

The importance of Sanitary Surveillance in the evaluation of architectural projects of establishments subject to sanitary control

A importância da Vigilância Sanitária na avaliação de projetos arquitetônicos dos estabelecimentos sujeitos ao controle sanitário

ABSTRACT

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Introduction: The assessment of the physical structure of health facilities and those of interest to health is complex and requires specific technical analysis regarding their spaces and equipment, and it is up to the trained professional to assess whether all these issues meet the minimum necessary to guarantee health care. **Objective:** To demonstrate the importance of sanitary surveillance in the evaluation of the physical structure of establishments subject to sanitary control through the analysis of architectural projects. **Method:** This is an exploratory, retrospective study, using a quali-quantitative approach. The research used secondary data, being authorized by the Board of Surveillance in Physical Structure (DVEF) of the Superintendence of Sanitary Surveillance of the State of Minas Gerais. The study considered the projects submitted to DVEF from January 2019 to December 2020. We sought to identify the main standards used and the main aspects considered in the health licensing process. **Results:** Lack of accessibility, crossing of flows, spatial disorganization of the environments, lack of ventilation or inadequate ventilation, little or no natural lighting, insufficient area or even the oversizing of environments, inadequate finishing materials, implantation in an inappropriate location (close to river beds, polluting industries), were some of the problems found in the evaluated architectural projects. **Conclusions:** The prior assessment of architectural projects of health facilities and of interest to health is another ally in obtaining services that bring together safety, efficiency, and effectiveness in their activities, aiming to eliminate, reduce or prevent health risks inherent to the activities carried out in all types of human health care establishments.

KEYWORDS: Health Surveillance; Architectural Project; Health Risk

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RESUMO

Introdução: A avaliação da estrutura física de estabelecimentos de saúde e de interesse à saúde é complexa e requer análise técnica específica quanto a seus espaços e equipamentos, cabendo ao profissional capacitado avaliar se todas essas questões atendem ao mínimo necessário para a garantia do cuidado à saúde. **Objetivo:** Demonstrar a importância da Vigilância Sanitária na avaliação da estrutura física dos estabelecimentos sujeitos ao controle sanitário mediante a análise de projetos arquitetônicos. **Método:** Trata-se de um estudo exploratório, retrospectivo, com utilização de abordagem quali-quantitativa. A pesquisa utilizou dados secundários, sendo autorizada pela Diretoria de Vigilância em Estrutura Física (DVEF) da Superintendência de Vigilância Sanitária do Estado de Minas Gerais. O estudo considerou os projetos apresentados à DVEF no período de janeiro de 2019 a dezembro de 2020. Buscou-se identificar as principais normas utilizadas e os principais aspectos considerados no processo de licenciamento sanitário. **Resultados:** Falta de acessibilidade, cruzamento de fluxos, desorganização espacial dos ambientes, falta de ventilação ou ventilação inadequada, pouca ou nenhuma iluminação natural,



área insuficiente ou até mesmo o superdimensionamento de ambientes, materiais de acabamento inadequados e implantação em local inapropriado (próximo a leitos de rios, indústrias poluentes) foram alguns dos problemas encontrados nos projetos arquitetônicos avaliados. **Conclusões:** A avaliação prévia de projetos arquitetônicos de estabelecimentos de saúde e de interesse à saúde é mais um aliado na obtenção de serviços que congreguem segurança, eficiência e efetividade em suas atividades, visando eliminar, diminuir ou prevenir riscos à saúde inerentes às atividades desenvolvidas em todo tipo de estabelecimento de atendimento à saúde humana.

PALAVRAS-CHAVE: Vigilância Sanitária; Projeto Arquitetônico; Risco à Saúde

INTRODUCTION

The complexity and importance of health regulation and the context of the Brazilian State reform led to the creation of the Brazilian National Health Surveillance Agency (Anvisa) through the enactment of Law No. 9,782, of January 26, 1999¹. An autonomous government agency whose purposes include the promotion and protection of the population's health through sanitary control of the environment, and how some of its competences establish norms, propose, monitor, and execute the policies, guidelines, and actions of sanitary surveillance.

Anvisa coordinates the National Health Surveillance System (SNVS) based on a process of negotiation between the members of this system, with no relationship of subordination between the federated entities, but the agreement and the sharing of competences between the instances, in terms of solidarity and responsibility².

It is incumbent upon the bodies that make up the SNVS, in the three spheres of government, to prepare the rules that regulate the operation of establishments that develop production processes and that offer services to the population within their scope².

The state component of the SNVS is made up of the Health Surveillance bodies (Visa) of the State Health Departments and some special authorities. The decentralization to the municipal component has not yet been completed, since not every municipality has a structured Visa service².

In Minas Gerais (MG), the State Health Surveillance was instituted from the State Law n° 13.317, of September 24, 1999, also known as Health Code of the State of MG³. In 2019, Decree No. 47,769 of November 29, 2019, was published⁴, which deals with the organization of the Secretariat of Health (SES) of MG. In its art. 4, the components of the organic structure of the SES are listed and, among them, is the Superintendence of Sanitary Surveillance, which is composed of four directorates: Physical Structure Surveillance Directorate (DVEF), Health Services Surveillance Directorate (DVSS), Drug Surveillance Directorate (DVMC), and Food Surveillance Directorate (DVA).

Among the various activities carried out by these directorates, the evaluation of architectural projects of health service establishments and of interest to health, which is performed by the DVEF, stands out. In addition to evaluating architectural projects, this board is responsible for participating in the elaboration of specific state and federal standards, contributing and

participating in technical groups at Anvisa, for issuing the necessary license for the establishment to operate, for the training, support, and monitoring of the evaluation of projects carried out in the Regional Health Superintendencies and Managements spread across the territory of MG, in addition to other activities.

In art. 35 of Decree No. 47.769/2019⁴, the powers of the DVEF are listed:

Art. 35 - The Physical Structure Surveillance Directorate has the competence to implement, monitor, and execute in a complementary way, the sanitary control actions related to the physical structure of establishments of interest to health, within the State, with attributions of:

I - establish rules and standards, on a supplementary basis, of health surveillance procedures in a physical structure;

II - evaluate and approve architectural projects of establishments subject to sanitary control, in accordance with current legislation;

III - coordinate, monitor, evaluate, and advise the regional health units and the municipalities in the actions of sanitary surveillance in physical structure;

IV - perform, on a complementary basis, inspection actions in the area of physical structure;

V - guide health service providers in the preparation of architectural projects for renovation, expansion, and construction of establishments subject to sanitary control;

VI - guide, monitor, and advise on actions and services, of a technical nature, performed by the Regional Health Superintendencies and Managements within the scope of their activities;

VII - execute and inspect contracts or similar instruments within the scope of its activities.

The physical structure of healthcare facilities and facilities of interest to healthcare is complex and constantly needs to undergo a specific technical assessment regarding their spaces, equipment, and work processes. Many aspects must be considered in the physical projects, and it is up to the architecture or engineering professional, with specific knowledge of sanitary standards, to evaluate those most suitable for each reality.



The establishment of health and health interest “is born” from a planned, organized, and well-structured architecture and engineering. The environments must enable the development of activities in an efficient, effective, and safe way for all involved.

Basic requirements such as: spatial organization, dimensioning of environments, flows, lighting, and ventilation must be met in their entirety, aiming at the greatest possible reduction of health risks. And it is up to the trained professional to assess whether all these items meet the minimum necessary to provide adequate care to the health of those who use the environment. It is important to note that the idea of quality is present in all types of evaluation whose main characteristic is the attribution of the value judgment⁵.

The objective of this study was to demonstrate the importance of Visa in the evaluation of the architectural projects of health establishments and of interest to health, aiming to eliminate, reduce, or prevent health risks.

METHOD

This is an exploratory, retrospective study, using a quali-quantitative approach. The research used secondary data, the internal database of the DVEF of the Superintendence of Sanitary Surveillance of the State of MG being consulted, with its authorization. Excel spreadsheets were analyzed with data referring to all establishments evaluated in the years 2019 and 2020. In addition, the Health Surveillance Portal of the State Department of Health of MG was consulted, on the physical infrastructure board page, to search for legislation on physical infrastructure⁶ and, on the sanitary licensing page, to search for legislation on sanitary licensing⁷. The Anvisa Portal was also consulted, on the legislation page⁸. To access the information on this portal, it is necessary to know the act number and year. The technical standards searched on the portal are listed in Table 2.

The present work considered the projects presented to DVEF from January 2019 to December 2020. We sought to identify the main standards used and the main aspects considered in the sanitary licensing process. Data were collected regarding the number of approved and disapproved projects and the main non-conformities found in the latter. In addition, a documentary analysis of several documents issued by the DVEF during this period was carried out.

RESULTS AND DISCUSSION

Standards most used in evaluation processes

The Resolution of the Collegiate Board of Directors (RDC) of Anvisa No. 50, of February 21, 2002⁹, is the base rule for any analysis of architectural projects in healthcare facilities. It is a normative and compulsory document, used by state/municipal secretariats in the evaluation of projects for health care establishments to be built, expanded, or renovated, whether public or private, whether or not they are part of the Unified Health System (SUS).

In addition to RDC No. 50/2002⁹, other Anvisa RDCs, Federal Laws, State Laws, Municipal Laws, Decrees, Ministerial Ordinances, Interministerial Ordinances, Regulatory Norms, State Resolutions, Normative Instructions, Manuals, etc. are used.

It is important to clarify that Anvisa RDCs are resolutions published by Anvisa's Collegiate Board of Directors, whose elaboration process relies on the collaboration of technical specialists in various areas of activity. These are disciplinary rules that must be followed nationally by all health care establishments and health care facilities. They establish minimum parameters for establishments to function properly, ensuring quality in the provision of health services.

Currently, only those establishments classified as high risk are required to have their architectural projects approved by Visa, that is, those that present a potential risk of damage to physical integrity and human health as a result of the exercise of their economic activity¹⁰.

Chart 1 presents the technical standards related to the degree of sanitary risk and its economic activities. Chart 2 brings the RDCs most used in the evaluation of architectural projects in the health area and Chart 3, the complementary technical standards of the Secretariat of Health of Minas Gerais (SES/MG).

In the evaluation of projects, the following Brazilian Standards (NBR) of the Brazilian Technical Standards Association (ABNT) can also be used: NBR 6.492/1994 Representation of Architectural Projects; NBR 13.532/1995 Elaboration of building projects - Architecture; and NBR 9.050/2020 Accessibility of buildings, furniture, spaces, and urban equipment.

Chart 1. Norms that detail the degree of sanitary risk of economic activities.

Norm	Detailing
RDC No. 153, of April 26, 2017	Provides for the classification of the degree of risk for economic activities subject to health surveillance, for licensing purposes, and makes other provisions
RDC No. 418, of September 1, 2020	Amends RDC No. 153/2017, which provides for the classification of the degree of risk for economic activities subject to health surveillance, for licensing purposes, and makes other provisions
SES/MG Resolution No. 7426, of February 25, 2021	Establishes the risk classification of economic activities subject to sanitary control for sanitary licensing purposes within the state of Minas Gerais

Source: Elaborated by the authors, 2022.

RDC: Resolution of the Collegiate Board of Directors; SES/MG: Secretariat of Health of Minas Gerais.



Chart 2. Resolutions of the Collegiate Board most used in the evaluation of architectural projects in the health area.

Norm	Detailing
RDC No. 50, of February 21, 2002	Provides for the technical regulation for planning, programming, elaboration, and evaluation of physical projects of health care establishments
RDC No. 189, of July 18, 2003	Provides for the regulation of procedures for analysis, evaluation and approval of physical projects of health establishments in the National Health Surveillance System, amends the technical regulation approved by RDC No. 50/2002, and makes other provisions
RDC No. 502, of May 27, 2021	Provides for the operation of a long-stay institution for the elderly, of a residential nature
RDC No. 302, of October 13, 2005	Provides for technical regulation for the operation of clinical laboratories
RDC No. 67, of October 8, 2007	Provides for good practices for handling magistral and officinal preparations for human use in pharmacies
RDC No. 36, of June 3, 2008	Provides for technical regulations for the operation of obstetric and neonatal care services
RDC No. 38, of June 4, 2008	Provides for the installation and operation of <i>in vivo nuclear medicine services</i>
RDC No. 51, of October 6, 2011	Provides for the minimum requirements for the analysis, evaluation, and approval of physical projects of health establishments in the SNVS and other measures
RDC No. 06, of January 30, 2012	Provides for good operating practices for healthcare clothing processing units and makes other provisions
RDC No. 06, of March 1, 2013	Provides for the requirements of good operating practices for endoscopy services with access to the body through exclusively natural orifices
RDC No. 222, of March 28, 2018	Regulates good health care waste management practices and other provisions
RDC 611/22: RDC No. 611, of March 9, 2022	Establishes the health requirements for the organization and operation of diagnostic or interventional radiology services and regulates the control of medical, occupational, and public exposures resulting from the use of diagnostic or interventional radiological technologies.

Source: Elaborated by the authors, 2022.

SNVS: National Health Surveillance System; RDC: Resolution of the Collegiate Board of Directors.

Chart 3. Norms of the Secretariat of Health of Minas Gerais (SES/MG).

Norm	Detailing
SES Resolution No. 1,332, of November 26, 2007	Establishes in the State of Minas Gerais complementary rules to RDC No. 67, of October 8, 2007, issued by Anvisa, which provides for good practices for handling magistral and officinal preparations for human use in pharmacies
SES Resolution No. 1,479, of July 29, 2008	Amends art. 12 and items 1.4, 1.7, 1.8 and 2.6 of the Sole Annex of SES Resolution No. 1,332/2007, which establishes in the state of Minas Gerais complementary rules to RDC No. 67/2007
SES Resolution No. 1,559, of August 13, 2008	Approves the technical regulation that establishes conditions for the installation and operation of DCE in the state of Minas Gerais
SES Resolution No. 1,889, of May 25, 2009	Approves the technical regulation, submitted to Public Consultation No. 25, on October 10, 2008, which establishes conditions for the installation and operation of dental prosthesis establishments in the state of Minas Gerais and other measures
SES Resolution No. 3,182, of March 23, 2012	Approves the technical regulation that establishes conditions for the installation and operation of physiotherapy services in the state of Minas Gerais
SES Resolution No. 3,962, of October 16, 2013	Establishes a physical program for type I, II, and III UBS and Support UBS
SES Resolution No. 7,533, of June 2, 2021	Approves the technical regulation that establishes the basic requirements for protection and safety in MRI and disciplines the practice, aiming to defend the health of patients, professionals involved, and the general public

Source: Elaborated by the authors, 2022.

SES: State Secretariat of Health; Anvisa: Brazilian National Health Surveillance Agency; art.: article; DCE: dental care establishments; UBS: Basic Health Units; MRI: magnetic resonance imaging.

In addition to these, there are several other standards that help in the process of evaluating the physical structures of establishments. Many health regulations do not deal directly with the

physical area, but they provide subsidies for requirements to be made according to the types of care/procedures performed in the establishments.



Data referring to the number of approved and disapproved projects

The DVEF of the Superintendence of Sanitary Surveillance of the State of MG (central level) carries out the evaluation of projects of high-risk establishments of the 853 municipalities that make up the state of MG, being responsible for evaluating projects of all degrees of complexity of 168 municipalities, in addition to those of high complexity of the other 685 municipalities.

Assessments are organized into Fail Documents and Approval Documents. In the years 2019 to 2020, the documents were named as follows: Fail Document - Official Letter (OF) and Preliminary Analysis (PA); Approval Document - Technical Opinion (TO).

The PA is the document that lists all the necessary adjustments to be made in the architectural project so that it becomes adequate to health standards. The OF, on the other hand, is used for timely communication to the regulator of pending issues in relation to the architectural project, being also a fail document, but different from the PA, since it does not present such an extensive list of adjustments. The TO is the approval document that attests to the regularization of the architectural project to the health standards related to its physical structure.

The number of evaluations to which an architectural project is submitted varies, and depends a lot on the quality of the engineering/architecture professional responsible for its elaboration, as well as their degree of knowledge, both of the health risk and of the specific health legislation, and of the typology and size of the establishment (drugstore, office, clinic, hospital, industry, etc.).

Throughout 2019, DVEF carried out a total of 2,500 assessments of architectural projects of health facilities and health care facilities located in all regions of the state of MG. A total of 1,314 establishments were evaluated (some establishments entered more than once in the same year). Among these 2,500 assessments, 1,195 were PA, 290 OF, and 1,015 TO. An average of 208 reviews/month. These data are presented in Table 1.

The number of PA corresponded to 46.0%; OF to 13.4%; and TO to 39.0% of the total projects evaluated in 2019. That is, the percentage of approval was 39.0% while the percentage of disapproval was 59.4%.

Table 2 presents data for the year 2020, the year of the advent of the COVID-19 pandemic. The number of evaluations suffered an impact, mainly in the initial months, resulting in a total of 2,118 evaluations, being 1,125 PA; 219 OF; and 774 TO. An average of 176 reviews/month. 1,175 establishments were evaluated.

The number of PA corresponded to 59.2%, that of OF to 5.3%, and that of TO to 35.4% of the total projects evaluated in 2020. That is, the percentage of approval was 35.4% while the percentage of disapproval was 64.5%.

Table 1. Number of architectural project assessments carried out in Minas Gerais for the year 2019.

Year 2019	Preliminary analysis (PA)	Technical Opinion (TO)	Official Letter (OF)	Total
January	87	71	16	174
February	101	66	12	179
March	72	85	26	183
April	91	74	13	178
May	117	106	30	253
June	129	11	36	276
July	123	72	14	209
August	91	85	18	194
September	83	102	27	212
October	101	93	31	225
November	92	58	36	186
December	108	92	31	231
Total	1,195	1,015	290	2,500

Source: Elaborated by the authors, 2022.

Table 2. Number of evaluations of architectural projects carried out in Minas Gerais for the year 2020.

Year 2020	Preliminary analysis (PA)	Technical Opinion (TO)	Official Letter (OF)	Total
January	88	60	46	194
February	99	54	21	174
March	108	60	20	188
April	100	77	18	195
May	70	68	11	149
June	70	63	17	150
July	94	72	19	185
August	88	60	08	156
September	71	63	18	152
October	98	54	12	164
November	117	70	18	205
December	122	73	11	206
Total	1,125	774	219	2,118

Source: Elaborated by the authors, 2022.

It appears that the number of projects that received disapproval is very high. Thus, it is possible to conclude that many establishments of health services and of interest to health are not adequate to health standards, compromising the quality and safety of care, which may generate health risks to the population.



The evaluation of health service establishments and those of interest to health

In order to obtain a health permit, establishments providing health services and those of interest to health, classified as high risk, must have the architectural design of their physical area approved by Visa. According to §1 and 2 of art. 8 of the Health Code of the State of MG³:

a health service establishment is one intended to promote the health of the individual, protect them from diseases and injuries, prevent and limit the damage caused to them, and rehabilitate them when their physical, psychological, or social capacity is affected.

an establishment of service of interest to health is one that carries out an activity that, directly or indirectly, may cause damage or harm to the health of the population.

Among the health services are: hospital and emergency care establishments, clinics, laboratories, offices, etc. In turn, services of interest to health range from manufacturers, traders and distributors of food, medicines, health products, cosmetics, and sanitizers to social and collective services related to health.

In order to evaluate the architectural projects of health service establishments and health service establishments, the bidder must submit, basically, the following documents: Application for Approval of the Architectural Project (RAPA); copy of the Technical Responsibility Annotation (ART/CREA), in the case of an engineer, or of the Technical Responsibility Registry (RRT/CAU), in the case of an architect, copy of the State Collection Document (DAE) referring to the payment of the public health fee (when the establishment is not exempt from this fee) and its respective proof of discharge, the Calculation Report of the intervention area, the Technical Report, and the Basic Architecture Project (PBA). In some specific cases, additional documents are requested, relating to the concrete case.

In the RAPA, the following are checked: the registration data of the establishment, the address, the type of work (construction, renovation/adaptation, or expansion), the areas of intervention, and the identification of those responsible for the establishment and the architectural project.

Then, the data and discharge of the ART/CREA or RRT/CAU of the person responsible for the architectural project are verified. It is verified if the professional has qualification for the development of architectural projects.

Next, the correspondence between the amount indicated in the RAPA and the amount paid in the DAE is verified, based on the Calculation Report and the architectural project presented; it may be necessary to recalculate the areas of intervention and request a supplementary payment of the amount due to calculation errors on the part of the author of the project.

After verifying these documents, the Technical Report is read, which should basically contain: the objectives and activities of

the establishment or of the services/sectors/units to be renovated, expanded, or built, the basic specification of finishing materials for floors, walls, and ceilings, among others, of all environments, the description of the adopted systems of mechanical ventilation and air conditioning (when provided), the table of the number of beds (in the case of a hospital), specifying the beds for hospitalization and Intensive Care Center (ICU)/Intensive Care Unit (ICU); in the case of industries: presentation in plant of the flowchart of industrial processes, from the input of raw material to the output of the finished product, in addition to the list of raw materials and equipment used in production, as well as manufactured products.

In addition, the Technical Report must include: the opening hours, the number of employees, the average demand and age group of the people served, the flow of service and work processes, the types and complexity of the services, procedures, surgeries, exams, and activities performed, the medical specialties served, how the articles, instruments and materials used will be processed, the outsourced services, the water supply and sewage systems, the collection of solid waste, etc.

All this information is important and crucial in defining the minimum program that the establishment must meet. They help to define whether the physical structure of the establishment can or should be expanded or reduced, if it needs a major or minor renovation, if it is well located, organized, structured or not.

After reading the Technical Report, the basic architectural project is evaluated. The basic architectural project is composed of architectural boards, which contain the graphic pieces (plans, sections, facades, details, maps, etc.) and their respective identifications, labels, and texts.

The main aspects observed in the PBA are: implantation/location of the establishment, accessibility, spatial organization, flow, number, dimensioning, and layout of environments, finishing materials, lighting, ventilation, gas installations, water, sewage, electricity, escape routes, and place for temporary disposal of solid waste.

The Technical Report and the PBA are indispensable and complement each other. The information contained in the Technical Report must be compatible with the information contained in the PBA and vice versa. In the specific case of health establishments and those of interest to health, the basic information found in simple Descriptive Memoranda, such as that found in other types of establishments, is not enough. A detailed description of everything that happens and how it happens in each environment is required. Thus, the Technical Report would encompass the usual Descriptive Memorandum and an Activities Memorandum with specific information related to health and activities of interest to health carried out in the establishment.

One of the main aspects verified in the projects is the spatial organization of the establishment. A good sectorization



of environments is essential to guarantee good practices in health procedures and in those of interest to health. The flow of people and materials must be optimized and well thought out in order to guarantee the efficiency and safety of the processes.

Main non-conformities found in the projects

Donabedian¹¹ proposed the evaluation of quality from the triad structure, process, and results. This approach has been widely used to obtain data on the attributes that constitute or define quality. For the author, the structure encompasses the instruments and resources, as well as the physical and organizational conditions.

Floor, wall and ceiling, equipment (physical resources), human resources and organizational resources, Standard Operating Procedures (SOPs), manuals and protocols are indicators of good practices related to the structure¹².

Hubner e Ravache¹³ highlighted the scenario, exposed by the COVID-19 pandemic, of Brazilian hospital structures, which is, in most cases, quite precarious and without projects that meet the standards established for the architectural projects intended for this purpose. According to these authors¹³, health care establishments must meet:

the requirements of any type of public, such as temperature, humidity, luminance, acoustics for both internal and external factors, from the position of the windows to the insulation of the walls, since natural ventilation not only provides comfort but also helps to combat hospital infections. Everything must be controlled to achieve adequate comfort.

The experience report in a university hospital¹⁴ showed that it was necessary to adapt the existing physical structure in order to care for the user with COVID-19, prioritizing the safety of professionals and users.

A review of the availability of medicinal gases was carried out; adequacy of the electrical network; acquisition of new generators to supply the high number of equipment, mainly related to the increase in ICU beds; inclusion of glass windows in the ward doors to reduce the frequency of entry of the multiprofessional team into the room; closing and signaling of places where COVID-19 users pass with indication on the ground and physical blocks restricting the movement of people as much as possible; exclusive elevator reservation for employees and users with COVID-19; adaptation and addition of sinks for washing hands, adjustment of rooms for dressing, cafeteria, accommodation for employees; review and adjustment of ventilation systems; signaling with signs and labels of the new environments, distinguishing between clean, potentially contaminated and contaminated areas; among others¹⁴.

This study also points to the need to face two issues highlighted by the pandemic: the physical and mental exhaustion of the health workforce and the worn-out hospital infrastructure¹⁴.

In the evaluations carried out by the DVEF, several irregularities were found in the architectural projects, such as, for example: implantation in an inappropriate location (near river beds, polluting industries) or inadequate implantation (without respect to legal and necessary departures, without considering the geographical map, insolation, ventilation); lack of accessibility; flow crossing; spatial disorganization of environments; lack of ventilation or inadequate ventilation; little or no natural lighting; insufficient area or even oversizing of environments; inadequate finishing materials, among others.

In the moments of attendance to the regulated ones, aiming at the resolution of doubts and questions about the items pointed out in the fail documents, it is noticeable the lack of knowledge of the work processes of each activity carried out in the buildings and the lack of interaction with the owners of these structures. The author of the project is often not specialized in architecture and engineering of healthcare facilities and facilities of interest to healthcare, which results in projects that are “disconnected” with the reality and specificity of each establishment.

Added to this are basic errors of representation in graphic pieces, denoting a lack of knowledge of technical drawing standards and also low technical quality of professionals.

In a scientific article, César et al.¹⁵ sought to determine the most frequently found irregularities during health inspections carried out in MG. It was found that a significant part was related to infrastructure:

The second most common type of irregularity was related to infrastructure requirements, in the form exemplified by: irregularities in floors, ceilings, walls, or other structure; ventilation and/or lighting problems; structure incompatible with approved architectural design; absence/non-approval of architectural design (when required); among others.

In Freitas and Santos¹⁶, 137 sanitary irregularities were identified during the various sanitary inspections carried out in 59 establishments and equipment of high complexity assistance and of interest to health in the municipality of Franca, in São Paulo, in the state of São Paulo, in the period from August 2008 to July 2009, of these, 32 (23.36%) were related to the physical area.

These irregularities are characterized by the disrespect “to the minimum requirements of sanitary legislation, whether due to the size of the area, the type of wall and floor covering, lighting and ventilation, layout, or the flow of circulation of personnel and materials”¹⁶.

Faced with so many problems found, both in the process of evaluating architectural projects and in the moments of sanitary



inspection, the importance of verifying the physical structure of health establishments and of interest to health is clear and evident.

The prior assessment of the architectural projects of the establishments avoids many mishaps during the execution of construction, renovation, adaptation, and expansion works. Furthermore, it prevents physical structure problems from being pointed out only at times of sanitary inspection, which can generate inconvenience and friction, in addition to the fact that the inspection team will not always be able to count on a sanitary agent with technical training in the area of architecture and engineering.

Implementation of quality management in the Physical Structure Surveillance Board

Quality management has been highlighted in the management context, asserting itself as a theoretical and practical space for the production of knowledge. In this way, qualifying Visa actions through the improvement of management processes became the work agenda of Anvisa and the other components of the SNVS¹⁷.

In this sense, Anvisa published in 2018, RDC n° 207, of January 3¹⁸, which provides for the organization of health surveillance actions, carried out by the three spheres of government, relating to Operating, Licensing, Registration, Certification of Good Practices, Inspection, and Standardization Authorization, within the scope of the SNVS.

This RDC has as one of its premises that: “the implementation of the Quality Management System is a structuring requirement for the qualification of health surveillance actions carried out by the Union, States, Federal District, and Municipalities”.

Thus, in order to achieve greater efficiency in serving the regulated sector and more quality in its work processes, MG's Visa has participated, since 2019, in the scope of the Institutional Development Support Program of the Unified Health System (Proadi-SUS) and the institutional partnership between Oswaldo Cruz German Hospital (HAOC) and Anvisa, of the project entitled “Institutionalization of evaluative practices: the strategic management of evidence-based health surveillance”¹⁹.

The proposal is to institutionalize evaluation practices through a modeling strategy that allows to know the actions developed by Visa organizations. To this end, it was necessary to discuss the principles, guidelines, and practices developed by Visa instances, as well as detail the relationships between activities and their effects¹⁹.

In this sense, DVEF started collecting data and reviewing its work processes. Some changes have already been implemented and others are still in feasibility studies and in the implementation process so that the analysis and approval of architectural projects becomes faster and more efficient.

Thus, the first change made was the reduction of 33.3% in the deadline for the analysis of architectural projects. The period

that was previously up to 90 days has now been increased to up to 60 calendar days. This significant reduction is primarily due to the advent of new rules on the classification of the degree of risk for economic activities subject to Visa^{10,20,21}. These rules ended the requirement for establishments classified as low and medium health risk to have projects in their physical areas approved by the Visa bodies.

In addition to the aforementioned rules, other aspects that contributed to the reduction in the period were: the reorganization and redistribution of the administrative processes (architectural project and the other documents that accompany it) based on their typology and degree of complexity and, also, based on the stage of obtaining a license in which the establishment is located. Each DVEF architect became responsible, preferably, for typologies and specific complexities and the processes started to be separated into processes for obtaining an initial license (1st license) and in processes for renewing a health license.

Another change already implemented was in the nomenclature adopted for approval and fail documents. The PA is now named the Technical Opinion of Rejection and the TO is now the Technical Opinion of Approval, resulting in a better standardization of documents.

The implementation of the Quality Management System at DVEF has been fundamental for the improvement of work processes and services offered to the regulated sector.

It is important to report that RDC No. 207/2018¹⁶ was revoked by RDC No. 560, of August 30, 2021²², but the new RDC maintained the aforementioned premise of implementing the Quality Management System in the SNVS.

CONCLUSIONS

The current COVID-19 pandemic has collaborated to demonstrate the importance of a well-planned physical structure, fundamental for guaranteeing the quality of the services offered there. In buildings related to the health area, this quality is indispensable and must be attested by safety, efficiency, and effectiveness.

Thus, in order to guarantee all these elements, especially with regard to minimizing the health risks inherent to any type of activity, it is essential that the minimum parameters necessary for the construction, renovation, adaptation and expansion of health service establishments and establishments of interest to health are observed and met.

After the architectural project has been prepared by the architectural or engineering professional, it must first undergo a technical evaluation by Visa professionals before being executed. This step is essential, given that many deficiencies, errors, and irregularities can be detected and corrected in time, avoiding future problems and resulting in a functional, economic, and efficient physical structure.



REFERENCES

1. 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.
2. Agência Nacional de Vigilância Sanitária - Anvisa. Introdução a vigilância sanitária. Fortaleza: Universidade Federal do Ceará; 2021[acesso 12 nov 2021]. Disponível em: <https://www.escolavirtual.gov.br/curso/117>
3. Secretaria de Estado da Saúde de Minas Gerais - SES-MG. Lei Nº 13.317, de 24 de setembro de 1999. Dispõe sobre o código de saúde do estado de Minas Gerais. Diário Oficial do Estado. 25 set 1999.
4. Secretaria de Estado da Saúde de Minas Gerais - SES-MG. Decreto Nº 47.7694, de 29 de novembro de 2019. Dispõe sobre a organização da Secretaria de Estado de Saúde de Minas Gerais. Diário Oficial do Estado. 30 nov 2019.
5. Aguilar MJ, Ander-Egg E. Avaliação de programas e serviços sociais. Petrópolis: Vozes; 1994.
6. Secretaria de Estado da Saúde de Minas Gerais - SES-MG. Estrutura física. Portal da Vigilância Sanitária. 2021[acesso 12 set 2021]. Disponível em: <http://vigilancia.saude.mg.gov.br/index.php/diretoria-de-infraestrutura-fisica/>
7. Secretaria de Estado da Saúde de Minas Gerais - SES-MG. Licenciamento sanitário. Portal da Vigilância em Saúde. 2021[acesso 18 set 2021]; Disponível em: <http://vigilancia.saude.mg.gov.br/index.php/licenciamento-sanitario/>
8. Agência Nacional de Vigilância Sanitária - Anvisa. Legislação. Portal da Anvisa. 2021[acesso 21 set 2021]; Disponível em: <https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao>
9. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 50, de 21 de fevereiro 2002. Dispõe sobre o regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. Diário Oficial União. 20 mar 2002.
10. 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.
11. Donabedian A. Evaluating the quality of medical care. *Milbank Q.* 2005;83(4):691-729. <https://doi.org/10.1111/j.1468-0009.2005.00397.x>
12. Hospital Moinhos de Vento. Curso de boas práticas de inspeção em serviços de saúde. Porto Alegre: Hospital Moinhos de Vento; 2021[acesso 2 nov 2021]. Disponível em: [https://lms.hospitalmoinhos.org.br/courses/course-v1:Moinhos+ANVISA_2021_BPISS+ANVISA_2021_BPISS_T1/courseware/f301c](https://lms.hospitalmoinhos.org.br/courses/course-v1:Moinhos+ANVISA_2021_BPISS+ANVISA_2021_BPISS_T1/courseware/f301c171f7e641a7bc67727661b61334/94abd160ccd470ea3f8b02ce353f805/?child=first)
13. Hubner MB, Ravache RL. Arquitetura hospitalar, desafios e influências na saúde. *Connect Line.* 2021;(24):105-14. <https://doi.org/10.18312/connectionline.v0i24.1635>
14. Bernardino E, Nascimento JD, Raboni SM, Sousa SM. Gestão do cuidado no enfrentamento da COVID-19 em hospital de ensino. *Rev Bras Enferm.* 2021;74(suppl1):1-6. <https://doi.org/10.1590/0034-7167-2020-0970>
15. César DF, Silva PMF, Figueiredo SC, Laguardia FC. Principais irregularidades em estabelecimentos sujeitos a controle sanitário. *Vigil Sanit Debate.* 2020;8(4):101-10. <https://doi.org/10.22239/2317-269x.01518>
16. Freitas FP, Santos BMO. Irregularidades sanitárias como marcador de risco à saúde: um desafio para a vigilância sanitária. *Vigil Sanit Debate.* 2013;1(1):43-51. <https://doi.org/10.3395/vd.v1i1.4>
17. Silva WM, Sousa AIA, Barca DAAV, Santos CM, Zanetta BL. Gestão da qualidade na administração pública: autoavaliação sobre a aplicação de práticas em órgãos do Sistema Nacional de Vigilância Sanitária. *Vigil Sanit Debate.* 2021;9(3):40-8. <https://doi.org/10.22239/2317-269x.01833>
18. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 207, de 3 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.
19. Dubeux LS, Almeida CK, Felisberto E, Medeiros GAR, Ávila SG, Barca DAAV et al. Institucionalização de práticas avaliativas em vigilância sanitária: aprimorando coletivamente a gestão por meio da modelização das intervenções. *Vigil Sanit Debate.* 2020;8(4):27-36. <https://doi.org/10.22239/2317-269x.01698>
20. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 418, de 1 de setembro de 2020. Altera a resolução de diretoria colegiada (RDC) Nº 153, de 26 de abril de 2017, que 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. 1 set 2020.
21. Secretaria de Estado da Saúde de Minas Gerais - SES-MG. Resolução Nº 7.426, de 25 fevereiro de 2021. Estabelece as regras do licenciamento sanitário e os prazos para resposta aos requerimentos de liberação de atividade econômica de que trata o decreto estadual Nº 48.036 de 2020, no âmbito da vigilância sanitária do estado de Minas Gerais. Diário Oficial do Estado. 26 fev 2021.



22. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 560, de 30 de agosto de 2021. 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. Oficial da União. 31 ago 2021.

Author's Contributions

Soldate MP - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Oliveira AMC - Conception, planning (study design), 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.



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