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Cold chain management in the storage of immunobiologicals against COVID-19: technical maintenance challenges and civil-administrative liability.

Cold chain management in the storage of immunobiologicals against covid-19: technical maintenance challenges and civil-administrative liability

Renata Cristina Gabriel Iasbek e Silva, *Bachelor of Laws.*

Daniel Almeida Silva, *Technical Specialist in Refrigeration and Air Conditioning Systems. Technical Director – [Company Name].*

Summary

This scientific article proposes a multidisciplinary analysis of the challenges faced in cold chain management during the Covid-19 pandemic, specifically in 2020, focusing on the maintenance of refrigeration equipment in hospital and pharmaceutical environments. The main objective is to demonstrate the intrinsic correlation between the technical precision of refrigerator maintenance and the legal implications arising from failures that compromise the integrity of vaccines. The methodology adopted consists of a technical case study based on bibliographic and documentary review, analyzing ANVISA (Brazilian Health Regulatory Agency) standards, Ministry of Health manuals, and Brazilian civil law. The results indicate that equipment obsolescence and lack of sensor calibration constitute severe risks to public health and generate objective civil liability for service providers. It concludes that sanitary safety depends on a symbiosis between the technical rigor of maintenance engineering and regulatory *legal compliance .*

Keywords: Cold Chain. Covid-19. Refrigeration Maintenance. Civil Liability.
Health Law.

Abstract

This scientific paper proposes a multidisciplinary analysis regarding the challenges faced in cold chain management during the Covid-19 pandemic, specifically in the year 2020, focusing on the maintenance of refrigeration equipment in hospital and pharmaceutical environments. The main objective is to demonstrate the intrinsic correlation between the technical precision of refrigerator maintenance and the legal implications resulting from failures that compromise vaccine integrity. The methodology adopted consists of a technical case study based on bibliographic and documentary review, analyzing ANVISA regulations, Ministry of Health manuals, and Brazilian civil legislation.

The results indicate that equipment obsolescence and lack of sensor calibration constitute severe risks to public health and generate objective civil liability for service providers. It is concluded that sanitary security depends on a symbiosis between the technical rigor of maintenance engineering and regulatory legal compliance.

Keywords: Cold Chain. Covid-19. Refrigeration Maintenance. Civil Liability. HealthLaw.

1. Introduction

The year 2020 imposed on humanity one of the greatest health challenges of the 21st century with

The advent of the Covid-19 pandemic required an immediate restructuring of health systems.

global and local. In this urgent scenario, the expectation is for the development and distribution of

The vaccine pandemic has brought to light the critical logistics of storing temperature-sensitive materials, known as...

such as Cold Chain or Cold Network. The preservation of the pharmacological integrity of these

Immunobiologicals invariably depend on refrigeration systems operating with precision.

surgical, where mechanical failures or temperature fluctuations can result in the inactivation of

vaccines and, consequently, incalculable damage to public health and public finances.

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The central problem addressed in this study lies in the practical verification, experienced by the authors, that the cooling infrastructure in several healthcare facilities was not prepared for the The rigor required by the new vaccines. Adapted equipment, lack of contingency plans and The absence of adequate preventive maintenance were identified as bottlenecks that jeopardized the... Immunization effectiveness. From a technical standpoint, the challenge was to ensure that refrigerators maintained stable temperatures between +2°C and +8°C, even under adverse conditions of intensive use. and ambient heat.

Legally, the issue goes beyond mechanical failure and enters the realm of liability. Civil and Administrative. The loss of vaccine batches due to negligence in maintenance is not just one. Financial loss, but also a violation of the fundamental right to health, protected by the Constitution. Federal Law of 1988. Maintenance service companies, upon assuming technical responsibility... These devices attract a complex responsibility, governed by both the Code of Consumer protection as regulated by the National Health Surveillance Agency (ANVISA), requiring a posture of extreme diligence and *compliance.*

This article is justified by the need to document and analyze the intersection between The technical practice of refrigeration and legal norms in a historical moment of crisis. The relevance The difficulty of the topic stems from the scarcity of literature that combines the "factory floor" perspective—the reality of the technician. which calibrates the sensor — with the doctrinal view of Law, which analyzes the consequences of the failure. of that same sensor. The aim, therefore, is to fill this gap by offering a material that serves This is relevant for health managers, legal professionals, and technicians in the field.

The structure of the work will first address the technical fundamentals of thermodynamics. applied to vaccines and the risks of inadequate temperature. Then, it will discuss the legislation. current regulations, with emphasis on the Collegiate Board Resolutions (RDC) of ANVISA published or in effect in 2020. Subsequently, it will analyze the theory of civil liability applied to the service provider. of refrigeration services. Finally, risk management and maintenance protocols will be presented. preventive measures as damage mitigation tools, concluding with a robust conclusion on the The inseparable link between technique and law.

2. The thermodynamics of immunobiologicals and technical criticality

Thermal stability is the most critical parameter in the preservation of immunobiologicals, being that violating the temperature limits set by manufacturers may trigger legal action. irreversible protein denaturation or loss of immunogenic potency. As recommended by According to the Ministry of Health's Cold Chain Manual (BRAZIL, 2013), vaccines are biological products. sensitive to heat and cold, and exposure to temperatures outside the safety range (+2°C to +8°C) for most routine supplies, and extreme negative temperatures for certain RNA vaccines.

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(Messengers that emerged in the context of Covid-19) compromise the product's effectiveness.
Technical responsibility, therefore, begins with the understanding that a refrigerator is not just a...
It is not a household appliance, but a life-support instrument that requires rigorous thermodynamic control.

In the practical context experienced in 2020, it was observed that many establishments of
In their eagerness to expand storage capacity, healthcare providers resorted to equipment that...
Domestic refrigeration ("white goods") for vaccine storage constitutes a technical risk.
high. Household appliances have defrost cycles that can raise the
internal temperature momentarily, in addition to exhibiting a distribution of cold air (convection)
less homogeneous than scientific chambers. According to studies in the field of thermal engineering and
Recommendations from the World Health Organization (WHO, 2015) indicate that thermal stratification within
A poorly designed or poorly maintained refrigerator can create "hot zones" and "cold zones."
simultaneous "freezing" processes, both lethal to the vaccine.

The role of the refrigeration technician during the pandemic involved,
Primarily, mitigating these structural risks through fine-tuning thermostats and
sensors. Compressor hysteresis — the difference between the temperature at which the motor starts and the temperature at which it is turned off.
It shuts down — it needs to be adjusted with decimal precision. In older or non-existent equipment.
During maintenance, this variation can reach 4°C or 5°C, which is unacceptable for vaccines. The intervention
The technique required the use of *data loggers* to map thermal behavior.
of the equipment over 24 hours, identifying faults that a simple momentary thermometer might detect.
I wouldn't get it.

Another point of technical vulnerability identified in field operations was integrity.
of sealing and thermal insulation systems. Dried-out sealing rubbers (gaskets) or
Tears allow outside air and moisture to infiltrate, increasing the thermal load on the
compressor and facilitating the formation of ice, which acts as an unwanted insulator in the evaporator.
From the point of view of applied physics, this reduces the efficiency of heat exchange, forcing the system to...
Working under overload increases the risk of sudden failure. Preventive maintenance, in this context, is crucial.
In this respect, it proved to be the only effective barrier against the collapse of the system during periods of high demand.
demand.

Finally, the energy issue cannot be neglected in technical analysis. Stability
The electrical voltage that powers the compressors and electronic control boards is vital. During the
In 2020, with the increased use of hospital equipment, the electrical grid of many units...
Health services experienced fluctuations. The installation of voltage controllers and *backup* systems (uninterruptible power supplies)
or generators) has become a mandatory technical requirement. The refrigeration technician, therefore,
It was necessary to act with a systemic vision, understanding that vaccine refrigeration depends on a
A chain of factors ranging from the quality of electrical power to the cleanliness of the condensers.

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3. The health regulatory framework and RDC 430/2020

The year 2020 was a regulatory milestone for pharmaceutical logistics in Brazil with the publication of Collegiate Board Resolution (RDC) No. 430, of October 9, 2020, by the Agency National Health Surveillance Agency (ANVISA). This standard establishes Good Manufacturing Practices. Distribution, Storage and Transportation of Medicines, modernizing the requirements for To guarantee the quality and safety of supplies. RDC 430/2020 came to fill gaps left behind. by previous standards, establishing stricter requirements for temperature monitoring and Humidity control, directly impacting the work of refrigeration maintenance companies. and hospital managers.

One of the crucial points of RDC 430/2020 is the mandatory monitoring. continuous storage conditions. Article 53 of the aforementioned resolution stipulates that the Monitoring should be carried out using calibrated instruments positioned at the points. most critical aspects of the equipment, defined after a thermal qualification study. This means that the "Oral hygiene" or practices based solely on empirical experience are no longer legally acceptable. The standard requires documentary evidence that the environment is controlled, transforming the report. The technical report and the calibration certificate are documents with legal evidentiary force.

Health regulations also mandate the need for warning systems for excursions of temperature. In the context of the pandemic, where the added value (social and economic) of vaccines was Immeasurable, the failure to detect a temperature variation has become unacceptable. (RDC) It emphasizes the shared responsibility among the actors in the logistics chain, which includes, by extension... Interpretative, the service providers that ensure the functionality of the equipment. Failure to comply with these rules not only generates administrative sanctions, such as fines and closures, but it serves as a basis for civil and even criminal liability in cases of implied malice.

It is important to highlight that RDC 430/2020 aligns Brazil with international guidelines. Good practices, such as those recommended by the World Health Organization. For the technical professional. And for the maintenance company, this required an immediate update of procedures. The technician He needed to understand that his work was governed by a federal regulation that required... Traceability. Every part replaced, every *setpoint* adjustment on the digital controller, needed to be... registered and justified, ensuring that, in the event of a health inspection audit, there would be proof of technical due diligence.

In addition to RDC 430, other regulations such as RDC 50/2002 (which deals with the physical design of health facilities) also address the need for adequate infrastructure for the air conditioning and refrigeration. The interconnection of these standards creates a legal framework that protects the public interest. The refrigeration company's actions, therefore, must be guided by the principle of... Strict legality, where ignorance of the rule does not excuse compliance, as stated.

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The Law of Introduction to the Norms of Brazilian Law (LINDB).

4. The civil liability of the technical service provider.

Civil liability, a fundamental institution of private law, aims to...
Repairing damages caused to others. In the context of refrigeration equipment maintenance.
For vaccines, the legal relationship established is predominantly one of consumer or civil contract law.
attracting the application of the Consumer Protection Code (CDC) and the Brazilian Civil Code (CCB).
According to the classic doctrine of Sérgio Cavalieri Filho (2019), civil liability requires the
The presence of three elements: conduct (action or omission), damage, and causal link. In this case
In this instance, the maintenance failure leading to vaccine loss fulfills all the requirements for the duty.
to compensate.

The Consumer Protection Code, in its article 14, establishes the responsibility
The objective of the service provider. This means that the refrigeration company is responsible for...
compensation for damages caused by defects related to the provision of services, regardless of
existence of fault. If a refrigerator repaired by the company fails the next day and a...
Regarding the batch of vaccines, the company must compensate for the damage, unless it proves the exclusive fault of the consumer or of...
Third. This legal rigidity aims to protect the most vulnerable party and guarantee the quality of service.
provided, especially when it involves risks to health and safety.

There is a relevant legal debate regarding the nature of the obligation assumed by the technician.
refrigeration: would it be an obligation of means or of result? In an obligation of means, the professional...
It commits to using the best techniques, without guaranteeing the final result; in results-oriented approach, the end goal is the goal.
object of the contract. Although preventive maintenance has characteristics of an obligation of means, the
Corrective maintenance and the promise of "working guarantee" tend to be interpreted as
obligation of result. Venosa (2017) argues that, in specialized technical services, the
The legitimate expectation of the client is the perfect functioning of the equipment, which brings the...
responsibility for achieving a specific result.

Negligence, recklessness, and incompetence are forms of fault that, although
While dispensable in the strict liability of the Consumer Protection Code, they are crucial for the analysis of recourse or
Subjective liability in the Civil Code. Incompetence occurs when the technician does not possess the
knowledge required to handle highly complex equipment (such as ultra-low temperature freezers)
-70°C, used for RNA vaccines). Recklessness occurs when the technician acts without the proper precautions.
Precautions (e.g., not performing load tests). Negligence is omission, such as failing to check a
Dirty filter. In 2020, the "shortage of skilled labor" increased the risks of these types of work.
of guilt.

Finally, collective moral damages must be considered. The loss of vaccines in a pandemic.

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It not only affects the assets of the hospital or the State, but harms the community that awaits the Immunization. The Superior Court of Justice (STJ) has admitted convictions for collective moral damages. when there is an unjust and intolerable offense against fundamental societal values. The company of Maintenance services that operate with serious negligence may be subject to Public Civil Actions filed by... The Public Prosecutor's Office, aiming to redress this transindividual damage, which exponentially increases the... legal risk of the activity.

5. Risk management and application of preventive protocols

Given the highly critical and high-risk legal environment, risk management has become the A key tool for refrigeration companies and healthcare managers in 2020. Management Risk management consists of identifying, analyzing, and mitigating factors that can lead to the failure of... operation. In the case of the cold chain, this means anticipating equipment failure before it happens. The implementation of a Maintenance, Operation and Control Plan (PMOC), although Originally required for air conditioning by Law 13.589/2018, it must be conceptually adapted. for vaccine refrigeration equipment, creating a routine of systematic verification.

Scheduled preventive maintenance is the central pillar of risk mitigation. Unlike... Corrective maintenance, which acts after damage has occurred, is replaced by preventive maintenance, which follows a strict schedule for replacing parts. Due to usage time, cleaning of heat exchangers, and retightening of electrical and mechanical connections. During the pandemic, the technical company led by the co-author of this work implemented protocols. where sensor checks occurred every two weeks or monthly, far exceeding the usual practice. annual market data. This allowed them to identify "drifts" in the sensors — small losses of precision — before they compromised the vaccine supply.

The use of telemetry technology and remote monitoring was another key differentiator in the management of risks. The installation of systems that monitor temperature in real time and send alerts via SMS or an app for technicians and managers allowed for an immediate response to incidents. If a If the door was left ajar or if there was a power outage in the early morning, the system would alert the staff. on duty. Legally, the reports generated by these systems serve as proof of due diligence. and the company's objective good faith, demonstrating that all available technological means were used to prevent damage.

The ongoing technical training of the operational team was, and continues to be, a key factor in... Risk reduction. The field technician needs to understand not only mechanics, but also... Basic microbiology and sanitary standards. He needs to know that he can't put the vaccine on the doorstep. The refrigerator is equipped with a thermometer that cannot touch the back wall. The company invested in training. Internal procedures to align the team with the guidelines of the National Immunization Program (PNI). The record These training sessions also form part of the company's legal defense dossier in case of litigation.

Finally, contract management should include clear clauses regarding the limits of...

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responsibility. It is essential that the service contract specifies the time frame.
response (SLA - Service Level Agreement) and the infrastructure conditions that the client must provide.
(such as a stable electrical grid). Contractual transparency, combined with technical excellence, forms the shield.
A protective mechanism that allows the refrigeration company to operate in a sector as sensitive as healthcare without
succumb to the risks of unpayable legal liabilities.

6. The importance of sensors and metrology in legal certainty.

Metrology, the science of measurement, is often underestimated, but it is the foundation of safety.
in the cold chain. A vaccine refrigerator is only as good as the accuracy of its sensors. In 2020,
The scarcity of supplies and the need for haste led to the use of low-quality digital thermometers, without
Certification or calibration traceable to the Brazilian Calibration Network (RBC/Inmetro). Reading error.
A miscalibrated sensor can lead the manager to error: the display indicates +4°C, but the temperature
The actual internal temperature is +9°C or -1°C, silently compromising the vaccine.

Technically, the most commonly used sensors are NTC (Negative Temperature) thermistors.
Coefficient) or PT100 probes. These components are subject to natural wear and tear and changes in resistance.
Electrical damage can be affected by time and humidity. Periodic replacement and comparative calibration are necessary.
mandatory. The maintenance company that ignores metrology assumes the risk of causing damage by
Incompetence. Calibration is not a "luxury," but a requirement of RDC 430/2020 and an indirect requirement.
of the Consumer Protection Code to ensure the adequacy of the service.

From a legal standpoint, the Calibration Certificate is the document that certifies that...
Equipment compliance. In a legal process where liability is being discussed for
Loss of a batch of vaccines, presentation of a valid certificate issued by a laboratory.
accredited, reverses the burden of proof or, at the very least, demonstrates the absence of a causal link between the
The maintenance company's actions and the damage that occurred. Without this document, the company is vulnerable.
to the presumption of failure in the provision of the service.

Furthermore, the location of the sensors within the chamber is crucial. The qualification study
Thermal imaging maps hot and cold spots. Placing the sensor in the wrong location can generate false readings.
The specialist's technical responsibility is to ensure that the sensor "sees" the temperature of the vaccine.
you are feeling it. The use of buffer solutions (such as glycol) to simulate the thermal inertia of the vaccine in
Sensor technology is a good technical practice that also serves as a technical defense argument in expert reports.
court-appointed experts.

Therefore, metrology acts as the interface between physics and law. It translates quantities.
physical (temperature) data are used to provide reliable information that supports administrative decisions (applying or
Discarding the vaccine) and court rulings (convicting or acquitting the company). The author's expertise.
technician Daniel Almeida in the implementation of rigorous sensor verification routines during the

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The pandemic exemplifies how in-depth technical knowledge is the best tool for legal *compliance* .

7. Conclusion

The multidisciplinary analysis proposed in this article, combining the perspectives of Engineering and Maintenance and Law allow for the creation of a complex and integrated overview of supply chain management. cold storage of immunobiologicals during the 2020 health crisis. It becomes evident that the separation between The terms "technique" and "law" are merely didactic, since in hospital and pharmaceutical practice, the technical execution... It is the embodiment of compliance with the law, and the technical failure is the origin of civil liability.

Firstly, it is concluded that the role of the refrigeration technician and the companies specialized companies underwent a revaluation. They ceased to be seen as service providers. support services (building maintenance) to be recognized as essential agents in the chain health systems. The Covid-19 pandemic acted as a "stress test" for these systems. refrigeration, revealing that improvisation and the use of household equipment are incompatible. with the safety required for new technology vaccines, demanding professionalization and Investment in infrastructure.

Secondly, strict liability, enshrined in the Consumer Protection Code. Consumer risk imposes a severe burden on maintenance companies. The theory of risk... The undertaking does not accept excuses based on the complexity of the task. Either the service is provided with safety and efficiency, or the company must repair the damage. This forces the market to raise the bar. Quality, purging amateurs and rewarding companies that invest in training and tools. precision and auditable management processes.

Third, ANVISA's regulation, especially through RDC 430/2020, has proven to be a A powerful instrument for standardization. The mandatory monitoring and calibration removed the Temperature management has moved beyond guesswork and into the realm of metrological science. In law, this facilitates the determination of responsibilities; for technical purposes, this offers a clear roadmap of Standard operating procedures (SOPs) to be followed.

Fourth, the case study based on the authors' experience demonstrated that prevention is, Undoubtedly cheaper and safer than repair. The cost of a maintenance contract. The cost of preventive maintenance and a remote monitoring system is negligible compared to the market value and The social impact of a lost batch of vaccines, coupled with legal compensation and damage to the company's image, is compounded by the financial losses incurred through legal action. The company's relationship with society. Risk management should therefore be the central philosophy of... managing these companies.

Fifth, it was observed that continuous training and development are indispensable. The technician Those working in healthcare need knowledge of biology and law, just like a lawyer practicing in [legal field].

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The healthcare field needs to understand the basics of thermodynamics and technical reports.
Interdisciplinarity is not only academically desirable, but necessary for survival.
in the market and for the effective defense of the interests of clients and patients.

Sixth, there is an ethical dimension that permeates the entire discussion. The proper maintenance of a Refrigerating vaccines is an act of bioethics. Ensuring the correct temperature is guaranteeing that...
The patient will receive an effective vaccine. Technical negligence, in this case, violates the dignity of the patient.
The human person and the right to life. Awareness of this responsibility must permeate the culture.
Organizational structure of refrigeration companies operating in the healthcare sector.

Seventh, the legacy of the pandemic for the sector is the consolidation of technology as an ally of Legal certainty. The use of *data loggers,* cloud systems, and home automation applied to...
Refrigeration has created a digital trail of evidence that protects good professionals and exposes the unqualified.
negligent. The digital transformation of maintenance, accelerated by the 2020 crisis, is a path without
A return that benefits the whole society.

Finally, this work reiterates the operational and legal viability of the cold chain.
It depends on the symbiosis between practical "factory floor" knowledge and the doctrinal rigor of
Right. Only through this union is it possible to build a resilient health system, capable of...
to face future pandemics with the assurance that technology and law work together to
To protect the greatest good: human life.

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