Periodic device testing

A part of patient safety and a healthy quality management system

by Richard Schule, BS, MBA, FCS, FAST

Risk of not performing periodic device testing

Depending on the size of your healthcare facility, you may easily be processing millions of surgical instruments and medical devices annually. Considering the number of processes or steps that go into processing these devices, it is important to understand the potential risk that each device could pose to patients and staff. Can you say with confidence that your department’s processes transition to the next step whereby each successive process is meeting the proper specifications, or would you say your processes are fragmented? Does your healthcare facility’s sterile processing department take processing of reusable medical devices for granted? Theoretically, probably not, but if your team does not make use of quality management systems it is more than likely that you are missing a much greater opportunity. How well does your department support patient safety?

Guidelines and standards

Guidelines from the Association of peri-Operative Registered Nurses (AORN) and Association for the Advancement of Medical Instrumentation (AAMI) standards -- required reading for all essential personnel performing device processing -- speak to and support safe device processing. For example, ANSI/AAMI ST 79 defines installation qualification (IQ) as a process of obtaining and documenting evidence that the equipment has been provided and installed in accordance to specification whereby operational qualification (OQ) means obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with its operational procedures. And performance qualification (PQ) is the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs according to predetermined criteria, thereby yielding a product that meets specification.

ANSI/AAMI ST79 further states that we have a quality system model in place for reprocessing medical devices in healthcare facilities using a validated system in which the sterilizer manufacturer and appropriate representatives of the healthcare facility conduct installation and operational qualification. In addition, the individual medical device manufacturer, the manufacturer of the packaging (wrap, container, or pouch), and the sterilizer manufacturer recommend validated means of sterilizing the specific devices to be reprocessed, in lieu of a formal performance qualification.

The standard also states that the “validated cycle” provided by the medical device manufacturer is often based on the assumption that the device is to be processed alone, not as part of a set of instruments. It is important to note, unless the user actually tests the contents of the various packs being processed, there is no documented evidence of a successful outcome for packs assembled in-house. Or is there?

Managing moisture events

Wet packs can occur in all sizes and models of steam sterilizers. When the boiler, steam delivery system, sterilizer performance, sterilization process, load content and tray configuration and the clinical practice all work in harmony and support the overall process we can expect to contribute to quality patient care, but when wet packs do occur, it appears clinical practice, and load content and tray configuration are the prevailing issues. It is hypothesized, a lack of sufficient documentation supporting periodic device testing, which is recom-
mended in ANSI/AAMI ST79, correlates to increased moisture events. In other words, sterile processing departments rarely verify that their particular clinical practices, tray configuration and load content are effective in producing sterile, dry sets.

Recent history shows a need to be vigilant and consistently committed to working with and educating our healthcare professionals, clinicians and technicians. Recommendations should support an unbiased eye occasionally checking on technical processes leading up to steam sterilization. We should also be reminded of ever-changing industry standards and the importance of updating current policies and procedures to reflect those changes. We should also work to ensure that the combination of product families does not create a greater sterilization challenge than set by those individual product families. Ensuring that we meet all requirements, consistently provide products that meet the requirements, and confirm that our staff understands and is in control of the processes are key to effective management.

**General attributes affecting steam sterilization**

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, specifically, Section 10 Quality Control, Part 10.9, speaks to periodic product quality assurance testing of routinely processed items. Unfortunately, this section does not go into great detail on how to perform said testing. There is a little-known document that supports the direction or periodic testing titled ISO DTS 17665-3: Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category. The general scope of the document provides guidance for the attributes (characteristics) of a medical device that should be considered by the user, when assigning a medical device to a product family, for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process. There are 28 device families described in this document whose four general attributes include: Material, Weight, Design, Sterile Barrier System and/or Packaging System (Figure 1).²

The document speaks to the increasing complexity of the design and nature of materials used to construct medical devices. Materials used in the manufacture of sterile barrier systems and/or packaging systems and the combinations of different medical devices in procedure sets can adversely affect conductivity, air removal and moist heat penetration, causing a failure to obtain the required sterility assurance level.

The classification of a medical device into a product family can assist with the development of moist heat sterilization process conditions for this medical device. Assigning a medical device to a particular product family is the first stage of performance qualification at the point of use as specified in ISO 17665-1 and ISO 17665-2. The efficacy of sterilization for a medical device using the sterilization process for that product family should be assessed and documented together with any pre-treatments, such as cleaning, disinfection to reduce bioburden, followed by the lubrication and humidification of some materials (e.g., those containing cellulose)³. In this part of ISO 17665, the attributes related to efficient sterilization and which are used to identify a product family have been selected from operational experience, engineering considerations, and experimental data relating to the efficacy of different types of moist heat sterilizers and their sterilization processes. Also considered are the types and design of differing medical devices and sterile barrier systems and/or packaging systems. Medical devices that are labeled by the manufacturer as capable of being sterilized via moist heat may be categorized into product families by users.

However, not all medical devices will fit into one of the product families described in this part of ISO 17665. In these cases, new product families will need to be identified based on the consideration of the products’ attributes and require additional performance qualification.

Medical devices that have been classified into different product families are often processed in the same sterilization load when assembled in randomly selected load configuration. This approach is common and acceptable in healthcare facilities where it is generally not feasible to qualify each sterilization load, provided that the sterilization process and sterilizer have shown to be capable of sterilizing the range of product families constituting the sterilization load.

Once your devices and sets have been placed in a product family, you will select and identify the master product for each product family. The master product is a medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category. Once identified, perform testing according to suggested guidance found in ANSI/AAMI ST791.

The processing category is a collection of different products or product families that can be sterilized together. Steam penetration resistance is the challenge to a sterilization process from a medical device, including any sterile barrier/packaging system that may delay attainment of the process parameters for moist heat sterilization on all parts of the medical device. Care should be taken to ensure that the combination of product families does not create a greater challenge than set by the individual product families.

Each medical device, whether new or modified, should be classified using the general attributes listed. Some combinations of physical characteristics may cause an unpredictable adverse change to the steam penetration resistance. This can lead to an underestimation of the difficulty to sterilize. In such situations, you should always carry out a performance qualification.⁴

Some attributes will be specialized by the manufacturer of the medical device and others by the user. The manufacturer of a medical device will usually specify the

See **SELF-STUDY SERIES** on page 36

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**Table: General Device Attributes**

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<thead>
<tr>
<th>Attribute</th>
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<tbody>
<tr>
<td>Design</td>
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<tr>
<td>Weight</td>
</tr>
<tr>
<td>Material</td>
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<tr>
<td>Sterile barrier system</td>
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**Figure 1. General Device Attributes**
attributes needed by the user to assess its steam penetration resistance and to select a processing category for a specific sterilizer and sterilization process. Both the resistance and the category should be reassessed when the medical device is to be combined with others in a sterile barrier system and/or packaging system.

The sterilization process should be qualified to verify that the required lethality will be delivered to all medical devices processed together.

Material

The materials used to manufacture a medical device will be either metallic or non-metallic or a combination of both. Typically, metallic materials will have a high thermal conductivity and non-metals will have low thermal conductivity. Materials with low thermal conductivity exhibit higher temperature differences throughout the material when compared to materials with high thermal conductivity. Both types of material present challenges to the sterilization process. The moisture content of the material may also influence the heat transfer into the product. This should be taken into account during performance qualification with the material in its most challenging state.

When compared to materials with low thermal conductivity, materials with high thermal conductivity and equal heat capacity will initially generate more condensate in a given time period; absorb and release energy faster; and attain a state of equilibrium faster.

Weight

The weight of a medical device, or part of a medical device (if processed separately), or for a collection of medical devices grouped into a single sterile barrier system and/or packaging system, may need to be processed when judging heat-up time; cooling time/drying time; exposure time in a mixed weight sterilizer load; stability of a single or composite construction material; and amount of condensate and its effect on steam penetration.

Except when a medical device is to be presented aseptically immediately after being re-processed, it will be contained in a sterile barrier system and/or packaging system prior to it being sterilized. When establishing the steam penetration resistance and moisture retention for a medical device or a collection of medical devices, the influence on the combined steam penetration resistance caused by

Documentation should reflect attention to detail

Documentation for any piece of equipment must be accessible at a moment’s notice. Training and education should include equipment in-service, checklist, and operator competency, as well as documentation establishing success at each level of knowledge. Devices to be processed in this equipment should have their original equipment manufacturer (OEM) instruction for use (IFU) reviewed for identity of special cycles, medical device compatibility as well as documentation supporting specific product and device testing performed. Sterility assurance products used to support equipment as well as product in-service education, checklist, operator competency, product compatibility are also necessary and lastly, FMEA – Failure Mode and Effects Analysis whereby determining the outcome of the product or service when steps/ parts are removed.

How does the change or elimination impact the end product?

Performance qualification is a critical part of the total equipment installation process and too often overlooked or misunderstood by the healthcare professional. Installation and operation qualifications should be performed and signed off by the installation team and/or field service representative completing the installation. Only upon completion and receipt of documentation of these first two steps should the healthcare professional begin performance qualification testing of identified product and device families frequently processed in the sterile processing department and or location of their new equipment.

Documentation should be complete, concise and reflect your department’s attention to detail. Documenting your work throughout the periodic device testing process establishes a baseline of successful performance and when necessary will serve as a reference during future root cause analysis should the need arise. Sample documentation seen in Figure 2 can be found on STERIS University http://university.steris.com/sterisu/assets/File/Wet%20Pack%20Troubleshooting%20Workbook.pdf.

Quality systems assure quality processing

Identify external resources and references used to support department systems, policy and procedures, specifically periodic device testing. Research and develop your department’s periodic device testing procedure and work instructions. Identify and place your medical device tray(s) in one of the product families. Document for effect; document to achieve sustainable reproducible results; establish and implement performance qualification testing; and ask your team, “How well does our department support patient safety?”

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References


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Circle the one correct answer:

1. Which qualification demonstrates consistent performance in accordance with predetermined criteria and thereby yields product meeting its specifications?
   A. Installation
   B. Operational
   C. Performance
   D. None of the above

2. Unless the user actually tests the contents of the various packs being processed, there is no evidence of a successful outcome for packs assembled in-house.
   A. True
   B. False

3. When wet packs do occur which events appear to be the prevailing issue?
   A. boiler and steam delivery system
   B. steam delivery system and sterilizer performance
   C. sterilizer performance and sterilization process
   D. load content & tray configuration and clinical-practice

4. Wet packs can occur in all sizes and models of steam sterilizers.
   A. True
   B. False

5. We should assure the combination of product families does not create a greater sterilization challenge than set by the individual product families.
   A. True
   B. False

6. Which document speaks to guidance on the designation of a medical device to a product family and processing category?
   A. ANSI/AAMI ST79
   B. ISO 13485
   C. ANSI/AAMI ST58
   D. ISO DTS 17665-3
   E. None of the above

7. Name the four characteristics of a medical device that should be considered by the user, when assigning a medical device to a product family.
   A. Steam penetration, weight, peel pouch, and type of metal
   B. Container system, design, material, and thermal function
   C. Design, weight, material, and sterile barrier system
   D. Length, lumen size, sterilization modality, and weight

8. The ________ is a medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category.
   A. Master Product
   B. Processing Category
   C. Product Family
   D. Processing Product

9. Typically, non-metal materials have a higher thermal conductivity than metallic materials.
   A. True
   B. False

10. Only upon completion and receipt of which two documents shall the healthcare professional begin performance qualification testing?
    A. Operator certification and ISO qualification
    B. Operational and installation qualification
    C. Operator and performance qualification
    D. Installation & operator qualification
    E. None of the above