CHALLENGE LOAD VALIDATION AND ASSEMBLY: FROM THEORY TO PRACTICE

Validação e montagem de carga desafio: da teoria à prática

Validación y montaje de carga desafío: de la teoría a la práctica

Emerson Aparecido Miguel[1], Paulo Roberto Laranjeira[2]

ABSTRACT: Objectives: The need to comply with the Collegiate Board Resolution (*Resolução da Diretoria Colegiada* – RDC) ANVISA No. 15/2012 presented many challenges to the Material and Sterilization Center (*Centro de Material e Esterilização* – CME), among which, was determining the greatest challenge load to be used during the sterilization validation process through moist heat in the performance qualification stage **Methods:** This article presents technical regulations which support this activity, as well as the result of a thorough analysis regarding a common result when there is lack of determination of the greatest challenge load: the problems with wet loads. **Results:** The many materials used as health products affect the performance of sterilizers and may compromise the sterilization process. **Conclusion:** Considering this scenario, the use of national and international technical regulations references, the use of devices to challenge the process, and validation of the sterilization are essential in order to ensure the quality of this activity and avoid risks to patients.
Keywords: Sterilization. Condensation. Credentialing. Patients.

RESUMO: Objetivos: A necessidade de cumprimento da Resolução da Diretoria Colegiada (RDC) ANVISA n° 15/2012 trouxe para o Centro de Material e Esterilização (CME) diversos desafios. Entre eles, determinar a carga de maior desafio para utilização durante a validação do processo de esterilização por calor úmido na etapa de qualificação de desempenho. **Métodos:** O presente artigo apresenta normas técnicas que respaldam essa atividade, assim como o resultado de uma análise profunda a respeito de um resultado comum quando há falha da determinação da carga de maior desafio: os problemas com carga molhada. **Resultados**: Os diversos materiais utilizados como produtos para saúde afetam o desempenho dos esterilizadores e podem comprometer o processo de esterilização. **Conclusão:** Diante desse cenário, o uso de referências normativas técnicas nacionais e internacionais, de dispositivos de desafio de processo e de validação do processo de esterilização é indispensável para garantir a qualidade dessa atividade, evitando riscos aos pacientes.
Palavras-chave: Esterilização. Condensação. Credenciamento. Pacientes.

RESUMEN: Objetivos: La necesidad de cumplimiento de la Resolución de la Dirección Colegiada (RDC) ANVISA n° 15/2012 trajo para el Centro de Material y Esterilización (CME) diversos desafíos. Entre ellos, determinar la carga de mayor desafío para utilización durante la validación del proceso de esterilización por calor húmedo en la etapa de calificación de desempeño. **Métodos:** El presente artículo presenta normas técnicas que respaldan esa actividad, así como el resultado de un análisis profundo al respecto de un resultado común cuando hay falla de la determinación de la carga de mayor desafío: los problemas con carga mojada. **Resultados**: Los diversos materiales utilizados como productos para la salud afectan el desempeño de los esterilizadores y pueden comprometer el proceso de esterilización. **Conclusión:** Ante este escenario, el uso de referencias normativas técnicas nacionales e internacionales, de dispositivos de desafío de proceso y de validación del proceso de esterilización es indispensable para garantizar la calidad de esa actividad, evitando riesgos a los pacientes.
Palabras clave: Esterilización. Condensación. Habilitación Profesional. Pacientes.

[1]Chemical Engineer; Post-graduate in Work Safety Engineering; Partner at OrionCE Serviços de Metrologia Ltda. - Barueri (SP), Brazil. E-mail: emerson@orionce.com.br
Avenida Sagitário, 138, sala 2405/616 – Alphaville – CEP: 06473-073 – Barueri (SP), Brasil.
[2]Electrical Engineer; PhD in Sciences, School of Nursing, Universidade de São Paulo (EEU SP); Partner at OrionCE Ltda. - Barueri (SP), Brazil. E-mail: prlaranjeira@usp.br
Received: 01 Sept. 2016 – Approved: 27 Sept. 2016
DOI: 10.5327/Z1414-4425201600040007

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With the publication of the Collegiate Board Resolution (*Resolução da Diretoria Colegiada* – RDC) ANVISA No. 15, from March 15th 2012[1], the standardization of several processes which occur inside a Material and Sterilization Center (*Centro de Material e Esterilização* – CME) is now mandatory. The centers are classified as CME class I and CME class II, in order to establish good practices for processing health products. In this context, load standardization, which undergoes the sterilization process, was also included. The concept defined in article 4°, item II, was used in order to meet article 37 of RDC ANVISA No. 15, whose objective is to represent the greatest challenge load, by considering the worst case scenario in the routine of a CME's service, and to verify which routines are used for sterilizers in the performance qualification stage during the validation process[1].

The institutions and their professionals have long realized the need to use a challenge load that tests the equipment limits during the validation process, in order to prepare for the worst case scenario in the institution's routine. However, the selection or definition of the parameters to be challenged are often misleading or lacking scientific or regulatory support[2].

A misleading selection results in harmful mistakes, which may compromise both the safety of the process and the sterilization's effectiveness, consequently presenting risks to the patient.

Most mistakes on the sterilization's effectiveness are observed and corrected in order to follow the best options. Currently, a very relevant issue (and which concerns professionals working in this activity) regards the quality level of drying during the sterilization process[2].

In theory, the standard sterilization cycle for moist heat is divided into three stages or steps:

- Step 1: preparation, in which air is removed from the internal sterilization chamber and the load is preheated.
- Step 2: exposure or sterilization, in which steam makes contact with the material under controlled pressure and temperature conditions to promote the death or inactivation of viable microorganisms.
- Step 3: drying, responsible for steam removal and steam condensate inside the load[3].

This last step is gaining more recognition in current discussions on the sterilization process; despite being a historical problem in institutions, it is worsening due to its increasing complexity and the rise of new materials used in the making of Health Products (HP).

More and more frequently, the loads that are to be sterilized are heterogeneous, with a great mixture of components within them, for example: plastic, fabrics, steel alloys and other metals, such as aluminum, titanium, etc. This diversity of materials comprising a box of HP has a direct negative impact on the sterilization cycle, which presents extreme difficulty in achieving efficiency, regardless of the sterilizer brand or model used.

The drying problems became the main cause for the compliance of RDC ANVISA 15[1] and, in order to solve them, the parameter definitions in the sterilization process need to improve in addition to improving the definition of the greatest challenge load.

An example of an assembly mistake with the greatest challenge loads is overloading a basket with HP with the intention of creating the worst possible conditions for the process, resulting in excessive condensate formation, and commonly not representing actual reality (Figure 1).

The definition of challenge loads must consider technical references, which support their selection and lead the process to an evaluation by a proven, safe scientific methodology.

The best reference to fulfill the requirements of RDC ANVISA No. 15[1] is the new technical regulation by ABNT NBR/ISO 17.665-1[3], which defines the greatest challenge load as the reference load created in order to represent difficult combinations of the items to be sterilized. This regulation also suggests the use of ISO/TS 17.665-3[4] in order to define the HP family to be processed.

ISO/TS 17.665-3 proposes the creation of HP families divided according to their conception, following a classification

Source: Photography collection of OrionCE

Figure 1. Excessive condensate formation.

based on the design, the material, the weight and the sterile barrier used in processing[4].

The division of loads into product families helps define which loads are more difficult to process[4] in order to correctly comply with the demands of RDC ANVISA No. 15[1], by looking for more efficient and safer pathways, working more clearly with the problems regarding the drying stage, ensuring sterilization effectiveness and increasing process quality (Figure 2).

Figure 3 shows an assembly with different types of HP: temperature sensors were placed to make contact with each type of material and the heating profile of these materials was observed during the sterilization cycle, which should represent the greatest challenge load of the institution. There were stainless steel, rubber, aluminum and plastic boxes within the loads.

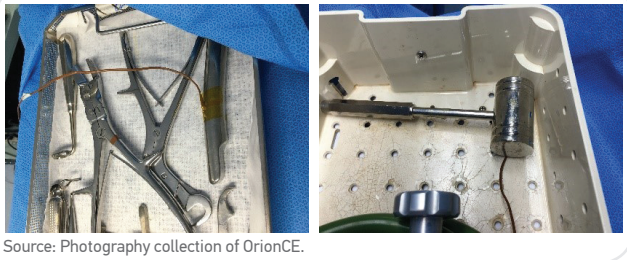
In the thermal study with the greatest challenge load indicated in Figure 3, 12 temperature sensors were selected and used according to ABNT NBR 16.328:2014[5] and placed to make contract with the material to be processed.

During the cycle's development, the temperature was monitored in each item. Figure 4 is the graphic with the results from monitoring a sterilization cycle by moist heat. Four materials of different compositions were selected. In addition to the sterilizer's control sensor located near the drain, the T-03 sensor was placed in contact with a plastic item; sensor T-04 with an aluminum item; sensor T-08 with a stainless steel item; sensor T-11 with a rubber item; and sensor T-12 was placed with the equipment's control sensor near the drain.

It is possible to observe in the Figure 4 graphic that the temperature differences in materials made of plastic, rubber, and aluminum are large when compared to steel materials (no temperature rise during most of the

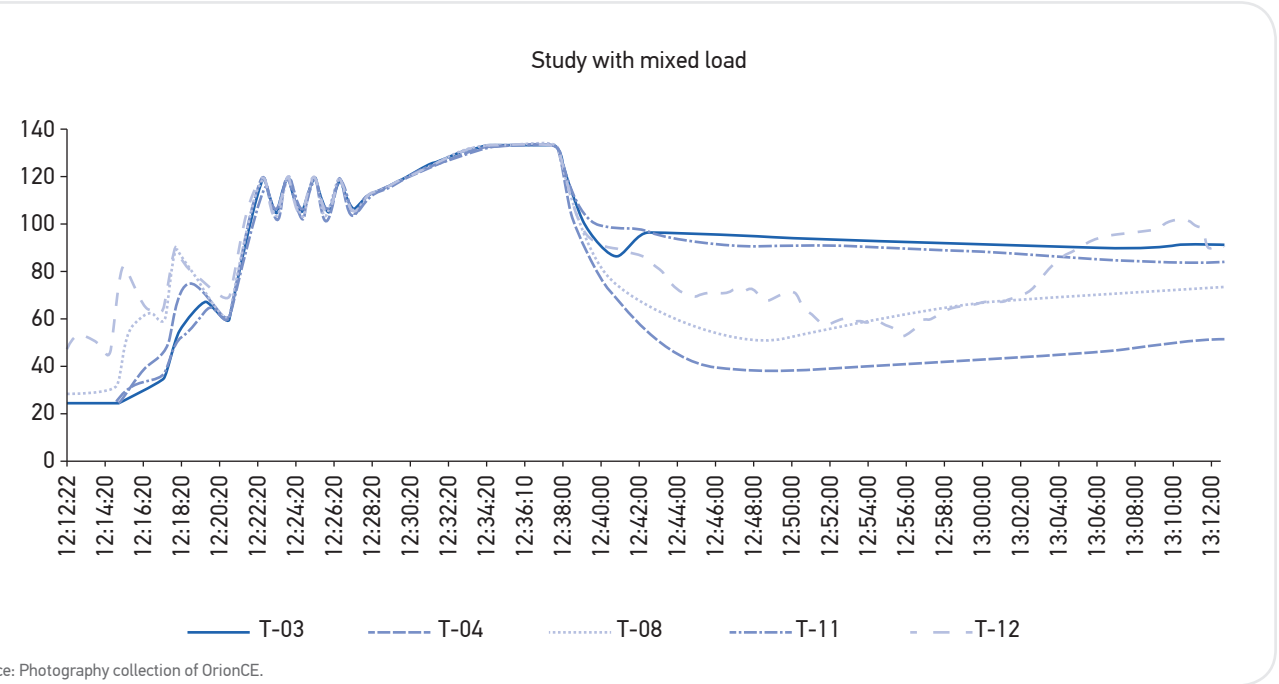
Source: Photography collection of OrionCE.

Figure 2. Greatest challenge load (fabrics, containers and cannulas).



Source: Photography collection of OrionCE.

Figure 3. Example of greatest challenge load.



Source: Photography collection of OrionCE.

Figure 4. Graphic with load temperature values.

packaging stage). Thermal differences are also observed during the drying stage. The thermal difference was irrelevant only in the heating and exposure stages (sterilization step) of the cycle.

The conclusion drawn from this study is that, due to the differences in the heating of materials, there was a high rate of moist condensate inside the boxes during packaging. Additionally, the condensate excess was not removed during the drying stage, resulting in wet packages at the end of the cycle and failing the cycle during the validation process.

The reasonable use of the principles and system established by ISO/TS 17.665-3[4] avoids the excessive formation of condensate and allows the loads to be dry at the end of the cycle, regardless of the brand of equipment.

Special attention should be given to the configuration of the sterilizer's cycle since it significantly influences the validation process results in the case they do not agree with the established criteria in technical variation regulations for values of temperature and pressure, dryness, and non-condensable gases[4].

All the points mentioned above must be tested in order to be checked for their compliance to the current and relevant technical regulation[3], allowing users to use the commercially available Process Challenge Devices (PCD), or to create their own, according to the technical regulation, in order to monitor the cycles according to the requirements of RDC ANVISA 15[1].

ABNT NBR ISO 17665-1[3] characterized these PCD as items designated to constitute a defined resistance to a sterilization process, and are used for the performance evaluation in the process. They challenge the process for air removal, steam penetration and the presence of non-condensate gases; they also verify if the energy present in steam is sufficient to promote the inactivation of microorganisms. Every PCD must meet the construction and technical efficiency regulations in order to ensure that the results definitely indicate whether the sterilization cycle was approved or not.

The institution may use these devices in their routine, according to article 96 of RDC ANVISA No. 15, for monitoring each cycle. However, they should be used within the chemical integrators devices (class 5 or 6), only by adding a biological indicator in implantable health products according to article 98[1].

When using these devices, the institution should also be attentive to the development of the following items, mandatory to the remaining parameters of their processes[3]:

- compliance regarding the definition of the product;
- compliance regarding the definition of the process to which they were developed;
- compliance during Performance Qualification (PQ);
- review and approval of the validation process; and
- monitoring and control of the routine.

It is recommended to create a validation group comprising teams of CME nurses, engineers and maintenance workers, suppliers and service providers (which need certified professional qualifications in order to perform their activities, to develop and carry out the qualification, to control changes and monitor equipment protocols)[3].

We conclude that the shared responsibility of each item of the process, the use of current and relevant technical regulations and the compliance with the recommendations from national and international associations are essential items in order to overcome current challenges in sterilization processes, to comply with legal requirements and to increase patient safety.

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