International Journal of Sociologies and Anthropologies Science Reviews
Volume 4 Issue 3: May-June 2024: ISSN 2985-2730
Website: https://so07.tci-thaijo.org/index.php/IJSASR/index

Capabilities of Medical Equipment to Response in Public Health Events at Chongqing Market

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Received 10/11/2023 Revised 21/11/2024 Accepted 08/01/2024

Abstract

Background and Aim: From this new crown pneumonia epidemic, it can be found that the existing system is still unable to meet the needs of emergencies such as public health. It is necessary to do a good job of system reserves for the accessibility of drugs and medical devices from the level of laws and regulations. This needs to be sorted out to achieve accessibility. The existing regulations and systems should be improved to meet the needs of medical device use in public health and other emergencies. However, medical devices cannot fully meet clinical needs due to factors such as long research and development and inspection cycles, wide applicable standards, insufficient production capacity, and cumbersome review processes. In public health emergencies, medical devices that serve as auxiliary or direct treatment play a crucial role and play an indispensable role. Therefore, whether medical devices can function safely and effectively has become a determining principle. By conducting procedural testing on a specific medical device in public health emergencies in 2022, the qualification status of such medical devices can be more clearly and intuitively analyzed, And the specific problems with unqualified medical devices, and these medical devices during this period based on the obtained data.

Materials and Methods: Safety testing of medical devices used in 8 public health events using Chinese national standards

Results: 87% of the samples meet national standards and pass the inspection

Conclusion: Laws and regulations need to be improved, there are hidden dangers in regulation, the ability of regulatory teams needs to be improved, medical device enterprises have problems, medical devices should strictly follow national standards, and the public should actively participate in medical device regulation

Keywords: Public Health; Medical Equipment; Safety and Reliability Capabilities; Inspect

Introduction

In the face of emergencies such as large-scale infectious diseases, some medical device manufacturers either do not have enough practical research and development experience in related epidemic prevention medical devices or use cheaper raw materials to reduce product quality in the research and development stage to save costs and increase profits. purpose, and even use various channels and means to bypass market supervision and produce problematic medical devices from the very beginning (Li, X., 2023). Or, to take advantage of the public's panic about unknown infectious diseases, some unscrupulous merchants falsely advertise products that do not meet medical requirements, confusing the masses without certain professional cognitive ability, blindly believing and following them, and causing sudden large-scale infectious diseases. It cannot effectively reduce and contain the spread of diseases or other public health events. Infectious diseases spread rapidly in various cities. This is the problem with the quality supervision of medical devices under public health emergencies (Wang, A., et al., 2023).

Research objective

1) To obtain the city's medical device guarantee system for dealing with public health emergencies, comprehensively improve the city's ability to respond to public health emergencies and the level of medical device management, establish and improve the city's medical device rescue and operation mechanism, and effectively respond to emergencies public health events.

2) The emergency inspection, inspection, and approval system for medical devices is an important system for dealing with public health emergencies.

Scope of the study

The scope of the research is the epidemic prevention medical devices in Chongqing in 2022. The research process starts from the quality inspection after the research and development of medical

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device enterprises, to the review and evaluation process after passing the inspection, to the listing after the review and approval, and finally to the market Sampling inspection of anti-epidemic medical devices for quality inspection is over.

Significance of the study

The technical specifications followed by the safety and reliability capabilities of medical devices are important technical support for regulating medical device regulation and promoting industrial development. The national standard management department, based on the actual development of the industry and regulatory work, continuously improves the medical device supervision and management system and carries out revisions to the medical device supervision system to continuously improve the medical device supervision system and enhance the technical support capacity for industrial development (Wei, J., et al., 2020).

Methodology

Samples and sampling

To strengthen the quality supervision of medical devices and ensure the safety of the people using them, by the general requirements of the "four most stringent" (the most stringent standards, the strict supervision, the most severe punishment, and the most serious accountability), according to the "Medical Devices According to the requirements of the "Administrative Measures for Quality Sampling Inspection" (National Drug Administration [2020] No. 9), combined with the actual situation of our city, the following sampling plan is formulated.

The overall batch plan for random inspection

Considering the time, economy, and energy costs of this research, and the requirement to screen samples covering multiple fields, regions, and links, the principle is to take up moderate resources, invest human and financial resources, and cover all districts of Chongqing with high accuracy. In 2022, the number of sampling inspections in the Chongqing market will be determined to be 8 batches, covering the links of manufacture.

Specific requirements for taking samples

In the manufacturing link, Class II active medical device products of real estate enterprises in Chongqing are selected. Focus on extraction in the following order of priority:

1) Unqualified products in the market sampling inspection in 2021, such as the specific electromagnetic wave therapy device of Chongqing Xinfeng Medical Devices Co., Ltd. that failed in the market sampling inspection in 2021 (see Appendix A for details).

2) High-risk products that were not selected in the national sampling inspection in 2021, and that were not arranged for sampling inspection in this year's national sampling inspection. For example, the surgical shadowless lamp of Shenzhen Keman Medical Equipment Co., Ltd. that was not picked up by the national sampling inspection (see Appendix A for details).

3) Epidemic prevention and control products. Varieties not included in the national sampling plan, such as forehead thermometers.

4) In 2021, the Chongqing Adverse Drug Reaction Monitoring Center disposed of products with more reports of suspicious medical device adverse events from registrants and filers in our city: specific electromagnetic wave therapeutic devices and infrared therapeutic devices.

5) Products registered with the self-inspect report.

6) Randomly select some newly registered and filed products in 2021, and medical device products commissioned by the registrant system (see Appendix A for details).

7) Products that are found to have major defects in the quality system of the enterprise during the inspection by the inspection bureau, and have hidden quality risks.

Note: If the same enterprise has many registered or filed products, in principle, one batch will be selected for each registration certificate. No more than 2 batches of active medical device products from the same enterprise (Try to extract the second-class products, and not the third-class products). Products that have been selected by the same company in the national sampling inspection in 2022 will no longer be selected.

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Sampling statistics table

Table 1: List of Sample Types

No.	Sample type	Sampling link	Stock	Sampling batch	Sampling ratio	application scenarios
1	Infrared therapy device	Manufacture	20	4	20.0%	adjuvant therapy
2	Electric hospital bed		6	1	16.7%	adjuvant therapy
3	Expectoration system		10	1	10.0%	treat
4	Immunoanalyzer		2	2	100.0%	detect
Total			**38**	**8**	**21.1%**	—

Research instrument

The choice of inspection basis is the GB 9706 series of standards, among which the GB 9706.1 series of medical device field standards is one of the core standards for the general requirements of medical devices, providing strong technical support for the quality and safety supervision of medical device products.

The national standard "GB 9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements" (hereinafter referred to as GB9706.1) was issued and implemented on July 1, 2008. The requirements of this safety standard are aimed at manufacturers and users of medical electrical equipment. GB 9706.1 stipulates in more detail the safety requirements applicable to various medical electrical equipment, including protection against electric shock hazards, mechanical hazards, excessive radiation hazards, flammable anesthetic gas ignition hazards, over-temperature and other hazards, and accurate working data. Eight aspects, including the prevention of sex and dangerous output, abnormal operation and fault state, and structural requirements (GB 9706.1—2007 Medical Electrical Equipment Part 1: General Safety Requirements [S]. Beijing: China Standard Press, 2007).

The safety inspection inspection involved in GB 9706.1 is a general type of inspection, that is, an inspection conducted with a sample that can represent the same type of item to be inspected. inspects that should only be made on those insulation, component, and construction features whose failure, under normal conditions or single fault conditions, would present a safety hazard (GB 9706.1—2007 Medical Electrical Equipment Part 1: General Safety Requirements [S]. Beijing: China Standard Press, 2007). Part of the inspection in the specific implementation process can be completed by the inspector without the use of tools. For example, the classification, appearance, structure, and circuit layout of medical electrical equipment in the standard mainly rely on inspection, experience judgment, and visual inspection. The other part can only be completed by the experimenter with the help of tools and instruments that meet certain technical parameters (The State Food and Drug Administration organizes the compilation of technical basis for medical device supervision [M] Beijing China Medical Science and Technology Press, 2009: 21-24).

GB 9706.1 gives clear requirements on the method and sequence of the inspection. However, the inspection items are covered in 58 chapters, 10 appendices, 16 tables, and 51 pictures. The relatively abstract text is boring, and the inspection tools required for most inspection items are not specified. GB9706.1, as the general safety requirements for medical electrical equipment, is the basis of the special safety requirements for medical electrical equipment. Therefore, for some medical devices designed to professional standards (such as "YY 0571 Medical Electrical Equipment Part 2: Special Requirements for Safety of Medical Electric Hospital Beds"), it is necessary to further refine

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the safety and performance requirements of medical devices through professional standards, and according to the professional Standard combined with GB 9706.1 for detection.

Inspection items and comprehensive judgment principles

According to the shape, structure, electrical safety type, electric shock protection level, application scenarios, applicable standards, etc. Of different types of samples, the inspection items are as follows:

1. Infrared therapy device

Table 2: Inspection Items of Infrared Therapy Device

No.	Inspection basis	Inspection items	Judgment principle
1	GB 9706.1-2007	6.1, 6.3, 6.4, 6.7, 7.1, 14.1, 14.2, 14.4, 14.5, 14.6, 16, 18, 19, 20, 23, 24.1, 24.3, 24.6, 49.1, 49.2, 49.3, 56.7, 56.8, 57.1, 57.6	All qualified
2	YY 0306-2008	6.1, 6.3, 24.1, 56.8	All qualified

2. Electric hospital bed

Table 3: Inspection Items of electric hospital bed

No.	Inspection basis	Inspection items	Judgment principle
1	Technology requirement	Performance inspects	All qualified
2	GB 9706.1-2007	All items	All qualified
3	YY 0571-2013	All items	All qualified

3. Expectoration system

Table 4: Inspection Items of Expectoration System

No.	Inspection basis	Inspection items	Judgment principle
1	Technology requirement	Performance inspects	All qualified
2	GB 9706.1-2007	All items	All qualified

4. Immunoanalyzer

Table 5: Inspection Items of Immunoanalyzer

No.	Inspection basis	Inspection items	Judgment principle
1	GB 4793.1-2007	5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5.1, 5.1.5.2, 5.1.5, 5.1.6, 5.1.7, 5.1.8, 5.2, 5.3, 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 6.3, 6.3.1, 6.3.2, 6.5.1.3, 6.11.1.1, 6.11.2.2, 9.5.1, 9.5.2	All qualified
2	GB 4793.6-2008	5.2, 5.4.3	All qualified
3	GB 4793.9-2013	5.1.1, 5.2, 5.3, 5.4.3, 5.4.4	All qualified

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No.	Inspection basis	Inspection items	Judgment principle
4	YY 0648-2008	5.1.1, 5.1.2, 5.2, 5.3, 5.4.3, 5.4.4	All qualified

List of score ratios for each inspection item

According to the standard, each chapter has multiple subsections. For example, GB 9706.1 chapter 14 has 6 subsections, namely 14.1~14.6, and each subsection has multiple inspection items, such as 14.2a)~14.2c). If at least one item in a subsection is unqualified, then this subsection is judged as unqualified. For example, if items 14.2c) of subsection 14.2 in Chapter 14 are unqualified, then subsection 14.2 will be judged as unqualified, but it will not affect the judgment of subsections 14.1 and 14.3 to 14.6. However, items of Investigate due to the large impact of transportation and storage on inspection items, only the actual measurement situation is recorded, and no scoring and judgment are made, For example, subsections 6.1, 6.3, and 6.4.

Table 6: list of score proportions for each clause of various samples

NO.	Sampling link	Sample type	Inspection basis	Inspection item	Score ratios	Remark
1	Manufacture	Infrared therapy device	GB 9706.1-2007	6.1	—	Must be 100% qualified, otherwise 0 points
				6.3		
				6.4		
				6.7		
				7.1		
				14.1		
				14.2		
				14.4		
				14.5		
				14.6		
				16		
				18		
				19		
				20		
				23		
				24.1		
				24.3		
				24.6		
				49.1		
				49.2		
				49.3		
				56.7		
				56.8		
				57.1		
				57.6		
			YY 0306-2008	6.1		
				6.3		
				24.1		
				56.8		
2		Electric hospital bed	Technology requirement	Performance inspects	—	Must be 100% qualified, otherwise 0 points
			GB 9706.1-2007	All items		
			YY 0571-2013	All items		
3		Expectoration system	Technology requirement	Performance inspects	—	Must be 100% qualified,
			GB	All items	—	

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NO.	Sampling link	Sample type	Inspection basis	Inspection item	Score ratios	Remark
			9706.1-2007			otherwise 0 points
4		Immunoan-analyzer	GB 4793.1-2007	5.1.1	—	Must be 100% qualified, otherwise 0 points
				5.1.2		
				5.1.3		
				5.1.4		
				5.1.5		
				5.1.5.1		
				5.1.5.2		
				5.1.6		
				5.1.7		
				5.1.8		
				5.2		
				5.3		
				5.4.1		
				5.4.2		
				5.4.3		
				5.4.4		
				5.4.5		
				6.3		
				6.3.1		
				6.3.2		
				6.5.1.3		
				6.11.1		
				6.11.1.1		
				6.11.2.2		
				9.5		
				9.5.1		
				9.5.2		
			GB 4793.6-2008	5.2		
				5.4.3		
			GB 4793.9-2013	5.1.1		
				5.2		
				5.3		
				5.4.3		
				5.4.4		
			YY 0648-2008	5.1.1		
				5.1.2		
				5.2		
				5.3		
				5.4.3		
				5.4.4		

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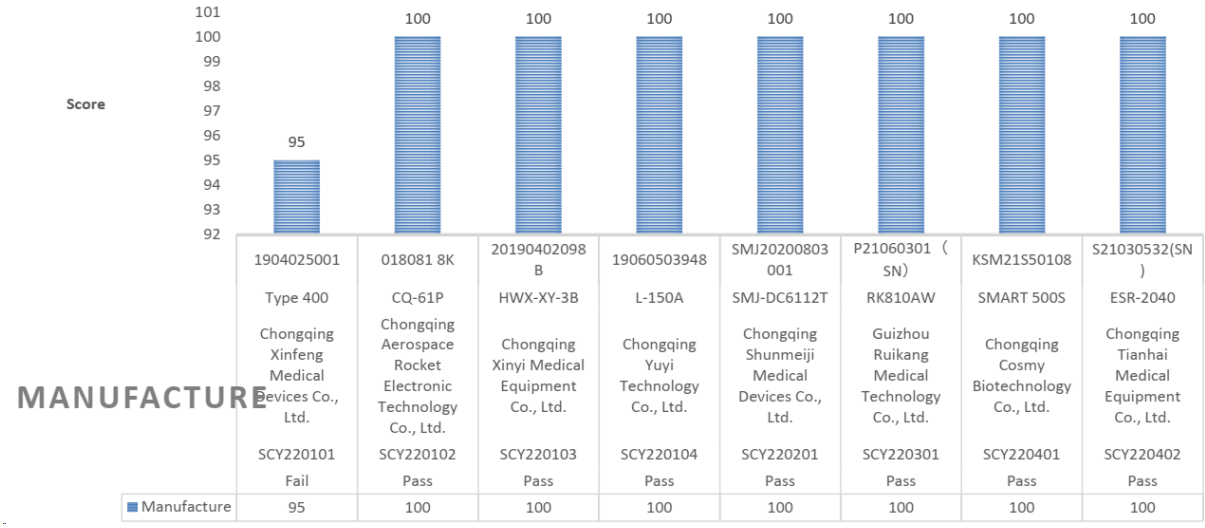
Results



	1904025001	018081 8K	20190402098 B	19060503948	SMJ20200803 001	P21060301（SN）	KSM21S50108	S21030532(SN)
	Type 400	CQ-61P	HWX-XY-3B	L-150A	SMJ-DC6112T	RK810AW	SMART 500S	ESR-2040
	Chongqing Xinfeng Medical Devices Co., Ltd.	Chongqing Aerospace Rocket Electronic Technology Co., Ltd.	Chongqing Xinyi Medical Equipment Co., Ltd.	Chongqing Yuyi Technology Co., Ltd.	Chongqing Shunmeiji Medical Devices Co., Ltd.	Guizhou Ruikang Medical Technology Co., Ltd.	Chongqing Cosmy Biotechnology Co., Ltd.	Chongqing Tianhai Medical Equipment Co., Ltd.
	SCY220101	SCY220102	SCY220103	SCY220104	SCY220201	SCY220301	SCY220401	SCY220402
	Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Manufacture	95	100	100	100	100	100	100	100

Figure 1: Histogram of sample scores in the manufacturing link

This infrared therapy device that failed the test was a model 400 product produced by Chongqing Xinfeng Medical Instrument Co., Ltd., and the failed clause was Chapter 20 of GB 9706.1-2007: Dielectric Strength Test A-a1 (in the part of network power supply) and the accessible metal part that has been protected and earthed), the test method of this article is to short-circuit L and N, and apply a voltage of 1500V, 50Hz, for 1min between the short-circuited L, N and the accessible metal, as shown in the figure 2. However, the voltage of this sample broke down the connection layer between the components during the test, which caused the test to fail. The main reason for the failure of the analysis test is that the thickness of the insulating layer at the connection of the components is not enough, and the creepage distance and the electrical gap are small, resulting in voltage breakdown.

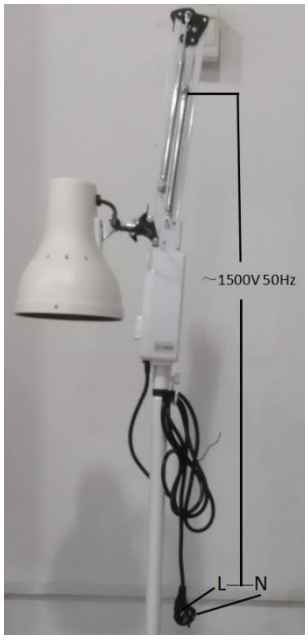


Figure 2: Example of test line connection in Chapter 20 A-a1 of GB9706.1-2007

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Combined with the sample information table in Chapter 3, draw the total pass rate of samples in the manufacturing link and the pass rate of each product in this process, See Figures 3, 4, 5, 6, and 7. Among them, the total number of samples in the manufacturing link is 8, with 7 qualified samples and 1 unqualified sample, and the pass rate is 88%. The total number of infrared therapy device samples is 4, of which 3 are qualified and 1 is unqualified, with a pass rate of 75%. The total number of electric hospital bed samples is 1, the qualified sample is 1, the unqualified sample is 0, and the pass rate is 100%. The total number of samples of the expectoration system is 1, the qualified sample is 1, the unqualified sample is 0, and the qualified rate is 100%. The total number of immune analyzer samples is 2, 2 qualified samples, and 0 unqualified samples, and the qualified rate is 100%.

It can be seen from Chapter 4 that medical devices in the production process need to fully comply with the national mandatory inspection standards and pass the strict registration review and approval process, and even some relatively strong companies cannot skip the review process through unconventional means, so the number of unqualified products in the manufacturing link is the lowest compared to the operating link and the in-use link. The only unqualified product is compared with the same type of product, and it is found that their structures are roughly the same, but the materials and usage of key components There are differences in the thickness of the material, but the cost of this part is not high after research. The reasonable analysis is that the company did not conduct relevant safety tests during the production and development stage or conducted safety tests but there was a possibility of failure. Out of luck Failure to pay attention to it failed the product inspection. According to industry insiders, many medical device manufacturers will purchase a certain number of parts during the production research and development stage. Some parts were unqualified during the national registration inspection. To pass the registration inspection, the manufacturer will replace some unqualified parts. Once the qualified parts pass the registration inspection, because the unqualified parts originally purchased involve cost issues, the manufacturer will use the problematic parts in the production process to reduce costs. These parts are often relatively hidden. It is difficult to detect the video and video, which also makes it difficult for the market supervision department to find out if it only monitors the appearance and operation of the product.

The supervision of medical devices needs to cooperate with high-level laws and regulations as the cornerstone. At present, China's medical device supervision and management regulations are mainly promulgated by the State Council. The legal effect of the regulations is lower than that of the constitution and general laws. It is a normative document belonging to administrative regulations and lacks a certain degree of binding force. In the future, it is necessary to refer to the regulatory practices of food and drug safety to speed up the legal construction of medical device supervision, so that it has the same legal status as drug and food supervision. At the same time, in the legislative process, it is necessary to pay attention to clarifying the legal responsibilities of medical device regulatory bodies at all levels, to provide a legal basis for scientifically controlling regulatory risks.

The quality of supervisory work is closely related to the professional ability of supervisors. To match the supervisory body and supervisory force in the supervisory work, it is necessary to regularly carry out professional knowledge and professional skills training for supervisory practitioners. By improving the professional level of supervisory practitioners, to ensure the quality of supervision. At the same time, the state should encourage colleges and universities to open majors related to medical devices to provide relevant talents for medical device supervision. Finally, in response to the phenomenon of medical device brain drain, it is necessary to improve the salaries and benefits of employees and expand promotion channels, to mobilize the enthusiasm of employees. Only in this way can we ensure that the regulatory force matches the scale of product development.

Discussion

Medical device manufacturing pass rates highlight both the advantages and disadvantages of quality control procedures. Data show that 88% of products pass overall, with certain products (like electric hospital beds, expectoration systems, and immune analyzers) passing 100% of the time. However, the pass rate for the infrared therapy devices was lower at 75%, suggesting inconsistent quality in the product (Chapter 3). This variability emphasizes how important it is to have strict

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quality assurance procedures in place during the manufacturing process, especially for complicated devices like infrared therapy units. To maintain high product quality across all categories, manufacturers must make sure that comprehensive safety testing is conducted and that national standards are followed.

According to the analysis, insufficient safety testing or production-related cost-cutting measures may be the cause of the lower pass rate for infrared therapy devices (Chapter 4). To cut costs, manufacturers will occasionally replace subpar parts after a preliminary inspection; this practice jeopardizes the effectiveness and safety of the device. This problem emphasizes the necessity of strong regulatory frameworks that guarantee ongoing adherence to safety requirements throughout the production process. Tightening these laws would make it more difficult to use inferior parts and guarantee that every product put on the market satisfies the required standards for quality and safety.

It is imperative to improve China's legal and regulatory framework for medical devices to tackle these obstacles. To provide more effective oversight, the current regulations—which are mainly administrative and have no legal force behind them—need to be raised to the status of general laws (Chapter 4). Enhancing the professional competencies of supervisory staff members via consistent training and providing better compensation and career advancement opportunities as a means of retaining talent is also essential. The medical device industry can uphold elevated standards of quality and better protect public health by promoting a more rigorous and professional regulatory framework (Zhou, 2023).

Recommendation

It is advised that medical device manufacturers adopt more stringent and ongoing safety testing procedures throughout the production process based on the data analysis. In particular, producers ought to;

1. Strengthen quality control procedures, especially for complicated devices like infrared therapy units, to guarantee constant adherence to performance and safety requirements. This will improve quality assurance measures. This can be accomplished by conducting thorough safety tests more frequently throughout the production process to spot possible problems early on and fix them.

2. Boost quality control processes to ensure consistent adherence to performance and safety standards, particularly for complex devices like infrared therapy units. This will enhance the measures for quality assurance. This can be achieved by carrying out comprehensive safety testing more frequently during the production process to identify potential issues early on and address them.

3. Increase quality control procedures to guarantee that performance and safety standards are consistently met, especially for sophisticated devices like infrared therapy units. This will improve the quality assurance measures. This can be accomplished by conducting thorough safety testing more regularly throughout the production process to find and fix any possible problems early on.

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