VALIDATION OF DAILY MEDICAL DEVICE CLEANING IN THE STERILE PROCESSING DEPARTMENT

Validação da limpeza de produtos para saúde no cotidiano do centro de material e esterilização

Validación de la limpieza de productos de salud en todos los días del centro de material y esterilización

Rafael Queiroz de Souza[1*], Ana Tércia Barijan[2], Jeane Aparecida Gonzalez Bronzatti[3], Paulo Roberto Laranjeira[4], Kazuko Uchikawa Graziano[5]

ABSTRAC: Objective: To discuss the aspects that should be considered in the concurrent cleaning validation at Sterile Processing Department (SPD). **Method:** Narrative review of scientific literature, legislation, and pertinent normalizations. **Results:** The routine cleaning validation should consider the product design, definition, and feasibility of standard operating procedures (SOP); SPD structure; staff sizing; selection and training; and the recording and interpretation of results obtained by routine chemical tests. **Conclusion:** The concurrent cleaning validation of health products at SPD points out the value of this stage to all employees in the sector such that cleaning becomes a core function of health service product processing.
Keywords: Operating Room Nursing. Perioperative Nursing. Consumer Product Safety. Quality Assurance, Health Care. Quality Control.

RESUMO: Objetivo: Discutir os aspectos que devem ser considerados na validação concorrente da limpeza no Centro de Materiais e Esterilização (CME). **Método:** Revisão narrativa da literatura científica, legislação e normatização pertinentes. **Resultados:** A validação da limpeza na rotina deve considerar: o *design* dos produtos, a definição e a exequibilidade dos procedimentos operacionais padrão, além da estrutura do CME, dimensionamento, seleção e treinamento de pessoal, registro e interpretação dos resultados obtidos pelos testes químicos na rotina. **Conclusão:** A validação concorrente da limpeza dos produtos para saúde no CME imprime a cultura da valorização dessa etapa do processamento entre todos os colaboradores do setor, de tal forma que a limpeza passa a ser, de fato, o núcleo central do processamento.
Palavras-chave: Enfermagem de centro cirúrgico. Enfermagem perioperatória. Segurança de produtos ao consumidor. Garantia da qualidade dos cuidados de saúde. Controle de qualidade.

RESUMEN: Objetivo: Discutir los aspectos que deben considerarse en la validación concurrente de limpieza en el Centro de Materiales y Esterilización (CME). **Método:** revisión narrativa de la literatura científica relevante, legislación y normas. **Resultados:** La validación de la limpieza en la rutina debe considerar: el diseño de los productos, la definición y la viabilidad de los procedimientos operativos estándar, además de la estructura del CME, dimensionamiento, selección y capacitación del personal, registro e interpretación de los resultados obtenidos por las pruebas químicas en el rutina **Conclusión:** La validación concurrente de la limpieza de productos de salud en CME impresiona la cultura de valorar esta etapa de procesamiento entre todos los empleados del sector, de tal manera que la limpieza se convierta, de hecho, en el núcleo central del procesamiento.
Palabras clave: Enfermería de quirófano. Enfermería perioperatoria. Seguridad de productos para el consumidor. Garantía de la calidad de atención de salud. Control de calidad.

[1]Nursing degree; post-doctorate in sciences. Researcher and professor of lato and stricto sensu graduate courses; hired speaker for product processing companies on patient health and safety - São Paulo (SP), Brazil.
[2]Nursing degree; Master's in Sciences. Specialization in scientific and educational matters at the Medical Solutions Division of 3M do Brasil - Sumaré (SP), Brazil
[3]Nursing degree; PhD in Sciences through the School of Nursing at the Universidade de São Paulo (USP). Researcher and professor of graduate courses lato sensu in Brazil and stricto sensu in Peru through the Universidad Alcalá. Technical Health Consultant; speaker hired by companies to address issues in the areas of surgical assistance and health product processing - São Paulo (SP), Brazil.
[4]Electrical engineering degree; doctorate in sciences. Sterilization Guarantee Manager at Cardinal Health. 3M speaker; member of the Association for the Advancement of Medical Instrumentation - United States.
[5]Nursing degree. Senior Professor, Department of Medical-Surgical Nursing, School of Nursing, Universidade de São Paulo; pedagogical coordinator of the MBA/CSSD course, from the Faculdade CEAT - São Paulo (SP), Brazil.
*Corresponding author: rafaelqsouza@hotmail.com
Received: 10/12/2019 - Approved: 01/19/2020
DOI: 10.5327/Z1414-4425202000010009

INTRODUCTION

The validation of standard operating procedures (SOP) has been a recurring theme in discussions involving safety in the processing of medical devices (MD). The growing concern with this topic is justified mainly by the complexity of products destined for less invasive procedures, which has imposed increasing challenges to Sterile Processing Department (SPD), such as clamps for robotic surgery and digestive endoscopes with inaccessible channels.

In the given context, cleaning stands out as a fundamental procedure, as it makes products safe to handle and prepares them for disinfection or sterilization[1]. In the United States, the Food and Drug Administration (FDA) has published its own guidelines for the validation of instructions for use (IFU) while processing health services products[2]. In Brazil, there have been similar initiatives, such as the translation of the ISO 17664[3] standard, which establishes information on processing that must be provided by the manufacturer to users, as well as the Resolution of the Collegiate Directorate of the National Health Surveillance Agency (ANVISA) number 15[1], which requires that each stage of processing follow a SOP based on updated scientific references and pertinent standardization.

For SOP to be validated, sophisticated laboratory methods are invariably used for the detection of organic waste, with high sensitivity and standardized procedures such as those published by the *International Organization for Standardization (ISO)*, *Association for the Advancement of Medical Instrumentation (AAMI)*, *FDA* and pharmacopoeias. Although necessary in prospective validations, these methods are often not routinely usable, and professionals often ask: *how can we ensure that the results "*validated*" (our emphasis) by the manufacturer are being achieved in practice?* Additionally, owing to the lack of clear direction from regulatory agencies and standardization of the validation process, manufacturers may provide IFU inconsistent with good practices, without proof of validation, validated under conditions that do not simulate a SPD, and which are sometimes impossible to follow, causing distrust about their applicability.

To answer this question, the concept of validation, which includes producing objective evidence such that the specific requirements for a certain purpose can be consistently fulfilled, needs to be reexamined[4]. In studies involving the validation of cleaning processes, consistent results can be obtained by elaborating and fulfilling a SOP, which aims at standardizing and reducing the variability of results.

Consistent results in a laboratory scenario are facilitated by the control of variables; however, in the cleaning area, many SOP compromising factors may be present, whether structural (undersized physical area), technological (obsolete and faulty equipment), materials (consumables, such as detergents) and human (variations in individual characteristics of staff members such as physical strength, ability, and familiarity with SOP), among others[2]. Thus, besides SOP, another procedure that is necessary to ensure quality is monitoring, which can be carried out by inspections through magnifying glasses and chemical tests for use at SPD[1], both of which are easy to incorporate into the routine.

Based on the information presented, this study will discuss the aspects that should be considered in the concurrent validation of cleaning at SPD. It should be noted that this study is not intended to replace methods described in the relevant standards, which should be used by manufacturers in the prospective validation of IFU; its purpose is to support professionals in the validation of cleaning SOP in SPD's daily routine.

OBJECTIVE

Discuss what aspects should be considered in the concurrent validation of the cleaning of health products at SPD.

METHOD

A narrative review of the scientific literature, and legal and regulatory documents that underpin validation procedures and how they tie in with SPD's day-to-day cleaning of MD.

RESULTS AND DISCUSSION

Characteristics of the MD that can be processed

The MD that can be processed allow for repeated cleaning, preparation, and disinfection or sterilization processes[1]. However, several characteristics can influence cleaning, such as being dismountable to favor the cleaning of areas with

difficult access; being transparent to allow the visualization of dirt; having a solid structure to avoid the accumulation of dirt; having an internal structure that allows the entry and exit of water, which facilitates the removal of dirt by the mechanical action of water[5]; and the quality of the finish of the internal surfaces.

In practice, it is noted that the design of the products does not always favor cleaning, and the difficulty of removing dirt is increased by the type of organic matter (e.g., blood, bone, or fat) contained in it. Additionally, scientific literature has shown that products routinely processed by SPD, such as flexible intramedullary reamers, are not cleanable owing to conformation[6]. Therefore, a careful analysis of the cleanability of each product is necessary, considering not only the technical capacity, but also the accessibility of the design.

Structure for the implementation of SOP

The concurrent validation of cleaning SOP is necessary owing to the variety of inputs and equipment at SPD. Although the instructions for use (IFU) contain all the information needed for cleaning[3], in practice, it is noted that the market offers different equipment, solutions, and artifacts for cleaning, such as brushes, sponges, and PULL THRU™ cleaning devices, among others. There are services where manual processes predominate, while in others, automated processes do, but SPD can only process MD compatible with their technical operational capacity and infrastructure classification[1].

In order to ensure consistency in cleaning results, the equipment used must be subject to installation, operating, and performance qualifications at least once a year[1]. The equipment must be qualified within the standardized interval of 12 months or each time it undergoes maintenance, change of location, and suspected failures[1,7]. These procedures must be in accordance with the change assessment, which consists of a protocol that establishes the critical operating points of the equipment and the routine, determining which qualification must be redone to ensure that the equipment remains qualified and the process validated[7].

These procedures aim to ensure that the equipment has been delivered and installed according to its specifications, operates within the original manufacturing parameters, and has consistent performance, with identical parameters, using the most challenging load defined by SPD[1]. According to the manufacturers, the equipment may require verification procedures at each use: daily, quarterly, annually, or in accordance with the change control established in partnership with the clinical engineering service[8]. However, there is equipment, such as ultrasonic washers and fluent steam cleaning systems, which does not yet have technical construction and qualification standards, and it is recommended that the IFU of the respective manufacturers be followed. In general, for the conservation and operation of cleaning equipment, the manufacturers also recommend the criteria established in the ABNT NBR ISO 17665-2:2013[9] standard regarding the quality of the water that is supplied to the equipment.

As for cleaning solutions, special attention should be given to IFU, including information on dilution, water quality for preparation, immersion time, temperature range, and pH. In addition, a SPD should have brushes compatible with the length, diameter, and IFU of the MD, with soft bristles so as not to damage the internal surfaces, and with a sufficient length of bristles to promote friction on the surface[10].

Finally, the validation of cleaning procedures is conditioned not only by the structure available at a SPD, such as equipment and consumables, but also by the documented evidence that they are in the right condition for use through periodic verifications.

Definition of SOP

In general terms, the SOP is an official document that describes each critical and sequential step that should be taken by the operator to guarantee the expected result of a task[11] and should be widely disseminated and elaborated on the basis of scientific literature and related standards[1]. As SOP is a standardized sequence for performing a given procedure, it is closely linked to the training of professionals working in the cleaning area.

The MD IFU includes all or some of the activities – point-of-use preparation, preparation, cleaning, disinfection, drying, inspection, maintenance, testing, packaging, sterilization, and storage – and is therefore the basis for defining a MD processing SOP in the SPD[3]. Any activities related to processing should be in accordance with the relevant national regulations and evidence-based recommendations from renowned national or international organizations.

However, the evaluation of the IFU provided by the manufacturer requires thorough analysis, especially in Brazil,

where they can be provided without validation. The literature has reported inconsistent recommendations, serious conceptual errors, and mistaken procedures in IFU[12]. Only the MD manufacturer can provide the IFU. If the IFU is translated by the distributor, it must be an official translation or the user may request the original manufacturer to verify the content. Additional care should be taken regarding translation errors.

Any procedures must have their steps clearly described and be technically feasible for SPD staff to implement. SOP with excessively long execution times and many manual cleaning steps can lead to the normalization of deviations and inconsistencies, constituting a major challenge for SPD, as well as seriously compromising the effectiveness of cleaning, especially in services with little infrastructure and/or high demand[6].

The total execution time of a given SOP can also be compromised by the logistics for receiving loaner sets (consigned MD) from SPD. The delivery of these MD outside the timeframe defined by SPD is a reality and can be a potential factor for non-compliance with SOP.

Sizing and training of personnel

In Brazil, historically, the operational activities developed at SPD have largely been carried out by technicians and nursing auxiliaries, while the technical and administrative management has been carried out by nurses. Despite the fundamental role that SPD plays in the quality of the assistance process, it is noted that it often has insufficient or inadequately qualified staff[13].

All steps of MD processing must be performed by professionals for whom these activities are regulated by their class councils[1]. In view of this situation, the Federal Nursing Council (COFEN) published the COFEN Resolution n.424/2012, which regulates the duties of nursing professionals at the SPD and MD processing companies[14].

Recently, considering the need to review and update parameters that subsidized the planning, control, regulation, and evaluation of nursing care activities, COFEN established Resolution n. 0543/2017[15]. Currently, the staff needs to consider issues such as mission, vision, size, staff policy, material and financial resources; organizational and physical structure; types of services and/or programs; technology and complexity of services and/or programs; and attributions and competencies specific to the members of the different services[15].

Technical–scientific and administrative aspects should also be considered, such as the dynamics of the units' operations in different shifts, managerial model, work methods, working hours, weekly workload, professional performance standards, technical safety index, proportion of senior and mid-level nursing professionals, and quality indicators[15].

Even after making adjustments for the number of professionals at SPD, it is necessary to establish the minimum competence an individual should have to perform the activities in this sector. As this is a service in which tasks involve very specific procedures, in addition to technical competence, improvement and development must be valued through ongoing education.

Professionals working at SPD should receive initial guidance on how to address all tasks performed for MD, including those related to policies and procedures for infection prevention and control, safety, clothing, personal hygiene, state and federal legislation, and regulations[16].

It is recommended that a continual education program be conducted at SPD at regular intervals, with the objective of reviewing and updating knowledge and skills (thus maintaining professional competence) and providing additional training whenever new products, equipment, and procedures are introduced[16]. The work associated with education and training provides workers with essential information to responsibly perform the activities assigned to them, reduce the risks of operational errors, and ensure that professionals are familiar with the techniques used[16].

The professionals who work at SPD and at processing companies must receive specific and periodic training in the following topics: MD classification; basic microbiology concepts; transportation of contaminated products; cleaning processes; disinfection, preparation, inspection, packaging, sterilization, and operation of existing equipment; monitoring of processes by chemical, biological, and physical indicators; traceability, storage, and distribution of MD; and the maintenance of product sterility[1]. Specific training for the use of personal protective equipment appropriate to the activities developed at SPD[1] should also be included.

Although SPD managers recognize the need for and importance of ongoing training for employees, the pace of work imposed on the sector rarely allows professionals to take leave from their jobs to receive the minimum training required by ANVISA or training on new procedures. To validate cleaning processes, in addition to having in place all the

standardized steps, it is essential to have committed professionals prepared to perform the SOP.

Chemical tests

A report of 234 events related to surgical MD associated 34% of the causes with inadequate cleaning and the dirt MD were detected in the operating room[17]. These data showed that there was a failure in inspection and monitoring, which are important tools for quality assurance at SPD[16].

Cleaning monitoring evaluates the presence of organic and inorganic residues in the instruments, such as blood, biofilm, fats, tissue fragments, body secretions such as feces, respiratory secretions, microorganisms, bone cements, viscoelastic, and salts, among others[16]. This procedure should be performed through visual inspection, with the aid of image intensifier lenses, and complemented, when indicated, by chemical tests available in the market[1]. Currently, some SPD already have higher resolution image amplification technologies, which are an excellent resource for monitoring as well as for the inspection of functionality, detecting fatigue and the onset of corrosion in small structures.

Some markers can assist in monitoring cleanliness, such as protein, hemoglobin, microbial load, and adenosine triphosphate[16]. Other tests are not yet routinely possible for carbohydrates, endotoxins, fats, and sodium; however, they can be performed in laboratories. Routine tests can be used to evaluate employee performance, effectiveness of cleaning SOP, and equipment functionality[16].

Chemical tests provide quantitative information such as the relative light units for Adenosine TriPhosphate (ATP) detection. The cut-off values can be determined based on scientific reference or, when not available, by trend analysis of the historical series; it is therefore essential that the values obtained are stored. Another example is semi-quantitative tests, which change color when a certain type of dirt is above pre-established reference values. Before determining the choice of test, one must take into consideration the IFU, indications, and limitations of each technology.

Ideally, the cleaning verification should include inspection results and chemical tests, including internal (lumens) and external surfaces, effectiveness tests of the equipment used in the process (specific tests offered by various manufacturers), and monitoring of critical process parameters such as temperature used (usually obtained from the forms and records made by the equipment itself)[16].

SPD technical managers and managers shall establish appropriate quality levels for the products and services they produce and ensure that these levels are consistently maintained[18]. Therefore, more important than the choice of one or more tests is the management of the information provided for SPD quality control.

The concept of quality refers to the degree of excellence of a product or service, and one of the ways of evaluating it is by means of indicators. The results of the indicators can indicate inconsistencies in the process, which can be resolved by carrying out a cause analysis, identifying the problem, and then proposing changes to resolve them[16,18]. Therefore, the implementation of any chemical tests should be accompanied by quality tools, such as the Pareto diagram, PDCA cycle (*Plan, Do, Check, Act*), *check* sheet, dispersion diagram, and cause-and-effect diagram.

In SPD's routine, it is noted that test results are recorded according to defined periodicity, but unsatisfactory results are often found and there is no action or contingency plan. In addition, professionals often make improper adaptations to monitoring technologies, for example, a product that was developed for monitoring thermodisinfectors is used in ultrasonic washers.

Sampling and comparative controls in concurrent validation

In the concurrent validation of cleaning, criteria must be established to select the MD to be examined, either by the visual magnified method or by commercially available chemical tests[1], as it is impossible and unnecessary to legitimize the cleaning of all MD processed on a daily basis by SPD. This procedure, characterized as sampling[19], should follow deliberately defined criteria, for example, the complexity of MD conformation from the perspective that "the more complex the MD, the more difficult it is to remove the retained dirt." In this sense, MD that have lumens should no doubt go through all the controls not only because of the assessment of the cleanliness of internal spaces but also if the lumens are patent passing rigid stems in search of, for example, solid residues such as bone remains in cannulated orthopedic instruments[6]. Another example is the evaluation of the presence of residues of viscoelastic solution solidified in hydrodissection cannulas. The rate of materials

found dirty, divided by the total number of units examined, will be the indicator of the quality of the cleaning that will signal problems that must be solved. These can be related to human resources performing the cleaning, the products and inputs used, equipment performance, and work overload in the cleaning sector. Other rational criteria suggested for sampling may be monitoring the cleaning quality of the employees starting the activity; monitoring the performance of recently acquired, obsolete, or after-maintenance cleaners; and monitoring the cleaning of complex MD, among others.

It should be emphasized that the competing validation of clean MD cleaning by automated methods should not be underestimated. The equipment may have different performances according to its history and origin, scheduled preventive maintenance, and time of use, and even those considered "excellent" in performance qualification may unexpectedly fail in a cycle owing to, for example, the "shadow area," where the mechanical action of the jet under pressure or ultrasound is smaller or even absent. That said, AAMI recommends the daily testing of equipment[16].

Besides this case, the problem may also be related to human failure in loading the machines, an aspect that is more difficult to control but no less important.

FINAL CONSIDERATIONS

Through this study, it was demonstrated that the concurrent validation is beyond the simple compliance of the SOP, as it contemplates aspects related to the design of the products, feasibility of the SOP, SPD structure, sizing and training of personnel, and selection, documentation, and interpretation of the results obtained by the chemical tests.

The practice of concurrent validation of MD cleaning at SPD points out the value of this stage of processing to all professionals working in this section such that cleaning becomes a core function of processing.

REFERENCES

1 Brasil. Ministério da Saúde. Resolução da diretoria colegiada nº 15, de 15 de março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. Brasília, 2012.

2 U.S. Food and Drug Administration. Reprocessing medical devices in health care settings: validation methods and labeling. Guidance for industry and food and drug administration staff. 2015 [cited 2018 May 30]. Available at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

3 Associação Brasileira de Normas Técnicas (ABNT). NBR ISO 17664:2015: Esterilização de produtos para saúde — Informação a ser fornecida pelo fabricante para o processamento de produto para saúde resterilizável. Rio de Janeiro, 2015.

4 U.S. Food and Drug Administration. Code of Federal Regulations Title 21 Part 820. Quality system regulation [cited 2018 May 30]. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820

5 Graziano KU, Bálsamo AC, Lopes CLBC, Zotelli MFM, Couto AT, Paschoal MLH. Criteria for evaluating dificulties in cleaning single-use articles. Rev. Latino-Am. Enfermagem. 2006; 14(1):70-76. Disponível em: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S010411692006000100010&lng=en. http://dx.doi.org/10.1590/S0104-11692006000100010.

6 Souza R, Bronzatti J, Laranjeira P, Mimica L, Silva C, Cruz A, Graziano K. Safety assessment of reprocessing of flexible intramedullary bone reamers for orthopedic surgery. Revista SOBECC [Internet]. 2017 Abr 4; [Citado em 2018 Jun 21]; 22(1): 17-22. Disponível em: https://revista.sobecc.org.br/sobecc/article/view/137

7 Associação Brasileira de Normas Técnicas (ABNT). NBR ISO 17665-1, Esterilização de produtos para saúde - Vapor – Parte 1: Requisitos para o desenvolvimento, validação e controle de rotina nos processos de esterilização de produtos para saúde. Rio de Janeiro: ABNT; 2010.

8 Laranjeira P, Bronzatti J, Souza R, Graziano K. Bases for safe use of thermal washer disinfectors emphasizing the release for use after technical intervention. Revista SOBECC [Internet]. 2016 Dez 2; [Cited 2018 May 11]; 21(3): 178-184. Available in: https://revista.sobecc.org.br/sobecc/article/view/129

9 Associação Brasileira de Normas Técnicas (ABNT). NBR ISO 17665-2, Esterilização de produtos para saúde - Vapor – Parte 2: Guia de aplicação da ABNT NBR ISO 17665-1. Rio de Janeiro: ABNT; 2013.

10 Bajolet O, Ciocan D, Vallet C, De Champs C, Vernet-Garnier V, Guillard T. et al. Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing Pseudomonas aeruginosa. J Hosp Infect. 2013 Apr;83(4):341-3.

11 Nogueira LCL. Gerenciando pela qualidade total na saúde. 3ª ed. Nova Lima: INDG Tecnologia e serviços LTDA, 2008.

12 Bruna C, Souza R, Almeida A, Suzuki K, Turrini R, Graziano K. Laryngoscope handles reprocessing: integrative review. Revista SOBECC [Internet]. 2016 Jun 8; [cited 2018 May 11]; 21(1): 37-45. Available in: https://revista.sobecc.org.br/sobecc/article/view/40

13 Costa JA, Fugulin FMT. Nursing activities in central supply and sterilization: a contribution to personnel design. Acta Paul Enferm. 2011; 24(2):249-56. Disponível em: www.scielo.br/pdf/ape/v24n2/15.pdf

14 Conselho Federal de Enfermagem – COFEN. Resolução COFEN n. 424/2012: Normatiza as atribuições dos profissionais de enfermagem em Centro de Material e Esterilização (CME) e em empresas processadoras de produtos para saúde. Disponível em: www.cofen.gov.br/resoluo-cofen-n-4242012_8990.html

15 Conselho Federal de Enfermagem – COFEN. Resolução COFEN n. 0543/2017: Atualiza e estabelece parâmetros para o dimensionamento do quadro de profissionais de enfermagem nos serviços/locais em que são realizadas atividades de enfermagem. Disponível em: www.cofen.gov.br/wp-content/.../RESOLUÇÃO-COFEN-Nº-543-2017-completa.pdf

16 American National Standard/Advancing Safety in Healthcare Technology – ANSI/AAMI ST79: 2017. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Arlington, VA, 2017.

17 Event Reporting & Analysis - Alerts. (2017). If It's Not Clean, It's Not Sterile: Reprocessing Contaminated Instruments. Institute, ECRI. Retrieved from https://www.ecri.org/components/PSOCore/Pages/e-lert041117.aspx?PF=1?source=print

18 International Association of Healthcare Central Service Material Management – IAHCSMM. Quality Assurance. Chicago-IL, 2016.

19 Silva NN. Amostragem Probabilística: Um Curso Introdutório. São Paulo: EDUSP – Editora da Universidade de São Paulo, 2001.