



EVALUATION OF COMPLIANCE WITH REGULATORY STANDARDS IN A CLINICAL ANALYSIS LABORATORY LOCATED IN THE MUNICIPALITY OF CASTANHAL/PA

AVALIAÇÃO DO CUMPRIMENTO DAS NORMAS REGULAMENTADORAS EM UM LABORATÓRIO DE ANÁLISES CLÍNICAS LOCALIZADO NO MUNICÍPIO DE CASTANHAL/PA

EVALUACIÓN DEL CUMPLIMIENTO DE LAS NORMAS REGLAMENTARIAS EN UN LABORATORIO DE ANÁLISIS CLÍNICOS UBICADO EN LA CIUDAD DE CASTANHAL/PA

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ABSTRACT

Work safety is mandatory in clinical analysis laboratories, as well as compliance with the Regulatory Standards (NRs). With a degree of risk 3 (medium), this environment falls within one of the sectors in which most occupational accidents occur in Brazil. The objective of this work is to evaluate compliance with the NRs that are pertinent to the Occupational Health and Safety Management System (OHSMS) in a pathological analysis laboratory. For this, a bibliographical research, on-site visitation and use of a checklist for data collection were carried out. For the analysis and treatment of data, some quality tools were used: Pareto diagram, GUT matrix, checklist and a 5W2H worksheet. The results showed that the company has some non-conformities, the most serious identified are the delay in licenses and the lack of mapping of risks and unhealthy activities. It is understood that the company studied needs an adequate mapping of safety processes; the use of quality tools for the verification of the process of change and control, thus adapting to safety standards and applying the methodology in companies of the same segment. In addition, it will serve as benchmarking for others.

RESUMO

A segurança do trabalho é obrigatória em laboratórios de análises clínicas, bem como o cumprimento das Normas Regulamentadoras (NRs). Com um grau de risco três (médio), esse ambiente se enquadra dentro de um dos setores nos quais mais ocorrem acidentes de trabalho no Brasil. O objetivo deste trabalho é avaliar o cumprimento

das NRs que são pertinentes ao Sistema de Gestão da Saúde e Segurança Ocupacional (SGSSO) em um laboratório de análises patológicas. Para isso, foi realizada uma pesquisa bibliográfica, visitação in loco e utilização de um checklist para a coleta dos dados; para a análise e tratamento de dados, utilizou-se algumas ferramentas da qualidade: Diagrama de Pareto, matriz GUT, checklist e uma planilha de 5W2H. Os resultados mostraram que a empresa possui algumas não conformidades, as mais graves identificadas são o atraso nas licenças e a falta de mapeamento dos riscos e atividades insalubres. Entende-se que a empresa estudada necessita de um mapeamento adequado dos processos de segurança; do uso de ferramentas da qualidade para a verificação do processo de mudança e controle, adequando-se, assim, às normas de segurança e aplicando a metodologia em empresas do mesmo segmento; além disso, servirá de benchmarking para outras.

RESUMEN

La seguridad laboral es de obligado cumplimiento en los laboratorios de análisis clínicos, así como el cumplimiento de las Normas Regulatorias (NR). Con un nivel de riesgo tres (medio), este entorno se ubica dentro de uno de los sectores en los que ocurren más accidentes laborales en Brasil. El objetivo de este trabajo es evaluar el cumplimiento de las NR relevantes del Sistema de Gestión de Seguridad y Salud en el Trabajo (SGSST) en un laboratorio de análisis patológicos. Para ello se realizó una investigación bibliográfica, visitas in situ y uso de una lista de cotejo para la recolección de datos; para el análisis y procesamiento de datos se utilizaron algunas herramientas de calidad: diagrama de Pareto, matriz GUT, lista de verificación y una hoja de cálculo 5W2H. Los resultados arrojaron que la empresa tiene algunos incumplimientos, siendo los más graves identificados el retraso en las licencias y la falta de mapeo de riesgos y actividades insalubres. Se entiende que la empresa estudiada necesita de un adecuado mapeo de procesos de seguridad; el uso de herramientas de calidad para verificar el proceso de cambio y control, adecuándose así a los estándares de seguridad y aplicando la metodología a empresas del mismo segmento; Además, servirá como punto de referencia para otros.



INTRODUCTION

According to the Jorge Duprat Figueiredo Foundation for Occupational Safety and Medicine (FUNDACENTRO, 2020), the Regulatory Standards (NR) must guarantee the rights and duties of companies with workers, in accordance with the Occupational Health and Safety Management System (SGSSO), through the prevention of risks, accidents and occupational diseases. As indicated by data from the Pan American Health Organization (PAHO, 2021), healthcare environments are places that present different risk situations arising from daily work operations.

Kira and Fonseca (2020) explain that these environments receive classifications at different levels, related to chemical, physical, ergonomic, biological and accident risks, which involve sharp materials that can cause the spread of infectious diseases and serious accidents. According to Silveira et al. (2019), a clinical analysis laboratory is a place where various biological materials are collected - such as blood, feces, urine, saliva, secretions, among others - in order to verify the health status of a patient and investigate possible illnesses. The Centers for Disease Control and Prevention (CDC, 2020) classifies these places at risk level 3 (medium), in which professionals and patients are exposed to chemical, biological, ergonomic and accident risks.

In this sense, the Ministry of Labor and Social Security (MTPS) determines that, for the operation of these establishments, in addition to compliance with NBR 14785 and biosafety manuals, compliance with all NRs is mandatory, in order to protect employees and customers, determining specifications and security measures that seek to preserve everyone's integrity.

Data from the Brazilian Occupational Safety and Health Observatory (2021) show that 571.8 thousand accidents at work were recorded, with the health sector having the most records of Communication of Accidents at Work (CAT), with 59.1 thousand occurrences. Most accidents are associated with sharp objects, such as syringes, needles, blades, among others, representing 85% of the records. In this perspective, Camisassa (2022) presents, in their work, the importance of complying with the NRs for the safety of people in the work environment, since laboratory environments have a greater risk due to exposure to viruses, bacteria and protozoa (more recurrent contaminations).

Thus, when observing the existing gap in academic exploration regarding work safety involving clinical laboratory environments, it was verified the need to elaborate a case study that addressed the evaluation of compliance with the NRs in the referred activity. Thus, considering the degree of risk involved in activities carried out in laboratory environments, this study seeks, through the use of quality tools - such as the checklist, GUT matrix, Pareto diagram and 5W2H -, to assess compliance with NRs in a clinical analysis laboratory, proposing solutions both for legal purposes and for organizational culture, risk prevention and occupational diseases, employee well-being and company productivity.



2 BRIEF HISTORY OF WORK SAFETY

According to the Superior Labor Court (TST, 2021), the first laws regarding work safety emerged in 1919, with decree n.º 3,724, which contained the first regulations. In 1930, with the beginning of Brazilian industrialization, the Ministry of Labor was created, as workers were exposed to various dangerous situations, causing accidents that became frequent (International Labor Organization [ILO], 2020).

Occupational safety actions advanced and, in 1943, the first legislation was approved, the Consolidation of Labor Laws (CLT). In 1966, FUNDACENTRO was created; it is an agency that seeks to promote the safety and health of workers with a focus on sustainable and human development. In 1978, the NRs were implemented, which contain guidelines on various aspects of the relationship between employer and employee. In 1991, Law nº 8.213 appeared, which brought the benefits of social security (Brasil, 1991).

2.1 BASIC CONCEPTS

For Camisassa (2022), occupational safety is a set of norms, studies, techniques and preventive actions used to ensure safety in the environment, acting in the prevention of accidents and occupational diseases, in addition to protecting the physical and mental integrity of the worker.

As provided in art. 19 of Law nº 8.213 (Brazil, 1991), an accident at work is what occurs due to the exercise of work at the service of the company or the exercise of the work of the insured persons referred to in item VII. Occupational health, according to Minette and Paula (2021), is a set of rules and procedures supervised by law, with the aim of ensuring that organizations adopt safety and medical measures for their workers, aiming to minimize or eliminate the risks arising from work activities, with the Risk Management Program (PGR) and the Occupational Health Medical Control Program (PCMSO), in addition to the requirements specified in the 37 NRs.

For Monteiro and Bertagni (2020), occupational diseases are any type of physical or mental problem that affects employees. They are divided into occupational diseases (caused by the activity performed by the employee) and work-related diseases (caused by the situation in which the work is carried out or organized).

According to Barsano and Barbosa (2018), the occupational hazards present in the workplace are potential threats to the employee's health. These risks are classified as ergonomic, biological, chemical, physical and mechanical.

2.2 GUIDELINES FOR THE OPERATION OF LABORATORIES

NBR, via resolution 14785/2005, aims to protect laboratory workers and patients through safety specifications and training, which seek to preserve the integrity of all those involved.

The Resolution of the Collegiate Board (RDC) nº 302/2005 - Manual of biosafety, qualification and training is mandatory for the operation of clinical analysis laboratories, so that activities are carried out in accordance with the general conditions of the organization,



such as equipment, people, laboratory instruments, waste management and biosecurity, seeking to guarantee and control the quality of records.

According to Camisassa (2022), NRs are characterized as obligations, rights and duties that must be fulfilled by employers and their employees. For clinical analysis laboratory environments, 13 applicable standards are relevant, classified as general, sectoral and special to the subject under study.

In addition to NR-1 (general provisions) and NR-3 (embargo and interdiction due to serious and imminent risk), the following general rules are part of the sector:

- NR-4: establishes the implementation of Specialized Services in Safety Engineering and Occupational Medicine (SESMT) in companies and institutions that hire employees;
 - NR-5: deals with the Internal Commission for Accident Prevention (CIPA), whose objective is to eliminate or reduce the possibility of accidents in the work environment, guaranteeing the health and safety of workers;
 - NR-6: establishes the measures that must be taken in relation to the acquisition and use of Personal Protective Equipment (PPE);
 - NR-7: provides for the mandatory elaboration and implementation of the Occupational Health Medical Control Program (PCMSO), with the objective of carrying out the promotion, control and preservation of workers' health;
 - NR-9: determines the necessary requirements for the evaluation of occupational exposures to chemical, physical, biological, ergonomic agents and accidents, which are identified in the PGR;
 - NR-15: identifies activities and operations considered unhealthy and that generate the right to additional salary of employees;
 - NR-16: defines dangerous activities and operations;
 - NR-17: helps reduce risks related to ergonomic problems, as well as optimizes the quality of activities carried out on a daily basis;
 - NR-23: determines which forms of protection are adequate for fighting fires within companies;
 - NR-24: deals with sanitary conditions and the necessary comfort in the workplace;
 - NR-26: deals with information related to safety signs that must be present in the workplace;
 - NR-28: establishes the measures to be adopted by labor inspection, as well as the application of penalties and fines;
- And the sectorial and special NR:
- NR-32: establishes the basic guidelines for measures to protect the health and safety of workers in health services.

3 QUALITY TOOLS

3.1 CHECKLIST

According to Bertazzi (2021), the checklist is a list of items that aims to verify whether a given product or process complies with the requirements established by market exigencies. With its use, it is possible to know the situation of the checked items, informing if there are unfulfilled requirements. Penachio (2019) shows, in his research, the importance of the checklist in construction companies in the area of work safety.



3.2 PARETO DIAGRAM

To Caxito and Golçalves (2021), the Pareto diagram is a method that generally has the form of a column chart that orders the frequency of occurrences based on the idea that 80% of the consequences come from 20% of the causes. Santos et al. (2019) corroborate this in their research, identifying the causes and following their evolution over time, making it possible to present gains at the end, showing the efficiency and importance of this tool in identifying failures.

3.3 GUT MATRIX

To Bassan (2018), the Gravity, Urgency and Tendency matrix (GUT) is a tool that assists in identifying situations, in which the prioritization of their resolutions is sought. It is very effective to support the manager in solving problems and making complex decisions. The tool helps define priorities, organizing demands according to Severity (G), Urgency (U) and Trend (T). Leite et al. (2018) use tools such as the Preliminary Risk Analysis (APR) and GUT matrix to identify and prioritize the risks present in a Food Technology laboratory at the Federal University of Paraíba (UFPB).

3.4 5W2H

Marklund and Laguna (2018) define 5W2H as an administrative checklist used to manage processes, deadlines and responsibilities that must be developed by those responsible for the project, with the main objective of defining what will be done, why, where, who, when, how and how much it will cost.

According to Alves (2019), the 5W represent: *what, why, where, when* and *who*; and the 2H stands for *how* like and *how much* it costs. Lima (2019), in his research, makes use of the tool, aiming to improve two processes present in the production of ophthalmic lenses. The tool proves to be important for obtaining the diagnosis of the production process, enabling the detection of opportunities for improvement and proposing future actions.

4 METHODOLOGY

The research is characterized as quali-quantitative, through an exploratory case study, which starts with a bibliographical research in books, scientific articles and specialized magazines. Technical visits were also carried out *in loco* at a clinical analysis laboratory located in the municipality of Castanhal-PA, to obtain documents and verifications regarding compliance with the NRs. From then on, the checklist was used for data collection and processing, and then quality tools such as the Pareto Diagram, GUT Matrix and 5W2H were also used.

4.1 BIBLIOGRAPHICAL RESEARCH

At this stage, a search was made for bibliographic material on the subject in question, consulting books, scientific articles and specialized magazines in the following databases: Science Direct, SciELO, Scopus, SPELL and Periódicos CAPES.

4.2 TECHNICAL VISIT TO THE COMPANY

The research used data referring to the documentation of conformity, confronting the measures adopted for compliance with the relevant NRs and applicable to the environment. The documentation for the release, as well as the company's confidentiality terms, was



previously authorized by those responsible. In September 2022, visits were made to the site, in the municipality of Castanhal-PA, where the data were collected.

4.3 QUALITY TOOLS USED

The *checklist* was used to identify existing risks, verify compliance with the NRs, maintain work organization, and organize and plan tasks.

The Pareto diagram helped to identify problems and monitor them throughout the analysis of the causes of non-compliance with the NRs, identifying those primarily responsible for non-conformities.

Through the GUT matrix, it was possible to know the possible causes of non-conformities, propose control and prevention measures, in addition to prioritize actions in a rational and safe way, considering the severity, urgency and tendency of the phenomenon, allowing the choice of the less harmful and more efficient action.

5W2H was used to propose improvement solutions for compliance with NRs in the laboratory, helping to organize tasks, with a focus on continuous improvement.

5 RESULTS AND DISCUSSION

5.1 CHARACTERIZATION OF THE COMPANY

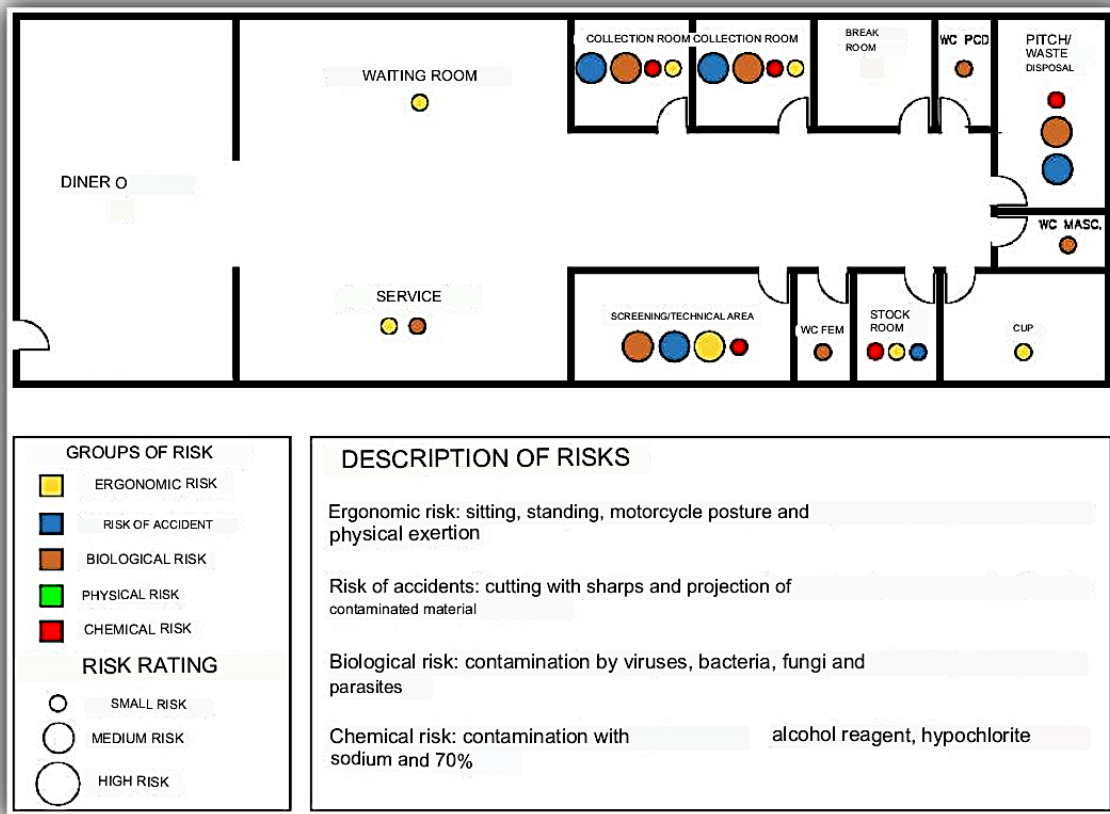
The company is located in the municipality of Castanhal, state of Pará, and has been operating in the pathological analysis market for 15 years, with more than 1,500 types of tests analyzed from the collection of materials, such as blood, feces, urine, secretions, among others. According to the company's PGR, it is classified at risk level 3 (medium), that is, there is constant danger in activities, mainly due to the environment containing risk of chemical and biological contamination.

5.2 RISK MAPPING

In preparing the risk map, the layout of the laboratory's floor plan was used, in which the risks present in each location were identified, as shown in Figure 1. The places with more possibilities for biological risks and accidents are the collection rooms, technical area and the septic tank/garbage disposal area. The space of the technical area is the one with the greatest ergonomic risk. In the collection rooms, technical area, storage room (where chemical materials are present) and the cesspool/waste disposal area (where there is an increased risk of contamination) are the places with the highest biological risk.



Figure 1. Mapping, description and classification of risks present in the company under study.



Source: Authors (2022).

5.3 APPLICATION OF QUALITY TOOLS

5.3.1 CHECKLIST (CHECKLIST)

The *checklist* was prepared based on the main guidelines of the NRs relevant to the activities carried out in the laboratory, with the aim of listing and identifying the conformities and non-conformities found, as shown in Table 1.

Table 1. Checklist of compliant or non-compliant NRs in the company under study.

Regulatory Standard (NR)	Compliance (C)	Non-Compliance (NC)	Does Not Apply (NA)
NR-4 (SESMT)			X
NR-5 (CIPA)			X
NR-6 (EPI)		X	
NR-7 (PCMSO)	X		
NR-9 (PGR)	X		
NR-15 (Unhealthy Work)		X	
NR-16 (Dangerousness)	X		
NR-17 (Ergonomics)		X	
NR-23 (Firefighting)		X	
NR-24 (Sanitary conditions)		X	
NR-26 (Safety signs)		X	
NR-28 (Inspection)		X	
NR-32 (General health promotion and assistance activities)		X	

Source: Authors (2022).



Of the 13 relevant standards, 3 are with all points in compliance, 2 are not applicable and 8 with points in non-compliance regarding compliance with some normative item. There is a total of 72 points evaluated, of which there are 42 in compliance, 18 that do not apply, and 12 points in non-compliance. The most serious points are highlighted regarding delays in operating licenses and the lack of mapping of unhealthy activities.

Considering NR-4, it is not applicable to the company, since the SESMT must be in places that have more than 50 employees, and the laboratory has 18. Thus, there is no need for regulation. However, all responsibility for preparing the PCMSO, PGR and legal obligations of the unit are carried out by SESMT at the headquarters, located in Belém.

The same happens in relation to the NR-5, since, according to Table I of the aforementioned norms, its constitution is not necessary, since the obligation is made from 20 employees. However, even though it is not mandatory, the company has one member designated by the SESMT, who is responsible for identifying the risks present at the site, supporting health programs, passing on information to other employees, promoting safety actions and help with the use of PPE.

Considering the NR-6, the company has specific PPE for each function and provides access to instructions with the Standard Operating Procedures (SOP) on their correct use. There is an obligation to use the equipment, in addition to providing and registering them. Employees sign the term of responsibility and are warned when there is non-compliance. All materials are sanitized and stored in appropriate locations that are easily accessible to all employees and are replaced without compromising their use due to lack of stock, damage or loss. There are 2 points of non-compliance observed during the analysis, the first being related to the use of PPE that do not have a Certificate of Approval (CA); and the second is the lack of training for the correct use of this equipment, since the company only has the POPs. It is worth noting that the use of PPE without the approval certificate represents a disrespect for the norms of the labor legislation. According to NR 6, the employer who complies with all provisions of the Law will be exempt from compensation in the event of an accident at work resulting from the inappropriate use of PPE.

Regarding the NR-7, the site has the annual preparation of the PCMSO, helping to prevent environmental risks, in accordance with the other NRs, mainly the NR-17 and the NR-32, with the subsidy of the occupational physician of the unit and an outsourced physician from the Castanhal branch. In addition, in the company, periodic examinations are mandatory, so it is possible to monitor the health of the worker and control immunization for infectious diseases, such as hepatitis, yellow fever, covid-19, H1N1, among others. There is one non-compliance observed, related to the elaboration of the PCMSO: a delay in its implementation was noticed, since the last one was carried out on 05/02/2021 and the forecast for a new elaboration was only at the end of November/2022, ignoring the established validity of 1 year. If the PCMSO is delayed or not delivered, the fines can reach R\$4.024,42, and can double in case of recurrence (CLINIMED, 2023).



Considering the NR-9, the company prepares the PGR annually within the legal deadlines. A survey of work processes is carried out for qualitative and quantitative evaluation and recommendations. Besides, there is a support program for employees, incentives for the use of PPE and encouragement for employees to participate in educational actions, aimed at protecting against accidents and occupational diseases.

With regard to NR-15, the company has all the necessary equipment for protection in activities considered unhealthy. In the company, 8 employees receive an additional 20% on their salary, 5 of which from collection, 1 from VIP collection and 2 biomedical workers exposed to various biological risks. However, there is 1 non-compliance related to the functions performed by the service and transport sectors that maintain contact with biological materials, which, due to the lack of an effective mapping of unhealthy activities, do not receive the proportional additional. According to Balthazar and Bitencourt (2023), the legal options for demanding payment of the unhealthy work premium include negotiating with the company, union mediation or denouncing the supervisory bodies and taking legal action. It is up to the worker to choose the option that best suits his case.

As for the NR-16, the site offers all mandatory PPE. At the company, the additional fee is paid for 2 employees, 1 for VIP collection and 1 for transporting materials. In this sense, both receive 30% of their salary for carrying out activities involving displacement on motorcycles.

Regarding NR-17, the laboratory manages to adapt to the working conditions and performs the Ergonomic Work Analysis (AET) of the functions. None of the roles involve lifting excessive weight. There is not a high level of noise, and the temperature is pleasant, remaining between 20° C and 23° C, through the use of 6 air conditioners spread throughout the unit. The lighting is natural and there is the presence of fluorescent lights with intensity control evenly distributed in the spaces.

To ensure the well-being of employees, in addition to the physiologically necessary breaks, for those who work 6 hours a day, a break of 15 minutes is mandatory. For employees who work 8 hours a day, in addition to the 1-hour break, a rest period of 20 minutes is mandatory. There is one non-compliance found in the furniture in the service area: the place has little space for the attendants to move around. In addition, there are obsolete equipment (computers, keyboards, fiber optic box, among others) that break down with some frequency. According to the Ministry of Labor, regardless of the size and number of employees, every company is subject to supervision by the Regional Labor Office. And if the lack of ergonomics is observed in the space, notification, fines and even bans will apply.

Analyzing the NR-23, the environment has fire-fighting mechanisms, with 6 large fire extinguishers of the “ABC chemical powder” type (Brazilian Association of Technical Standards [ABNT], 2010), intended for combating fires Class A (Solid Waste), B (Flammable Liquids) and C (Electrical Equipment) fire hazards. They are distributed throughout the area, which requires at least one fire extinguisher every 20 meters of area. As of May2022, the laboratory opted for a fire brigade. A non-compliance was found regarding the signs of



emergency exits and firefighting equipment that were not signposted. The lack of identification and signage can generate fine and even ban the place during the inspection of firefighters and labor agencies.

According to the analysis, the company complies with NR-24 regarding the correct disposal of waste, both in relation to common waste and infectious waste (carried out by a third-party company). The structure of the place has four bathrooms (one male, one female, one PCD (person with a disability) and one for general use). In addition, it has a filtered water system in two places for customers and employees, spots with 70% isopropyl alcohol (hand sanitizer) and ventilation through air conditioning. It has a pantry for meals, a rest room and specific clothing and uniforms for each function.

However, there are two perceived non-conformities: the first is related to the toilet cesspool system, as there is an accumulation of rainwater in its reservoir that reaches maximum capacity in a short time; the other is in the site's structure itself, which has walls with infiltrations in several parts and does not have non-slip floors. According to the Ministry of Labor, it is the responsibility of the site to adapt the septic system with a stability period by the supervisory body; non-compliance will result in the application of fines and interdiction. In addition, non-compliance with the standard can have serious consequences, such as accidents, occupational diseases and lawsuits.

With regard to NR-26, the laboratory complies with it by identifying all chemical substances, reagents, solutions and other products. However, one non-compliance was found: the lack of signs on the emergency exit, on the power switchboards (electric) and on the internet cabling box. Penalties of fines and interdiction of the site during the inspection of firefighters and labor agencies can be applied.

In relation to NR-28, there is one non-compliance in matters relating to licenses that need to be renewed annually, which are the responsibility of an outsourced company. However, during the analysis of the laboratory's documentation, it was noticed that some of these licenses are overdue. According to NR, if the company does not regularize the nonconformities, it may suffer serious consequences, which may include higher fines, shutdown of the workplace and even the suspension of the company's activities. In addition, it may suffer lawsuits filed by workers who have been harmed by irregularities found during inspection.

Considering the NR-32, the laboratory, through the PGR and the PCMSO, is able to identify and map the risks present at the site. In the company's SOPs, there is a description of all the activities that must be carried out by each function, as well as guidelines and procedures. In addition, there is a robust vaccination control for employees, and a monthly check of all necessary vaccines is carried out. The periodic examination is the main ally to monitor the individual health of each employee and is developed and organized by PCMSO. The laboratory has the correct disposal of common waste and biological and infectious materials,



which is carried out by a third-party company that performs the disposal and incineration of materials.

The company also has the Risk Prevention Plan for Accidents with Sharp Materials (PPRAMP), which aims to guide employees so that this type of incidence is reduced, providing guidance on the risks of accidents, confirming the possibility of contamination by diseases and contagious infections such as hepatitis, HIV, among others. The lack of training and recycling for the functions performed in the laboratory was a non-compliance found.

5.3.2 GUT MATRIX

Analyzing the matrix, as shown in Chart 1, the problems were identified in order of priority.

Chart 1. GUT matrix of non-conformities in compliance with the NRs in the company under study.

GUT Matrix							
Process: Non-Conformity in Compliance with NR							
Cause	Cause (%)	Problems (Causes)	G	U	T	G x U x T	Priority
1	20,79%	Delayed operating permits	5	5	4	100	1
2	16,63%	Lack of identification of unhealthy activities for additional payment for unhealthy work	5	4	4	80	2
3	9,98%	Lack of guidance and training for the use of PPE	3	4	4	48	3
4	7,48%	Lack of identification and signs referring to risks and safety on site	4	3	3	36	4
5	7,48%	Delay in the implementation of the PCMSO	4	3	3	36	4
6	7,48%	Failure to comply with all relevant NRs	4	3	3	36	4
7	7,48%	Ineffective water and sewer system	3	3	4	36	4
8	5,61%	Lack of training and recycling for the proper functions	3	3	3	27	5
9	5,61%	Purchase of PPE without certification and approval by the competent body	3	3	3	27	5
10	5,61%	Lack of signs on firefighting equipment and emergency exits	3	3	3	27	5
11	4,99%	Lack of washable and waterproof floors and coatings	3	2	4	24	6
12	0,83%	Inadequate equipment and furniture for some jobs	2	1	2	4	7
Total (%)	100,00%		Total			481	

Source: Authors (2022)

1. The delay of licenses for proper operation is the problem with the highest priority for solution, since it is mandatory for operation and, without them, the site may receive penalties;
2. The other problem to be solved, listed as priority 2, is the lack of an efficient mapping of the unhealthy activities of the service and transport functions that do not receive the unhealthy premium;
3. Then, as priority 3, there is the lack of guidance and training regarding the correct use of PPE. Because the unit is far from the headquarters, there is difficulty in carrying out training;
4. There are problems that are at the same level of priority 4, namely: lack of identification and signs of all security risks present on site; the delay in the elaboration of the PCMSO (something that was verified during the search for the documentation for the research); non-compliance with all points of the NRs (something that encompasses all standards);



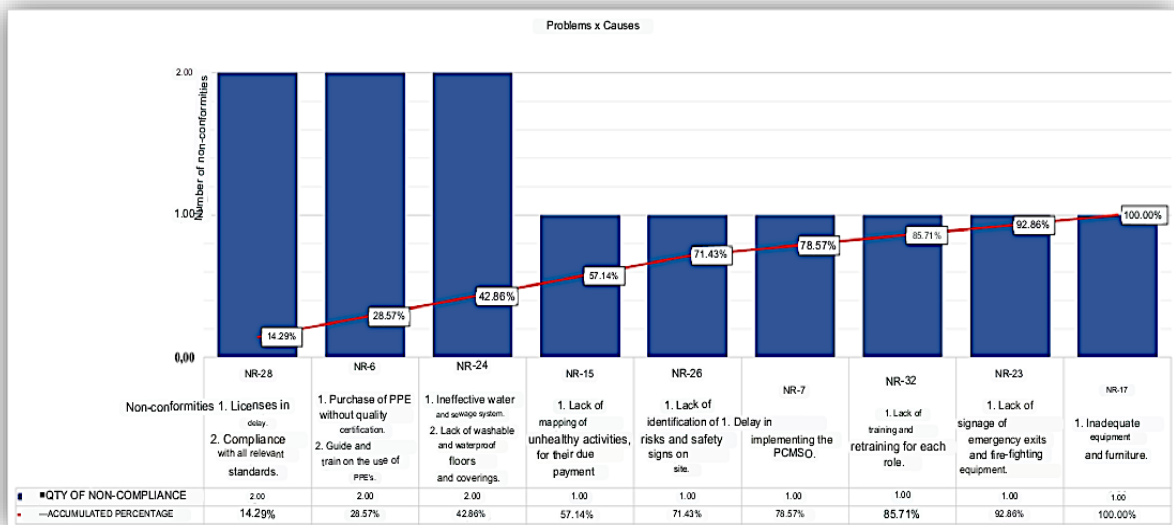
and the laboratory's sewage and water system, which sometimes obstructs and reaches the maximum limit of the cesspool;

- Regarding priority 5, there are three problems at the same level, which are: lack of training and recycling for the functions performed (in order to update procedures and changes in the sector); the purchase of PPE without a quality certificate and inspection by the responsible body (which puts the employees who use them at risk); and the lack of signs on firefighting equipment and emergency exits;
- As priority 6, there is a lack of washable and waterproof floors and coatings, which makes cleaning difficult, generating infiltrations in the walls;
- As a last priority are the equipment and furniture, which are unsuitable for use in some functions, both for ergonomic reasons and because they are obsolete.

5.3.3 PARETO DIAGRAM

Through Graph 1, it was possible to verify the incidence of non-conformities of the relevant NRs. The points were placed in order of priority considering the results of the GUT matrix. Standards 28, 6, 24, 15, 26 and 7 represent 78.57% of the causes of non-compliance, considered vital problems. Through the identification of the main norms that cause the most serious nonconformities, it is possible to focus on the search for solutions for the most urgent normative points, leaving the other NRs for a second moment.

Graph 1. Pareto Diagram of the non-conformities found in the company under study.



Source: Authors (2022)

5.3.4 5W2H

5W2H was created with the aim of suggesting possible solutions to problems encountered in complying with regulatory standards, as shown in Table 2.



Chart 2. 5W2H application to non-conformities found in the company under study.

Root Cause	Objective: Solve Non-Conformities					Date Of Creation: 01/02/2023	
	5W					2H	
	What? O Que?	Why? Por Quê?	Where? Onde?	Who? Quem?	When? Quando?	How? Como?	How Much? Quanto?
Delay in operating licenses	Keep licenses up to date	Required for operation	In the company	SESMT and Financial Sector	Within 6 months	Request with the responsible bodies	BRL 8.448,00
Lack of identification of unhealthy activities for additional payment for functions	Identify unhealthy activities and payment of the amount	required by law	Service and transport sector	SESMT, security engineer and financial sector	Within 6 months	Through a correct risk mapping	10%, 20% or 40%
Purchase of PPE without certification and approval	Buy certified PPE	required by law	In the company	Purchasing and warehouse sector	Within 6 months	Purchasing from responsible and legally authorized suppliers	unmeasured value
Lack of identification and safety signs	Identify and signal risk situations	Required by law and essential for safety	In the company	SESMT, CIPA and Laboratory Safety Engineer	Within 6 months	Through risk mapping	unmeasured value
Delay in the implementation of the PCMSO	Implement the PCMSO within the legal deadline	Mandatory by law and essential for the company and its employees	In the company	SESMT	Within 6 months	Through a follow-up schedule	BRL 1.200,00
Non-compliance with relevant NRs	Comply with all relevant regulations	Obligatory by law and indispensable for the operation of the company	In the company	sectors in general	Within 6 months	Through a follow-up Checklist	unmeasured value
Lack of guidance and training for the use of PPE	Guide and train everyone on the use of PPE	Mandatory by law and essential for employee protection	In the company	sectors in general	Within 6 months	Through training and verification checklist	unmeasured value
Lack of training and recycling for each role	Conduct training and retraining for each role	Essential for updating processes and changes in each sector	In the sectors of the company	Human Resources (HR) Sector	Within 6 months	Through periodic training	unmeasured value
Absence of signage on emergency exits and firefighting equipment	Signaling emergency exits and firefighting equipment	Obligation on the part of the company and necessary for those present on site	In the company	SESMT	Within 6 months	Through the correct mapping and signaling of the site	unmeasured value
Inefficiency of the water and sewer system	Reform sump and hydraulic system	Indispensable for the well-being of customers and employees	Hydraulic system, toilets and septic tank	maintenance sector	Within 6 months	Renovating the sump, plumbing and gutter	BRL 2.000,00 to BRL 4.000,00
Inadequate equipment and furniture	Change of equipment and furniture	Improved ergonomics and well-being for employees	In the workplaces of each sector	purchasing sector	Within 6 months	Purchase of new equipment and furniture	BRL 40.000,00 to BRL 50.000,00
Absence of washable and waterproof floors and coatings	Change to suitable floors and coatings	Improved cleanliness and upkeep of the site	In the company	Purchasing and maintenance departments	Within 6 months	Reform and change the type of floor and wall coverings	BRL 30.000,00 to 40.000,00

Source: Authors (2022)



6. FINAL CONSIDERATIONS

Compliance with the NRs is of great importance for maintaining the safety and health of employees and customers in a clinical analysis laboratory, as well as the identification of physical, chemical, ergonomic, biological risks and accidents present on site. With the use of quality tools, the standards relevant to the laboratory were listed, also verifying the main points to be remedied among the nonconformities.

Through the *checklist*, the main points of each NR were listed. Regarding the analysis, it was possible to identify the conformities and nonconformities related to the standards: of the 13 regulatory standards evaluated, 8 have points of nonconformities, 3 are in compliance, and 2 do not apply to the location. The negative points are considered serious, since they involve delayed licenses, PPE without certifications, lack of payment for unhealthy conditions and inadequate environments and machinery.

Right after the results obtained with the checklist, the GUT matrix was used to verify the degree of severity, urgency and tendency of each item in non-compliance, which had the main problems, and which would require more attention. They are: the delay of operating licenses and the lack of identification of unhealthy activities and payment of additional unhealthy work. Both points can generate fines and even ban the site. In the process of issuing licenses, the biggest problem is the absence of a schedule for monitoring the licenses and the lack of a strategy by the outsourced company, which is unable to properly serve the units in the interior. Regarding the lack of mapping of unhealthy activities, there is the service and transport sector, which maintains contact with biological materials and does not receive the mandatory additional value.

Through the analysis of the Pareto Diagram, the main causes responsible for 78.57% of the cases of non-compliance were identified: the delay of operating licenses; the lack of identification of unhealthy activities and payment of additional unhealthy work; the purchase of PPE without an approval certificate; the lack of training for the correct use of this equipment; the absence of an adequate water and sewage system, of washable and impermeable floors and coverings; the lack of mapping of unhealthy activities for the due payment of the additional to the service and transport sectors; the lack of identification of risks and safety signs on site; and the delay in implementing the company's PCMSO.

Thus, to propose improvements for the nonconformities found, the 5W2H was used, suggesting actions, through guidelines, regarding compliance as specified by the NRs for each problem found. As for the negative points, for delayed operating licenses, a follow-up schedule was suggested. Regarding the lack of identification of unhealthy activities, the company was suggested to hire a work safety engineer to carry out a correct risk mapping of activities in all sectors.

It is understood as necessary a culture of safety in all sectors of the laboratory, focused on the safety of employees and with the participation of SESMT as an agent of change, in addition to the use of checklists that accompany the processes of changes and maintenance of improvements in the routine of the company. These points, combined with improvements in the physical space, will certainly make the company safer and more comfortable for both employees and customers, in addition to being a model for complying with the relevant NRs.



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