CRITICAL ANALYSIS OF TECHNICAL SPECIFICATIONS IN BIDDING PROCESSES FOR THE ACQUISITION OF AUTOCLAVES

Análise crítica das especificações técnicas em processos de licitação para aquisição de autoclaves

Análisis crítico de especificaciones técnicas en procesos de licitación para adquisición de autoclaves

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ABSTRACT: Objective: To analyze technical specifications in bidding processes for the acquisition of autoclaves with more than 90 L, based on the related standards. **Method**: Descriptive, documentary research, with a quantitative approach, based on bidding processes available online. **Results**: 112 bidding processes were analyzed, of which 106 (94.6%) came from Brazil and six (5.4%) from Mexico, Honduras, El Salvador, Panama and Paraguay. The documents were assessed according to construction aspects, sterilization cycles, optional items, safety items and management tools. **Conclusion**: Most of the technical specifications are outdated, in some cases compromising safety in the sterilization process.
Keywords: Steam. Sterilization. Equipment and supplies. Competitive bidding.

RESUMO: Objetivo: Analisar as especificações técnicas em processos de licitação para aquisição de autoclaves com mais de 90 L, com base na normatização relacionada. **Método:** Pesquisa descritiva, documental, com abordagem quantitativa, baseada em processos de licitação disponíveis *online*. **Resultados:** Foram analisados 112 processos, dos quais 106 (94,6%) foram provenientes do Brasil e seis (5,4%) do México, Honduras, El Salvador, Panamá e Paraguai. Os documentos foram analisados de acordo com aspectos construtivos, ciclos de esterilização, itens opcionais, itens de segurança e ferramentas de gestão. **Conclusão:** As especificações técnicas, em sua maioria, estão desatualizadas, em alguns casos comprometendo a segurança no processo de esterilização.
Palavras-chave: Vapor. Esterilização. Equipamentos e provisões. Proposta de concorrência.

RESUMEN: Objetivo: Analizar las especificaciones técnicas en los procesos de licitación para la adquisición de autoclaves con más de 90 L, en base a la estandarización relacionada. **Método:** Investigación descriptiva, documental, con enfoque cuantitativo, basada en procesos de licitación disponibles *online*. **Resultados:** Se analizaron 112 casos, de los cuales 106 (94,6%) procedían de Brasil y seis (5,4%) de México, Honduras, El Salvador, Panamá y Paraguay. Los documentos fueron analizados según aspectos constructivos, ciclos de esterilización, opcionales, elementos de seguridad y herramientas de gestión. **Conclusión:** La mayoría de las especificaciones técnicas están desactualizadas, en algunos casos comprometiendo la seguridad en el proceso de esterilización.
Palabras clave: Vapor. Esterilización. Equipos y suministros. Propuestas de licitación.

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INTRODUCTION

Bids are administrative procedures used by public organizations to select a proposal with the most advantageous conditions, providing equal opportunities to suppliers and strictly complying with the regulation, criteria and details of the process[1]. Overall, the permanent or special commission[2] appoints the support team for the bidding. It consists of a technical staff that will describe the characteristics of the equipment based on indications of preliminary technical studies and on the demand. The technical staff can be constituted of a nursing, engineering or maintenance professional, or all these segments.

The bidding has a rigid system that qualifies bidders; a technical analysis is carried out against the technical specifications requested in a method that will tell if it complies or not with details[2,3]. Therefore, if a company does not comply with the specifications, it will not be approved for the second stage, in which the winner with the lowest price will be chosen among the proposals approved in the technical analysis.

This procedure is different in some countries in Latin America, which use a percentage or weight factor to score the technical superiority of the proposals[4,5]. In Bolivia[4], for example, the process is similar to that in Brazil, with the first stage of technical specification and the method "complies/does not comply", named "Form C-1 technical specifications". However, an important difference is found in Form C-2, entitled "Additional conditions" with 35 extra points computed for companies that fulfill certain conditions or benefits other than the stipulated in the bidding, but not being eliminatory.

Another example is Chile[5], where there is no strict procedure for bids, but each customer places a percentage for factors such as delivery time, guarantee, price and requirements. In the technical specifications phase, they indicate the minimum characteristics that the equipment must comply with and the additional requirements, which score and rank the proposals as superior to the request.

In the current scenario, even with different bidding processes, like the examples above, empirical evidence has shown that recent processes in Latin America have specifications that may not be in accordance with the standards related to steam sterilization or make it difficult to interpret items requested. In general, this can substantially impact patient and operator safety, as well as the costs associated with the equipment, thus constituting a subject of interest for health surveillance, managers and users of health services.

OBJECTIVE

To analyze the technical specifications in bidding processes for the acquisition of autoclaves with more than 90 L, based on specific standardization.

METHOD

Descriptive, documentary research with quantitative approach. In descriptive research, researchers observe, describe and document several aspects about a certain phenomenon, discussing them without manipulating variables or searching for cause-and-effect relationships[6].

From January to June 2019, the documents were identified in an electronic search on the websites NET Purchases, Banco do Brasil Portal, Minas Gerais Purchasing Portal, São Paulo Electronic Purchasing Exchange and Public Purchasing Portal.

In total, 112 bidding processes available online for the acquisition of autoclaves with more than 90 L in the year 2018 were characterized as the access sample of this review. The documents were analyzed using a spreadsheet with variables related to the process identification data, constructive aspects, sterilization cycles, optional items, safety items, and management tools.

RESULTS

Of 112 cases analyzed, six (5.4%) were from Mexico, Honduras, El Salvador, Panama and Paraguay, and 106 (94.6%), from Brazil, distributed in 61 cities of the five regions of the country.

On average, the volume of the internal chamber requested was 326 L, varying from 90 to 970 L, with tolerance of variation between 2.4 and 35% of the specified volume. The variable chamber thickness did not comprise 77.7% (n=87) of the processes and varied from 3.12 to 8 mm between the ones that had it specified. The period over which the company must be responsible for defects in the chamber, provided that the manufacturer's guidelines were followed, was absent in 74.1% (n=83) of specifications,

and varied between 5 and 10 years in the others. The constructive aspects are summarized in Table 1.

Regarding the vacuum system, 78.6% (n=88) of them did not contain information about the design and 40.2% (n=45) did not define the type of vacuum pump. In the remainder, simple (37.5%, n=42), two-stage (14.3%, n=16) and water-free (7.1%, n=8) pumps were predominant; and only one requested gravitational equipment (0.9%, n=1). Regarding the power of the vacuum pump, 91.1% (n=102) of them did not disclose information, but among the ones presenting such information, it ranged from 1.5 to 4 horsepower (hp).

The following specifications about the steam generator were not found: material (39.3%, n=44), float or electronic controls (92%, n=103), standardized and calibrated safety valve at 3 kgf/cm², with an access device for cleaning and function check (70.5%, n=79), electrical power (73.2%, n=82) and automatic cleaning (98.2%, n=110). The most common heating system was electric (86.6%, n=97).

As for the cycles, 32.1% (n=36) of the specifications did not provide information on the temperature. In the others, it varied from 90 to 135°C, with range between 121 and 134°C being common (25%, n=28). With regard to the programmed cycles, 40.2% (n=45) did not stipulate the number of cycles, while in the others a variation of 3 to 30 cycles was specified. The characterization of the cycles is described in Table 2.

Table 1. Distribution of the constructive aspects obtained in the technical specifications for the acquisition of autoclaves with more than 90 L, in 2018, according to frequency.

Inner chamber	Material	N	%
	316 L Steel	87	77.6
	NS	14	12.5
	304 Steel	6	5.4
	Stainless steel	5	4.5
	Format	-	-
	NS	75	67
	Rectangular	35	31.3
	Cylindrical	1	0.9
	Finishing	-	-
	NS	74	66.1
	Polished	35	31.3
	Sandblasted	2	1.8
	Electropolished	1	0.9
External camera	**Material**	**-**	**-**
	316 L Steel	45	40.2
	NS	38	33.9
	304 Steel	26	23.2
	Stainless steel	3	2.7
Doors	**Quantity**	**-**	**-**
	Two	72	64.3
	One	31	27.7
	NS	8	8
	One or two	1	0.9
	Opening	-	-
	Automatic	59	52.7
	Hatch	17	15.2
	NS	17	15.2
	Others	14	12.5
	Sliding, no detailing	5	4.5
Autoclave structure	**Material**	**-**	**-**
	NS	57	50.9
	Anti-corrosion, NS stainless steel	37	33
	316 L, 304, 1.020 steel, carbon steel, brass	18	16.1
Hydraulics	**Material**	**-**	**-**
	NS	46	41.1
	316 L Steel	29	25.9
	Anti-corrosion	17	15.2
	Stainless steel	13	11.6
	Others	7	6.3
	Valves	-	-
	NS	88	78.6
	Pneumatic	21	18.8
	Solenoid valves	3	2.7
External enclosure	**Material**	**-**	**-**
	NS	71	63.4
	304 steel	24	21.4
	Stainless steel	14	12.5
	Anti-corrosion	2	1.8
	430 steel	1	0.9

NS: not specified.

Only one process required interaction devices between operator and equipment on the autoclave discharge side (0.9%), while in the others the most frequent request was the touch screen (48.2%), with dimensions between >3.5 and >7 inches. In general, the request for optional items, alarms and software management tools (Table 3) was not commonly expressed, as well as safety items (Table 4).

Table 2. Distribution of the sterilization cycles obtained in the technical specifications for the acquisition of autoclaves with more than 90 L, in 2018, according to frequency.

Cycles	N	Yes (%)	N	No (%)
Bowie & Dick	59	52.7	53	47.3
Leak test	49	43.8	63	56.3
Liquids	52	46.4	60	53.6
Lactary	3	2.7	109	97.3
Integrated F (zero) calculation	13	11.6	99	88.4
Cycle validation	7	6.2	105	93.8

Table 3. Distribution of optional items and software management tools obtained in the technical specifications for the acquisition of autoclaves with more than 90 L, in 2018, according to frequency.

Optional items	N	Yes (%)	N	No (%)
Printer	85	75.9*	27	24.1
Compressor	21	18.7	91	81.3
Water treatment system	92	82.1	20	17.9
Water storage system for recirculation	5	4.5	107	95.5
Connectivity for traceability systems	3	2.7	109	97.3
Remote access	1	0.9	111	99.1
Discharge cooling system	2	1.8	110	98.2
Redundancy in temperature measurement	9	8	103	92
Software management tools	**N**	**Yes (%)**	**N**	**No (%)**
Control of the number of operators	3	2.7	109	97.3
Access levels for operators	3	2.7	109	97.3
Preventive maintenance control	4	3.6	108	96.4

*Including thermal and matrix.

Table 4. Distribution of safety items obtained in the technical specifications for the acquisition of autoclaves with more than 90 L, in 2018, according to frequency.

Items	N	Yes (%)	N	No (%)
Closed door control	17	15.2	95	84.8
Door anti-crushing system	13	11.6	99	88.4
Door interlocking system	13	11.6	99	88.4
Cycle starts only in the presence of steam pressure in the generator or supply line	4	3.6	108	96.4
Emergency button	30	26.8	82	73.2
Depressurization of the chamber when in excess pressure	2	1.8	110	98.2
Automatic purge	3	2.7	109	97.3
Safety thermostat for protection of electrical resistances in the steam generator	10	8.9	102	91.1
System for interrupting the electrical supply of the resistances in the absence of water	9	8	103	92

There was no specification about the temperature sensor in 75.9% (n=85) of the processes, while in 22.3% (n=25) PT-100 was specified and in 1.8% (n=2) the generic term "thermocouple" was used.

The following items were considered vague or difficult to understand: manometer with silicone gasket (0.9%, n=1), system to save energy in standby mode (0.9%, n=1), RS232 port interface (1.8%, n=2), graphic recorder (1.8%, n=2), USB port (10.7%, n=12), water- or energy-saving system (5.4%, n=6), data export interface (1.8%, n=2), drainage system (0.9%, n=1) and water-draining and cooling-process smart system (0.9%, n=1).

No information on the space/side for maintenance was identified in 89.3% (n=100) of the processes.

DISCUSSION

Constructive aspects

The volume of the chambers is usually described in liters, and rectangular chambers allow for greater useful load capacity compared to cylindrical chambers. There are chambers with different nominal volumes, while the useful load capacity is the same, considering the number of sterilization units or baskets, which can vary in shape (trapezoidal or rectangular) in addition to the standard: ISO[7] or DIN[8] (48 or 54 L, respectively).

The specification per sterilization unit may be more advantageous for the chamber capacity, as it translates its useful, not the nominal volume. Another reason for following the concept of sterilization units comes from the shape of the chambers. In this case, the manufacturers define their standard measures according to the cubing in multiples of sterilization units (48 or 54 L), where the width of a chamber can vary from 640 to 670 mm, that is, surplus volumes that do not translate to greater load capacity.

As for the chamber building material, 25.9% (n=29) of the processes specified materials that may be used do not comply with the Brazilian Technical Standards Association (ABNT) 11816, which requires 316 stainless steel[7]. Some models use 316 L or 316 Ti, which are added with titanium to reduce the risk of intergranular corrosion due to the welding process[9].

The structure material was not described in 50.9% (n = 57) of the processes, while the rest described it in a variety of ways: anticorrosive, carbon steel and various types of stainless steel, from 316 to 304 L. "Structure" means all support for the components of the autoclave: the sterilization chamber (known as the internal chamber), the hydraulic and electrical components, and the front and side panels.

For the equipment conservation, it is important that carbon steel structures are not used, because of the contact with other noble metals; then, galvanic corrosion can be avoided[10]. However, any anti-corrosion materials, such as stainless steel or aluminum, can be selected.

Regarding hydraulic piping, 74.1% (n=83) of the processes requested materials that may not comply with the NBR ABNT 11816 rules, which sets the requirements for autoclaves with a volumetric capacity greater than two sterilization units[7]. This document recommends 316 L stainless steel for pipes and does not recommend the use of 304 stainless steel as well as any other type of material, however only 25.9% (n=29) specified 316 L stainless steel. The choice of the hydraulic piping material is important to prevent corrosion or scale formation, which can considerably decrease the autoclave's life and even the efficiency of the cycle, greatly increasing the need for corrective maintenance.

Regarding the doors, 52.7% (n=59) of the bids required automatic doors, while the others did not specify the type of closure or requested a hatch type door. Automatic systems normally operate with dynamic sealing joints, while systems with manual closing use static joints, in which the tightness of the chamber can vary according to the manual force applied and the mechanical adjustment of the positioning sensors. There are numerous sources of air leakage in the autoclaves, including door gaskets, which can compromise the sterilization process[11].

In view of this scenario, automatic closing systems are one of the options to minimize the risk of air leakage. Additionally, the use of devices that check the door seals increases the protection of both the operator and the equipment, such as the leak test, used to demonstrate that the air leakage from the chamber during the use of the vacuum pump does not exceed a level that compromises the quality of the sterilization[8].

Sterilization cycles

As for the programmed cycles, 46.4% (n=52) of the processes requested cycles for liquids, but there was no

specification for their parameters. The controls for these cycles can be different. That is, depending on the equipment, there is a temperature sensor dedicated to the products, while in others the same reference sensor of the camera is used. Therefore, certain equipment does not have a temperature sensor positioned in the liquid, which can result in underestimated or overestimated temperatures, inducing the loss of the liquid's properties, such as culture media.

Likewise, some equipment can technically and more quickly promote forced cooling, while others perform natural cooling in a longer cycle time. The longer cycle can impact productivity and cause the loss of the liquid characteristic.

No bidding process specified the criteria for cycle performance in terms of productivity or time. Some manufacturers offer options to optimize the sterilization process time, with high productivity steam generation systems and vacuum systems with more flow and a better vacuum level. For example, an autoclave that uses a liquid ring vacuum pump can reach a maximum vacuum of 33 mbar, since values with a higher depth are not reached because of the cavitation that occurs inside the pumps, especially in Brazil, where the water temperature easily exceeds the required 15°C[12].

However, there are vacuum systems with better performance that use atmospheric ejectors, with no damage to the system by cavitation, or water-cooling chiller systems, which use electricity.

It is recommended that the autoclaves have controls that identify the vacuum value that must be reached and the vacuum rate or time, in order to emit alarms in the phases in which the vacuum pump is used. The performance of the pump can be influenced by the temperature of the water in different seasons of the year, as well as by the wear or leak in the vacuum system.

Regarding the leak test cycle, also known as leak test or vacuum test, 43.8% (n=49) of the bids analyzed did specify the automatic cycle. NBR ABNT ISO 17665-2 requires that the procedure be performed on a quarterly basis[13]. However, with the modernization of the equipment that brings the automatic leak test cycle, many establishments run it daily, increasing the safety of the process.

It must be considered that the leak test does not guarantee total seal of the chamber in cases in which air enters through the door trim, for example, because the pressure profile of the leak test cycle is made only in vacuum, while the sterilization cycle is dynamic, ranging from vacuum to superatmospheric pressures. Thus, the Bowie & Dick cycle is indicated to complement the leak test.

Optional items and management tools

Of the processes analyzed, 75.9% (n=85) requested matrix or thermal printers to register physical indicators. The thermal printer has the advantage of not using a ribbon ink cartridge as an input, but the major disadvantage is linked to the storage of information. Normally, autoclaves with a thermal printer do not use special papers to maintain the recorded data and, as they are not indelible, the records that should be archived for the purpose of traceability and sanitary inspection can be lost before five years[14]. In this context, dot matrix printers have advantages over data maintenance.

Record systems that do not use paper are also a viable alternative for data maintenance and still allow statistics and speed in the search for information, since they are integrated with management software.

Most processes required water treatment systems already incorporated in the purchase of the equipment, generally describing the treatment by reverse osmosis. According to EN285[8], considered one of the main standards for the construction of large volume autoclaves, the water that feed the autoclaves must meet the minimum requirements for certain contaminants. In some situations, depending on the parameters of the water entering the system that may not undergo pretreatment, reverse osmosis alone is not sufficient. For example, supposing that the reverse osmosis system reduces 95% of conductivity, in an inlet water with 100 $\mu S/cm^2$, 5 $\mu S/cm^2$ would remain, thus meeting the requirements. However, if the water is 200 $\mu S/cm^2$ after treatment, 10 $\mu S/cm^2$ would remain, which would not be in compliance. Therefore, it is recommended that the parameters of the feed water are known to define the most appropriate treatment system.

The bidding processes did not clearly specify the construction characteristics or even the performance of the storage systems for water recirculation in the vacuum pump. Only 4.5% (n=5) of the processes requested a water storage system for recirculation, in order to save the water used in the vacuum system, since the autoclave may require approximately 500 L per cycle in the case if liquid ring vacuum pumps[15]. However, the performance of water recirculation vacuum systems may vary depending on the cycle configuration, load and room temperature.

Currently, not only are recirculation systems available for reusing the water in the pump, but also vacuum systems that do not use water (water free). The reduction in water consumption can be achieved with this type of pump, present in only 7.1% (n=8) of the processes.

Another benefit is the return on investment, since the value of the water consumed and its disposal must be monetized. Additionally, although not tangible for accounting, the lack of water supply can damage vacuum systems or interrupt the equipment's operation indefinitely. From a mechanical point of view, the temperature of the water used in liquid ring pumps directly influences the performance of the system, whereas water-free pumps do not depend on this variable.

Contrary to expectations, 8% (n=9) of the processes specified a redundancy system for measuring the temperature of the internal chamber, although it is considered a critical process variable. Since 1996, the EN285[8] requires redundancy in the sterilization temperature and pressure measurement systems. The document also indicated that the temperature and pressure measurement system must be independent for the registration and indication/control sensors. Thus, a minimum configuration of the autoclave with two-sensors drainage would be allowed, as the registration sensor would be an instrument to validate the measurement of the control sensor, increasing the safety of process.

In the 2015 edition of the same standard, this specification was updated. In addition to requesting at least two temperature and pressure sensors for process redundancy, it also requests communication between sensors, so that one of them can automatically perceive the pre-established temperature deviation and inform the user of a process failure. This update adds safety to sterilization, since new alarms can be automatically generated by the autoclave, without requiring an operator to manually compare values. One way to meet this requirement is to install independent microprocessors, each with its analog system to measure temperature and pressure. There is a tendency in several countries, including Brazil, for the standards for building autoclaves to have this redundancy configuration, and it is wise to consider it in specifications.

Computerized management tools, remote access, operator control, maintenance control and integration with traceability systems were not included in most bids. This goes against the quality control and traceability required for the safety of the processes. No requirements for data recording were found.

Autoclave manufacturers normally have software as an optional item in accordance with Title 21 of the Federal Regulations Code (CFR 21) part 11[16], a United States of America standard that establishes the Food and Drug Administration regulations on electronic records and electronic signatures that are reliable and equivalent to paper records. In practice, this software is applied to manufacturers of medical devices and other industries for the implementation of controls and audit trail, being possible to track the accesses to the autoclave and, in a structured and reliable way, to learn all the changes in revenue from cycle, calibration and other parameters, with constant reporting and recording of the reason for each change.

These items were the least contemplated by the processes, while the most mentioned ones were emergency button (26.8%, n=30) and closed-door control (15.2%, n=17). There were no requests for detectors of non-condensable gases (NCG), which cannot be liquefied at the temperatures and pressures used in saturated steam sterilization[8]. The maximum limit of NCG allowed for the sterilization process is 3.5%. That is, each 100 mL of condensate steam can contain a maximum of 3.5 mL. This criterion was determined in national and international standards, after experiments with an air detector in 1960[8,13].

Currently, the detection of NCG in sterilization processes occurs with challenging packages, with chemical and biological indicators during the cycles, in addition to the Bowie & Dick test in the first cycle of the day[13]; however, there is evidence that the failures related to the presence of NCG do not occur only in the first cycle of the day. Therefore, the recommendation is to control these gases in every cycle[17].

The physical controls of pressure and temperature measurement systems alone are not able to identify NCG[8,16]. Thus, to increase the safety of sterilization, it is possible to install an air detector in the autoclave and unleash it in each cycle. This device is mandatory in some European countries and monitors possible failures in air removal, steam penetration and the presence of NCG in all sterilization cycles.

The main advantages of the NCG detector are: monitoring of all cycles, integration with the equipment, acting independently of the operator to cancel the cycle in the event of failure, and providing objective results instead of the colorimetric results of the chemical indicators, whose reading can be subjective[18].

The main limitation of this study was the sample, since the access to it depended on data available on the internet.

Therefore, not all bidding processes in Brazil and Latin America were analyzed.

This article did not aim to provide rigid models to guide the elaboration of technical specifications or restrict/frustrate the competitive character, but to contemplate theoretical bases that can subsidize the choices.

In this sense, the authors reinforce the need to comply with legislation related to public bids and contracts and to monitor updated scientific evidence for decision-making.

CONCLUSION

We could conclude that certain technical specifications are outdated, in some cases compromising the safety of sterilization and professionals who work directly with the equipment. The applications, as well as the cycles, parameters and performance criteria of the equipment were not adequately described in some processes.

That being said, it is recommended that the technical specifications in new bidding processes consider standardization, new technologies and safety items in accordance with the legislation. Additionally, the direct participation of professionals involved in the health product processing committees should be mandatory in these processes.

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