating in the research meet, at most, "less than half of the requirements [of each] section, across Visa", with 53.8% of Health Surveillance in section 1 (organizational context); 57.7%, in 2 (leadership); 65.4% in 5 (operations), 80.8% in 6 (performance analysis), and 65.4% in 7 (improvement). In this sense, the rates above 60.0% of the Health Surveillance in sections 5, 6, and 7 stand out. In the case of section 5 (operations), the value can be explained by the higher number of requirements in relation to the other sections, even though 50.0% of the Health Surveillance Departments responded that they meet "less than half of the requirements of the section, across Visa", as these are requirements linked to the finalistic processes, most commonly performed by them. In the case of sections 6 and 7, in turn, the percentages must be explained by the incipient application of monitoring and evaluation processes and practices and continuous improvement in the management of Health Surveillance, especially section 6, with 80.8% of them focusing on the lowest three levels of the ruler.

It is worth mentioning that the purpose of monitoring the existence of evidence in the QMS is to confirm compliance with the requirements by means of verification at the time of auditing the management model. Thus, as previously reported, the managers of the Health Surveillance participating in the study were given the possibility to present documents that evidence the responses sent about meeting the minimum requirements. Considering that the electronic form was composed of 27 questions, and that 26 Health Surveillance agencies sent their answers, the maximum possible limit of evidence to be received was 702, also emphasizing that evidence can meet more than one requirement, and only 109 were sent by the Health Surveillance, or 15.5% of the possible total. Furthermore, it should be noted that, of the 26 bodies that responded to the electronic form, a total of nine Health Surveillance Offices did not send any document with evidence for their responses. The evidence groups were categorized according to their nature, in order to analyze the relevance of being used to demonstrate compliance with the minimum requirements of each section of the QMS. In this sense, seven categories were identified, presented below with the respective total amounts of evidence received: 55 quality documents, 29 general management documents, ten minutes/reports of activities carried out, seven images extracted from information systems, six legislation reproductions, a course certificate, and a news item (Table 2).

Although the percentage of responses with evidence is low in relation to the total, it is possible to establish some relationships by grouping this evidence. Thus, 49 evidences were received from the participating state Health Surveillance agencies and 60 from the municipal ones, which represents a proportionately smaller number, considering that the number of participating municipalities was more than three times higher than the number of states. This result may be related to the fact that State Health Surveillance agencies have participated more actively in Brazil's accession process to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), international cooperation in the field of good manufacturing practices between regulatory authorities and the pharmaceutical industry, which involves, among other activities, the need to implement QMS in regulatory bodies. Along the same lines, it is observed that, of the total of 55 quality documents presented, 33 were sent by the state Sanitary Surveillance and 22 by the municipal ones.

Regarding the distribution of the amount of evidence across the seven sections of the QMS model, it is noteworthy that sections 1 to 5 were covered with a higher number of evidence

Table 2. Quantitative distribution of evidence presented by Health Surveillance bodies, in relation to categories of evidence, sections of the Quality Management System model, and government sphere, 2019.

Evidences / Setions/ Government sphere	Quality documents	Management documents	Minutes / reports	System screen	Legislation	Certificates	News	Grand total
Section 1	13	1	3	0	3	0	0	20
Section 2	18	1	0	0	2	0	0	21
Section 3	0	10	3	2	0	0	0	15
Section 4	4	8	4	0	1	1	0	18
Section 5	11	5	0	5	0	0	1	22
Section 6	4	4	0	0	0	0	0	8
Section 7	5	0	0	0	0	0	0	5
Total SS	33	11	3	1	1	0	0	49
Total MM	22	18	7	6	5	1	1	60
Total	55	29	10	7	6	1	1	109

Source: Prepared by the authors from the documents sent by the Health Surveillance agencies that responded to the electronic form, 2020.
SS: States; MM: Municipalities.

than sections 6 and 7, which converges with the results found in Table 1, in which the Health Surveillance Departments performed poorly in meeting the requirements of these last two sections. At the same time, it is interesting to compare the amount of evidence in sections 1, 2, and 5, which were 20, 21, and 22, respectively. Although the absolute values are very close, it is worth noting that the weight of section 5, in terms of the number of requirements, is greater than that of sections 1 and 2, which may denote a proportionately more complete fulfillment of the requirements of these two sections than those of section 5. In the same sense, when considering only the quality documents, 13 and 18 were sent, respectively, to sections 1 and 2, and 11, to section 5.

An important result to be discussed is the practices related to leadership (section 2), considering that about 59.0% of the Health Surveillance agencies were positioned in the three lowest levels of the ruler, which means that, at most, they meet less than half of the requirements of the section, in all Health Surveillance. This result can be characterized as a future difficulty, considering that, according to Campos[14], Santos[15], Carvalho[16], and Maekawa[17], the involvement of top management is a determining factor for the successful implementation of a QMS in organizations. Leaders in organizations are responsible for giving strategic direction and creating favorable conditions for people to engage in achieving quality objectives. The leader's capacity and involvement in the conduction of the change process for the implementation of the QMS are decisive factors in achieving the objectives.

In a study carried out with units of Central Public Health Laboratories (LACEN), Campos[14] stated that

> as a common point among the most developed LACENs in the implementation of the quality system, the fundamental role of the management's involvement is observed. Those who understood the importance and saw this goal as essential for the strengthening and growth of the laboratory were able to advance and encourage the technical staff to become proactive in the search for quality.

A more recent study identifies that meeting leadership requirements was fundamental for improving the quality of services provided by clinical analysis laboratories in the state of Santa Catarina[18].

In the analysis of the results per Health Surveillance unit, it was possible to test and confirm the relevance of the ruler used to measure the application of QM practices as an indication of the existence of practices related to the initial requirements (Chart 2). The ruler presented in the electronic form made it possible to verify and express, in this study, that the implementation of practices to meet the requirements of the QMS, even those considered initial, must take place in two dimensions, considering the implementation of the practices themselves and the scope of this implementation within the Health Surveillance agency. In this sense, for example, even when the agency meets all the requirements of a given section, if the respective practices are not performed throughout the agency, the answer will be, at most, 60.0% of the total ruler. In this way, we intend to portray the complexity of the two dimensions of implementation of the QMS in percentage values, in order to compare the responses sent by the Health Surveillance agencies participating in the study (Table 3).

In this analysis, presenting the results of the measurement ruler in Table 3, it is possible to identify that, according to the type of federated entity, there are differences regarding the degree of organization of the Health Surveillance bodies that point to the existence of QMS in an initial phase (40.0%) or in expansion (60.0%) in almost all responses from state Health Surveillance. However, only Visa 2.00 and 4.00 responded that they had practices related to more than 60.0% of meeting the initial requirements in all sections analyzed.

With regard to the municipalities, none of them met more than half of the requirements for the set of seven sections, that is, the

achievement of the last three levels of the rule. In the analysis by section, such achievement falls within a range of 5.0% to 35.0% of the total number of municipalities, according to each section (Section 1 - 35.0%, Section 2 - 35.0%, Section 3 – 45.0%, Section 4 – 45.0%, Section 5 – 25.0%, Section 6 – 5.0%, and Section 7 – 25.0%).

A result that stands out is related to the high percentages of a third of the Health Surveillance bodies in the state 7.00, here identified as 7.02, 7.03, 7.09, and 7.12, as they are municipalities in a state that has decentralized the execution of health surveillance actions to the municipalities existing in its territory, including among these activities those related to the control of products and services of high sanitary risk. Such results seem to reflect the degree of organization necessary for entities to carry out more complex actions in their respective territories.

In Brazil, the singularities of the federative model and the conformation of the area of health surveillance are pointed out as the background of a federative coordination effort aimed at building SUS. Health surveillance contributes both to the realization of the

Chart 2. Answer ruler for identifying the application of quality management practices in Health Surveillance bodies.

Does not meet any of the requirements in the section	Meets less than half of section requirements	Meets less than half of section requirements	Meets more than half or all section requirements	Meets more than half of section requirements	Meets all section requirements
-	In part of Visa	Across Visa	In part of Visa	Across Visa	Across Visa
0%	20%	40%	60%	80%	100%

Source: Elaborated by the authors, 2020.
Visa: Health Surveillance.

Table 3. Percentage of compliance with the initial requirements of sections 1 to 7 of the Quality Management System by Health Surveillance bodies (n = 26), 2019.

Visa	Section 1	Section 2	Section 3	Section 4	Section 5	Section 6	Section 7
Visa 1.00	60.0%	60.0%	60.0%	60.0%	60.0%	20.0%	60.0%
Visa 1.01	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
Visa 1.02	40.0%	80.0%	40.0%	0.0%	40.0%	0.0%	0.0%
Visa 2.00	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%
Visa 2.01	80.0%	40.0%	**100.0%**	40.0%	40.0%	40.0%	40.0%
Visa 3.00	60.0%	40.0%	40.0%	80.0%	40.0%	60.0%	60.0%
Visa 3.01	80.0%	80.0%	80.0%	80.0%	40.0%	20.0%	20.0%
Visa 3.02	60.0%	20.0%	**100.0%**	60.0%	40.0%	0.0%	0.0%
Visa 3.03	40.0%	**100.0%**	**100.0%**	80.0%	40.0%	40.0%	40.0%
Visa 4.00	80.0%	**100.0%**	**100.0%**	80.0%	80.0%	60.0%	80.0%
Visa 5.00	40.0%	**100.0%**	**100.0%**	**100.0%**	60.0%	60.0%	20.0%
Visa 5.01	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
Visa 6.00	60.0%	40.0%	80.0%	80.0%	40.0%	0.0%	20.0%
Visa 6.01	80.0%	40.0%	**100.0%**	80.0%	80.0%	40.0%	80.0%
Visa 7.01	40.0%	20.0%	20.0%	20.0%	20.0%	20.0%	80.0%
Visa 7.02	40.0%	80.0%	80.0%	80.0%	60.0%	20.0%	40.0%
Visa 7.03	40.0%	**100.0%**	**100.0%**	**100.0%**	80.0%	**100.0%**	**100.0%**
Visa 7.04	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
Visa 7.05	80.0%	80.0%	60.0%	60.0%	40.0%	0.0%	20.0%
Visa 7.06	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%
Visa 7.07	0.0%	0.0%	80.0%	40.0%	40.0%	0.0%	0.0%
Visa 7.08	0.0%	0.0%	0.0%	40.0%	40.0%	40.0%	0.0%
Visa 7.09	80.0%	40.0%	**100.0%**	80.0%	80.0%	40.0%	**100.0%**
Visa 7.10	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%
Visa 7.11	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	0.0%
Visa 7.12	80.0%	80.0%	80.0%	80.0%	80.0%	40.0%	80.0%

Source: Elaborated by the authors, 2020.
Visa: Health Surveillance.

social right to health and to the interference in the functioning of the market subject to it, granting greater predictability, transparency and stability to the regulatory process and action, in order to provide a safe environment for the population and favorable to the country's social and economic development[19,20]. However, according to Lucchese[4], the poverty of the debate on the SNVS highlights the difficulties that have been presented in the process of structuring the SNVS itself, above all those referring to the definition of roles of entities at each level of government and the process of decentralization and federative coordination[4].

The existing differences in the organization of Health Surveillance bodies, identified according to the type of entity, also considering the form of regional organization, have a direct impact on the construction of SUS and the scope of health rights. The normative approach of Health Surveillance, configured by a series of routines that aim at the quantitative control of goals related to the coverage of actions, can favor innovation through the implementation of a management model that aggregates aspects related to the quality of the actions carried out and the social benefit.

CONCLUSIONS

The results obtained in this study contribute to the understanding of the level of adequacy and the respective effort that the entities that make up the SNVS must undertake to adjust to the demands for improved management imposed by the national and international regulatory environment. Knowing to what extent there are QMS initiatives in the SNVS and translating what needs to be done to advance work and management process improvement initiatives are fundamental steps to achieve adherence and feasibility in the implementation of a QMS model.

It was possible to draw an overview of meeting the initial requirements related to the seven sections of the QMS model for SNVS units. In this scenario, it was found that some quality management practices are already part of the work processes of all the Health Surveillance bodies that participated in the study. The most widespread practices are related to the planning and support sections.

Possibly, the long tradition of consolidating planning practices within SUS and the strong bureaucratic normative structuring related to support activities may have contributed to the more applied requirements related to these sections. However, as the practices related to the requirements of the performance evaluation sections (section 6) and improvements (section 7) are expanded, the challenges to be considered when implementing a QMS model in the SNVS become greater. The findings related to the low application of the requirements of these sections may indicate that the current management models of these services follow bureaucratic normative standards and are stagnant, without dynamic evaluation of results and improvement based on them, two fundamental guidelines of the QMS, with direct reflexes in satisfying the needs of citizens and other interested parties.

As a limitation of this study, it is possible to identify the fact that the material collected - object of analysis - is the result of self-assessment by the teams of the Health Surveillance bodies, and a low amount of evidence was presented compared to the possible upper limit, calculated considering the total requirements analyzed. It was not planned to use techniques for verifying the information obtained for comparison with the reality of the facts, which would allow to correct impressions and correct possible errors in the interpretation of the practices and evidence under analysis, including with regard to the lack of familiarity of professionals with the terms used in the QM language. Also, the selection of entities to compose the study was not done with the objective of having a representativeness of the reality of the whole of the SNVS, but of knowing the practices already implemented in Health Surveillance bodies that have, under their scope of action, an industrial park of companies manufacturing drugs, APIs and health products risk classes III and IV, therefore, establishments with activities and products of high health risk. The action qualification of the Sanitary Surveillance in these territories contributes to the fulfillment of the requirements of the globalized processes of products production and commercialization, aiming to expand the market of Brazilian products abroad from the compliance with the standards of international regulatory convergence.

Finally, the results of this study signaled incipience in the application of the initial requirements by the analyzed bodies, indicating the potential and the wide space for the implementation of QM principles and guidelines, from the development of strategies and instruments, shared and continuous, to the execution of planning, monitoring, evaluation and auditing, by Health Surveillance bodies in the three spheres of government, with a possible increase in the effectiveness of health promotion and protection actions, supporting the transformation of practices in the SNVS and contributing to the availability, with safety and quality, of regulated products and services.

REFERENCES

1. Monaco FF, Mello AFM. A gestão da qualidade total e a reestruturação industrial e produtiva: um breve resgate histórico. Race Rev Adm Contab Econ. 2007;6(1):7-26.
2. Carpinetti LCR, Miguel PAC, Gerolamo MC. Gestão da qualidade ISO 9001:2000: princípios e requisitos. São Paulo: Atlas; 2009.
3. Associação Brasileira de Normas Técnicas – ABNT. ISO 9001:2015: sistemas de gestão da qualidade: requisitos. Rio de Janeiro: Associação Brasileira de Normas Técnicas; 2015.
4. Lucchese G. Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil [tese]. Rio de Janeiro: Fundação Oswaldo Cruz; 2001.
5. Associação Brasileira de Normas Técnicas – ABNT. ISO 18091:2014: sistemas de gestão da qualidade: diretrizes para a aplicação da ABNT NBR ISO 9001:2008 em prefeituras. Rio de Janeiro: Associação Brasileira de Normas Técnicas; 2014.

6. World Health Organization – WHO. Delivering quality health services: a global imperative for universal health coverage. Geneva: World Health Organization; 2018[acesso 30 ago 2019]. Disponível em: https://apps.who.int/iris/bitstream/handle /10665/272465/9789241513906-eng.pdf
7. World Health Organization – WHO. Annex 13: WHO guideline on the implementation of quality management systems for national regulatory authorities. Geneva: World Health Organization; 2020[acesso 5 fev 2021]. Disponível em: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/trs1025/trs1025-annex13.pdf?sfvrsn=8e6a17ee_2
8. Brasil. Lei Nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial União. 20 set 1990.
9. Alencar MLSM, Bacelar VMB, Magajewski F, Silva WM, Sousa AIA. Qualificação das ações de vigilância sanitária: harmonização e descentralização. Vigil Sanit Debate. 2019;7(4):111-18. https://doi.org/10.22239/2317-269x.01401
10. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 207, de 3 de janeiro de 2018. Dispõe sobre a organização das ações de vigilância sanitária, exercidas pela união, estados, Distrito Federal e municípios, relativas à autorização de funcionamento, licenciamento, registro, certificação de boas práticas, fiscalização, inspeção e normatização, no âmbito do sistema nacional de vigilância sanitária SNVS. Diário Oficial União. 5 jan 2018.
11. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 61, de 18 de novembro de 2011. Dispõe sobre as regras de classificação dos produtos para diagnóstico de uso *in vitro* e dá outras providências. Diário Oficial União. 19 nov 2011.
12. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 153, de 26 de abril de 2017. Dispõe sobre a classificação do grau de risco para as atividades econômicas sujeitas à vigilância sanitária, para fins de licenciamento, e dá outras providências. Diário Oficial União. 27 abr 2017.
13. Centro Latino-Americano e do Caribe de Informação em Ciências da Saúde – Bireme. Biblioteca virtual em saúde: descritores em ciências da saúde. São Paulo: Centro Latino-Americano e do Caribe de Informação em Ciências da Saúde; 2020[acesso 26 fev 2020]. Disponível em: http://decs.bvs.br/
14. Campos A, Mattos S. Avaliação de requisitos referentes à implantação do sistema de gestão da qualidade nos laboratórios de saúde pública. Rev Inst Adolfo Lutz. 2009;68(3):461-70.
15. Santos LL, Mainier FB. Fatores críticos para implantação do sistema de gestão da qualidade em laboratórios de ensaio e calibração. In: Anais do 7º Congresso Nacional de Excelência em Gestão; Rio de Janeiro, Brasil. Rio de Janeiro: Congresso Nacional de Excelência em Gestão; 2011.
16. Carvalho R. Implantação de sistema de gestão da qualidade: um estudo de caso em uma importadora de medicamentos. In: Anais do 7º Congresso Nacional de Excelência em Gestão; Rio de Janeiro, Brasil. Rio de Janeiro: Congresso Nacional de Excelência em Gestão; 2011.
17. Maekawa R, Carvalho MM, Oliveira OJ. Um estudo sobre a certificação ISO 9001 no Brasil: mapeamento de motivações, benefícios e dificuldades. Gest Prod. 2013;20(4):763-79. https://doi.org/10.1590/S0104-530X2013005000003
18. Lescowicz G, Melo R, Rateke E, Martinello F. Dez anos da RDC 302/2005: avaliação da implantação em laboratórios de análise clínicas do estado de Santa Catarina. Rev Bras Anal Clin. 2018;50(2):161-70. https://doi.org/10.21877/2448-3877.201800617
19. Brasil. Lei Nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Diário Oficial União. 27 jan 1999.
20. Agência Nacional de Vigilância Sanitária – Anvisa. Cartilha de vigilância sanitária. 2a ed. Brasília: Agência Nacional de Vigilância Sanitária; 2002.
21. Agência Nacional de Vigilância Sanitária – Anvisa. Projeto qualificação da gestão das ações estratégicas de vigilância sanitária no sistema nacional de vigilância sanitária SNVS: IntegraVisa II. Brasília: Agência Nacional de Vigilância Sanitária; 2018.

Acknowledgment

We are grateful to Oswaldo Cruz German Hospital (HAOC), which, through the Institutional Development Support Program of the Unified Health System (Proadi-SUS), financed the study. We are also grateful to all the participants in the IntegraVisa II project, Anvisa professionals, HAOC consultants and employees, who made this work possible.

Author's Contributions

Silva WM, Bacelar VMB, Sousa AIA, Barca DAAV, Santos CM - Conception, planning (study design), analysis, data interpretation, and writing of the work Zanetta BL - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.