

CHANGE ASSESSMENT PROTOCOL FOR STEAM STERILIZATION PROCESS*

Protocolo de avaliação de mudança para o processo de esterilização a vapor

Protocolo de evaluación para el proceso de esterilización a vapor

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ABSTRACT: Objective: To report on the experience of creating a protocol, which evaluates changes in the steam sterilization process. **Method:** Experience report, based on the theoretical basis and validation of new equipment at the Central Sterile Supply Department. The validation occurred between May and July of 2016, and tested the suitability of the process and the material, using ISO 17665-1. The protocol includes main points that influence the decision of whether to maintain or re-evaluate the equipment. The protocol validation was carried out by five nurses from the Central Sterile Supply Department. **Results:** The protocol was composed of six actions, which required verification of the equipment, and three actions that did not impact any critical points in the process. The most critical point observed was with wet materials. The protocol was validated by the nurses from the Central Sterile Supply Department, and presented as a flowchart. **Conclusion:** The protocol promotes the idea of nurses acting critically in corrective and preventive maintenance of steam sterilization equipment. **Keywords:** Sterilization. Steam. Equipment and supplies, Hospital. Perioperative nursing.

RESUMO: Objetivo: Relatar a experiência da criação de um protocolo de avaliação de mudança do processo de esterilização a vapor. **Método:** Relato de experiência, com base no fundamento teórico e na validação de novos equipamentos do Centro de Material e Esterilização. A validação ocorreu entre maio e julho de 2016, e testou a adequação ao processo e ao material, utilizando a NBR ISO 17665-1. O protocolo contempla os principais pontos para influenciar a decisão de manter ou reavaliar o equipamento. A validação do protocolo ocorreu por cinco enfermeiros atuantes no Centro de Material e Esterilização. **Resultados:** O protocolo foi composto por seis ações, que exigem requalificação do equipamento, e três ações que não impactaram em nenhum ponto crítico do processo. O ponto mais crítico observado ocorreu com materiais úmidos. O protocolo foi validado pelos enfermeiros do Centro de Material e Esterilização e apresentado na forma de fluxograma. **Conclusão:** O protocolo favorece que enfermeiros atuem de forma crítica na manutenção corretiva e preventiva do equipamento de esterilização a vapor.

Palavras-chave: Esterilização. Vapor. Equipamentos e provisões hospitalares. Enfermagem perioperatória.

RESUMEN: Objetivo: Informar la experiencia de la creación de un protocolo de evaluación del proceso de esterilización a vapor. **Método:** Relato de experiencia, basado en el fundamento teórico y en la validación de nuevos equipos del Centro de Material y Esterilización. La validación ocurrió entre mayo y julio de 2016, y probó la adecuación al proceso y al material, utilizando la NBR ISO 17665-1. El protocolo contempla los principales puntos para influir en la decisión de mantener o reevaluar el equipo. La validación del protocolo fue realizado por cinco enfermeros actuantes en el Departamento Central de Abastecimiento de Esterilización. **Resultados:** El protocolo fue compuesto por seis acciones, que exigen recalificación del equipo, y tres acciones que no impactan en ningún punto crítico del proceso. El punto más crítico observado ocurrió con materiales húmedos. El protocolo fue validado por los enfermeros del Departamento Central de Abastecimiento de Esterilización y presentado en forma de diagrama de flujo. **Conclusión:** El protocolo favorece que los enfermeros actúen de forma crítica en el mantenimiento correctivo y preventivo del equipo de esterilización a vapor.

Palabras clave: Esterilización. Vapor. Equipos y suministros de hospitales. Enfermería perioperatoria.

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INTRODUCTION

According to the Resolution from the the Collegiate Board of Directors of the Brazilian Agency for Sanitary Surveillance (*Agência Nacional de Vigilância Sanitária - ANVISA*) no. 15, of March 15, 2012, it is mandatory to standardize the various processes that occur within a Central Sterile Supply Department (CSSD). The centers are classified as CSSD class I and CSSD class II, and are intended to establish good practices for the processing of health products (PHP)¹. Article 37 of this regulation describes the need to verify the installation, the operation, and the performance of the equipment used in the automated cleaning and in the sterilization of PHP, with minimum annual periodicity. These components make up the equipment validation process².

The validation of the sterilization depends on a set of steps called verification, which certifies the adequacy of the evaluated parameters. Among them, the validation of the sterilizing equipment's performance, which is carried out by physical, chemical and biological controls, aims to ensure that the probability of microorganism survival is less than 1:1,000,000 (10^{-6})^{3,4}. Thus, verification is defined as the set of actions taken to attest and document the proper installation and function of all facilities, systems and equipment, leading to the expected results. The verification is part of the validation, but the isolated stages of the verification do not constitute the validation of the process⁵.

Sterilization is the process of destroying microorganisms to such an extent that it is no longer possible to detect them in the standard culture medium in which they had previously proliferated^{3,6}. It can be performed by physical, chemical and physicochemical means. Among the physical processes exists high-pressure saturated steam sterilization.

This monitoring of the sterilization processes should incorporate a physical, chemical and biological evaluation. The physical control includes monitoring the critical parameters of each process, by means of manual recording or through a printer that is interconnected to the sterilizer. For the chemical control, indicators and integrators with different market presentations are used. Biological indicators are characterized by a standardized preparation of bacterial spores designed to produce suspensions with 10⁵ to 10⁶ spores per filter paper units⁷.

Theoretically, a standard moist heat sterilization cycle is divided into three phases or stages¹: conditioning, in which the air is withdrawn from the sterilizer's inner chamber, and

the load is preheated; exposure or sterilization, in which contact of the vapor with the material occurs under controlled pressure and temperature conditions to promote the death or inactivation of viable microorganisms; and drying, which is responsible for the removal of steam and vapor condensate from the interior of the load.

Validation is documented evidence that the equipment sterilization process is effective and reproducible. Reproducibility issues are fundamental to a well-defined validation process, therefore, it is important that a hospital has defined and approved its working protocols. Furthermore it is ideal that there is an operative quality system set in place to ensure the verification of the procedures and their reproducibility⁵.

The validation process consists of the following steps⁵:

1. project verification: before purchasing the equipment, the manufacturer's installation requirements must be known;
2. facility verification: documented evidence, provided by the manufacturer or distributor, that the equipment has been delivered and installed in accordance with the specifications;
3. operation verification: documented evidence, provided by the manufacturer or distributor, that the equipment operates within the original manufacturing parameters, after the facility has been verified;
4. performance verification: documented evidence that the equipment, after verifying its installation and operation, performs consistently for at least three successive cycles of the process, with identical parameters, and using the most challenging load determined by the health service.

Regardless of the sterilization method, the equipment must be approved by ANVISA, validated by the manufacturer at the time of installation, re-verified at least annually, and monitored, before being routinely used. Furthermore, the equipment must undergo preventive and repair maintenance from hospital engineers or from the equipment manufacturer⁵.

OBJECTIVE

To report on the experience of creating a change assessment protocol for the steam sterilization process.

METHOD

This is an experience report of creating a change assessment protocol for the steam sterilization process at a large philanthropic hospital located in the city of São Paulo. The protocol was built based on theoretical bases⁸, norms and resolutions, and the monitoring of the validation process of the CSSD's new equipment.

Equipment of great productive capacity and low operating costs were acquired for the new CSSD, which opened in August of 2016. They were obtained with the objective of improving logistics in relation to refilling supplies and improving the work structure, with a focus on health, and on patient and employee safety⁹.

In March of 2016, in conjunction with the CSSD's coordinator nurse, the need to develop this study was observed. Nurses should not only be part of the processing of the material, but also when the equipment undergoes modifications and when it presents problems. Hence arose the question that guides the present work: When is it necessary to verify the equipment? Do the nurses know this? Based on these questions, the nurses sought information about the validation process of the equipment and observed the performance verification of the autoclaves three times, since the operational verification was already in process.

The implementation of a new CSSD, with the installation of new steam sterilization equipment (Century v120 and Evolution HC1000), requires that its processes be validated and verified before the unit begins to operate.

The validation process of the steam sterilization equipment must be carried out by the manufacturer — the company *Steris*, which is responsible for the installation and thermal verification. The thermal calibration of the equipment is performed by the company *Escala* and the performance verification is carried out by the company *Orion*, both of which are contracted by the hospital unit. These steps are essential for the equipment to operate properly and be cleared for use.

The professionals involved in the autoclave verification processes were listed. The company *Steris* was represented by the following professionals: service supervisor, technical officer and clinical specialist. The company *Escala*, which was responsible for the calibration, was represented by the operational technicians. And the company *Orion*, which carried out the equipment's performance verification, was represented by the field technicians and their

managing partner. The hospital's maintenance and clinical engineering teams, and the CSSD's nursing team — comprised of the coordinator, the lead nurse, the resident nurse, and nursing technicians — were also involved throughout the process.

The verification process requires norms that govern that the work be conducted in an appropriate way. To this end, the manufacturer's standards, national regulations and also international regulations — translated and used in the country — such as RDC n. 15² and NBR ISO n. 17.665-1¹⁰. This process should be developed within the hospital unit's CSSD.

Thus, in the period from May to July of 2016, the validation process occurred. For performance verification to be effective, the following tests should be performed: leak test, three empty sterilization cycles, Bowie Dick, and three unloaded sterilization cycles. All of the cycles were monitored with thermometers placed at specific points in the equipment, which evaluated the process points.

At the end of this process, the authors began to construct the protocol, with the objective of following the main points that guide the decision to maintain or re-evaluate the equipment.

Subsequently, the CSSD nurses validated the protocol through reading the constructed material. They were then asked about the flowchart's understandability, clarity, and readability.

The creation process of the change assessment protocol was finalized and presented to the CSSD nursing team, printed on A3 bond paper, and made available in the unit's preparation area.

RESULTS

On May 25, 2016, the equipment's performance verifications began, with technicians from Orion, representatives from Steris, the CSSD nursing technicians and the unit's lead nurse. At the time of the first tests, there were problems with the wet load, which made it impossible to perform the tests, so the activities had to be halted. The possible reasons for the wet load were: piping, equipment, vacuum and heating curve.

The performance verification was resumed on June 15, 2016, starting with equipment number 02, which has a cycle for prions. The tests described above were carried out both for the normal cycle and for the prion cycle, that

is, six tests with no load and six tests with a load were performed. This performance verification process took three days to complete.

On June 22, 2016, autoclaves number 02 and 03 were approved, and the lead nurse supervised the second day of tests in autoclave number 04. Orion's technicians installed thermometers in the equipment, and monitored its heating curve using a laptop. First, the tests without a load were carried out, then the tests with a load. The materials used were prepared and packed by the CSSD technicians.

Equipment number 01 was submitted to the tests on June 23, 2016. The express cycle was excluded in this process because the institution does not use it, and the other cycles were approved without interurrences.

After the performance verification phase, the equipment validation was completed and the autoclaves were cleared for use. The established sterilization time was 4 minutes, at 134°C, and 40 minutes of drying time for non-woven fabric (NWF) or surgical grade paper. For the container cycle, 20 minutes of drying time was established. In cases of materials that correspond to a special cycle, 90 minutes of drying time was required.

In October 2016, the validation documents were analyzed, dates and phases of the validation were registered, NBR ISO 17.665-1¹⁰ was acquired and, from that moment, the protocol was constructed. At the end of that month, the protocol was finalized and presented to the unit coordinator to be validated for layout and content.

After the coordinator validated it, changes in the flowchart format were necessary to make it more understandable, and to add on points that would lead to re-verification. Additionally changes were made to identify which points would not cause an impact, and may require only corrective or preventive maintenance.

In November of 2016, a new version of the flowchart was presented to the unit coordinator, and a redesign was deemed necessary. At this time, a change to the flowchart's color was requested, in order to make it more understandable, as well as changes to some sentences, in order to improve their clarity.

At the end of November, the reformulated version of the flowchart (Figure 1) was presented to the CSSD nurses to validate understandability and to assess clarity and applicability. This was carried out through informal conversation.

There were no changes after this phase, and the flowchart was printed and made available on colored A3 bond

paper in the preparation area, near the autoclave and close to the location of the CSSD nurses. It is to be used as a guiding instrument in the autoclave's change assessment process.

DISCUSSION

The results of this work demonstrate that the change assessment process is complex and requires the involvement of the nursing team in all of its phases.

Among the difficulties experienced during this period, understanding the equipment process, the possible failures in the validation process, and the parameterization of the sterilization processes were challenges faced when finishing the construction of the flowchart.

The validation process, including the verification of sterilization equipment performed by companies that provide validation services, has evolved in recent years. The process of sterilization by autoclaving has basically stayed the same since its inception in 1880 by researcher Charles Chamberland. It can be affirmed that the equipment's evolution focused on the control of the sterilization cycle phases, made possible by safety and registration devices. Also, requirements about the sterilization quality management system were put in place in documents¹¹.

Nowadays, it is imperative that CSSDs at health care institutions validate their sterilization processes, including the verification of their sterilizing equipment. To that end, it is necessary to choose a technical standard that can be used as a reference for the creation and execution of validation protocols. Other standards may be adopted in conjunction with the main one, such as the use of references for acceptance criteria, procedures and indicators, as well as technical recommendations from class associations and the manufacturer¹¹.

The validation protocols should inform all of the procedures to be performed, and the expected results of each step of the PHP processing, including the justification for each acceptance criterion adopted. Evidence should be provided demonstrating that the achievement of these criteria will ensure that the materials processed in the equipment will be sterilized. This evidence, considered an outcome indicator, should be obtained through sterility tests, which correspond to the biological indicators¹¹.

The choice of the technical standard to be followed should be based on the date of publication, since it is imperative

to use the most recent standard as possible and, preferably, one that is already officially translated into the Portuguese language. For steam autoclave, the standard applied is NBR ISO 17.665-1¹⁰ by the Brazilian Association of Technical Standards (*Associação Brasileira de Normas Técnicas - ABNT*), which came into effect on February 22, 2010. This standard includes the full translation of the international standard ISO 17.665-1:2006, which cancels/replaces ABNT NBR ISO 11.134:2001¹¹.

Because the sterilization process validation has several stages, the norm allows them to be concluded in a random order, as there is no need for one step to be satisfactorily completed before the next is initiated. The key point is that all of the steps are completed satisfactorily¹¹.

In NBR ISO 17.665-1¹⁰, item 12.5 says that any change should be evaluated as to its impact on the effectiveness of the sterilization process. Changes to be considered — if applicable — should include:

1. replacement of a part that could cause a process parameter to change;
2. replacement of a part that could cause increased leakage into the sterilization chamber;
3. variation of the homogeneity in the sterilization chamber;
4. modified program and/or driver;
5. any changes to the process parameter;
6. any changes to the services and to a service's maintenance results;

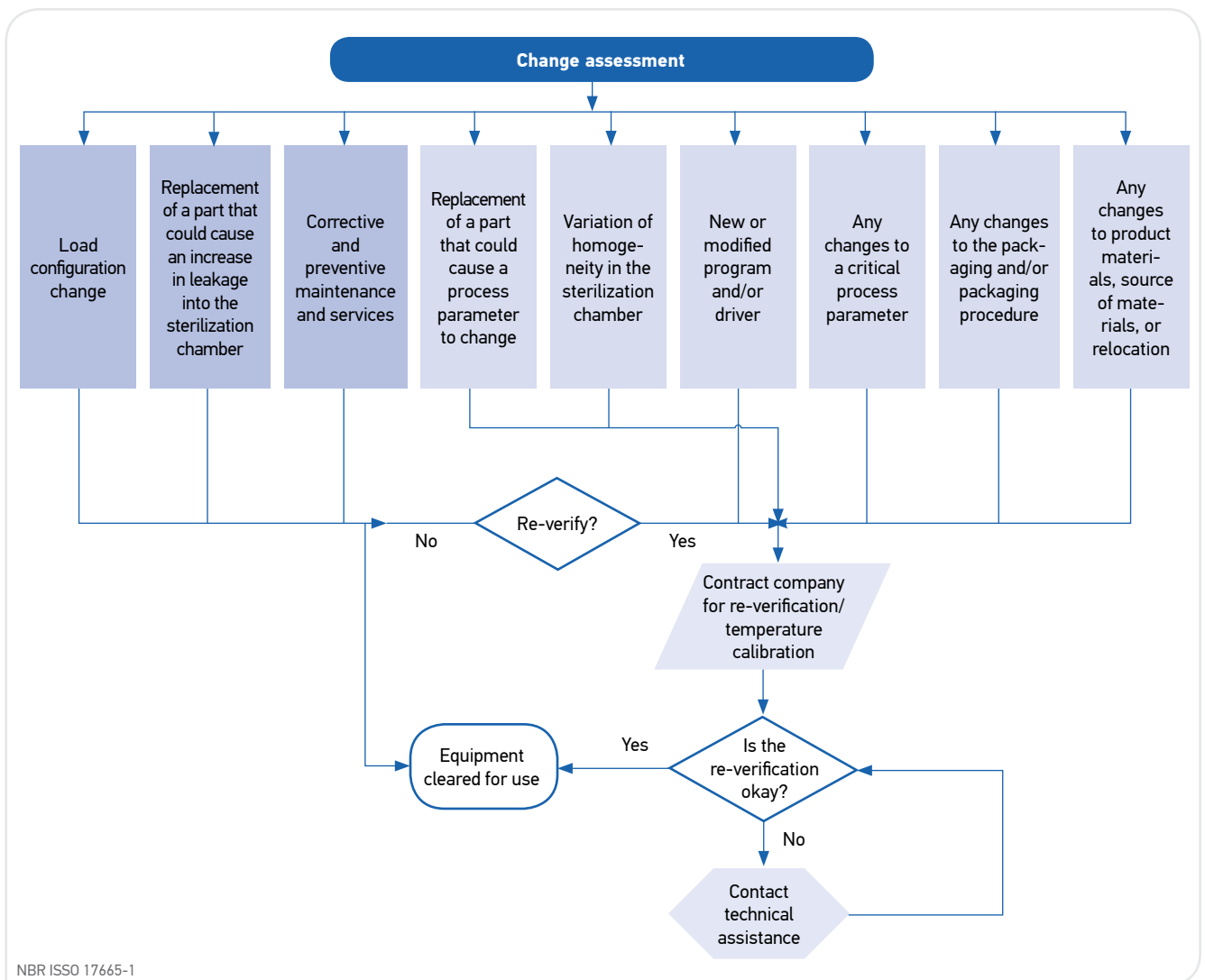


Figure 1. Flowchart for the Steam Sterilization Change Assessment Protocol.

7. any changes to the packaging and/or packaging procedure;
8. any changes to load configuration;
9. any changes to product materials, source of materials, or design.

The outcome of this evaluation should be documented, including the justification for the decisions made and the extent of changes made to the sterilization process, product or re-verification required (if applicable)¹⁰.

It is recommended that a validation group be created, composed of the CSSD's nursing team, engineering and maintenance teams, and suppliers and service providers, who must have a proven professional qualifications to carry out their activities, elaborate and execute the verification, and change control and equipment monitoring protocols¹.

FINAL CONSIDERATIONS

This study confirmed the importance of the validation process and its application in the nurses' work routine. Producing the protocol comes in the interest of encouraging the nursing team to be more active in all processes within the CSSD. As a key part of the process of receiving and delivering sterile materials, nurses must seek theoretical bases and have an active voice in the verification process of the steam sterilization equipment.

Despite the pertinence of this topic in the current context, it is necessary to consider that the nursing team is not involved in the equipment re-verification process, leaving the matter to the maintenance and/or hospital engineering teams. Therefore, in addition to the necessity of encouraging nurses to look more critically at the process, it is essential to develop an indicator that evaluates this protocol's applicability in the day-to-day work of nursing teams.

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