

February 2010

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Learning Objectives

1. Understand the definition of parametric release
2. Understand the basic content of international sterilization process standards
3. Understand the documentation and validation requirements for the application of parametric release

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SELF-STUDY SERIES

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The facts about parametric release

Can it work in your facility?

by Craig Wallace

Parametric release ... the phrase produces a vision of a fast and simple system for the release of sterile loads. No need for biological indicators, no need for chemical indicators, no need to wait for load release, no need to spend money on indicators ... sounds like sterility assurance heaven. However, like most things in life that appear to be too good to be true, there is more to the story. One must understand the whole picture of parametric release, before a decision can be made as to how well this process might work in your health care facility.

Parametric release – the basics

Parametric release is defined as the “Declaration that a product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances.”¹ In other words, the decision to release a load of processed devices is based on the results of physical measurements. The concept of releasing sterile goods without the use of biological or chemical indicators originated in the area of “industrial” sterilization, which refers to the processes and systems employed by medical device and pharmaceutical manufacturers to produce sterile products. The parametric release approach evolved from the very high level of product and process understanding, change control, and documentation that are demanded of these manufacturers by government regulators. In theory, parametric release can be used for any sterilization method, but is most commonly used for steam, ethylene oxide, and radiation processes in industry. It is important to note that many device manufacturers, while following the strict requirements for control and documentation, still utilize biological monitoring rather than parametric release. Even in industry there are situations where parametric release is not beneficial or appropriate, and the use

of biological monitors is simpler or more cost effective.

The “release” part of “parametric release” describes the last step in the sterilization process, that is, the release of processed devices for patient use. The definition does not provide any information on what is required *before* this final step. So, we will have to look more closely at the bigger picture.

The sterilization process

Understanding the concept of parametric release begins with an understanding of the sterilization process as used in health care facilities. It is common to think of the “sterilization process” as only the events that occur within the sterilizer itself. In reality, the sterilization process refers to any activity that may impact the outcome of the process and includes *all* of the steps required to reprocess a medical device. These process steps include:

- Cleaning and decontamination
- Inspection and assembly
- Packaging, including the materials and techniques
- Sterilizer loading
- Sterilization cycle (all conditions including conditioning, exposure, and cool down in a *fully functional* sterilizer)
- Storage and distribution
- Record keeping

This concept of the “total” sterilization process demonstrates that the success of the sterilization depends on the successful completion of each of the elements of the process. An error or failure in any one of the steps could result in a sterilization process failure.

International standards

The fundamental requirements for setting up a parametric release system begin with the international standards that define the development and control of sterilization processes. The International Organization for Standardization (ISO) publishes these

standards. The ISO standards are then reviewed and adopted by national standards organizations such as AAMI (Association for the Advancement of Medical Instrumentation) in the United States.

The requirements for moist heat (steam) sterilization processes are defined in ANSI/AAMI/ISO 17665-1:2006² and the document defining requirements for ethylene oxide processes is AAMI/ISO 11135-1:2007.³ Both documents have the same format and general content, with specific information and requirements suited to each sterilization method. These standards do not differentiate sterilization processes that are performed in health care settings from those performed in industrial settings. However, as we will see, the requirements are much more achievable in industrial settings due to the nature of industrial operations and the available resources.

These standards are quite comprehensive, and provide significant detail on a wide range of topics pertaining to all aspects of the sterilization process. We will look at the information and documentation required for three key areas that are essential for the implementation of a parametric release program:

- The quality management system
- Product and process definition
- Process validation

The quality management system

The quality management system is the organization's documentation framework that ensures that the reprocessing of medical devices is completed in a consistent and controlled manner. Its scope is quite broad and will include responsibilities, processes, procedures and resources for ensuring specified requirements are consistently met. It is a documentation package containing the quality plan, policies, procedures, work instructions, test measurement protocols and reference documents applicable to all of the elements of the sterilization process.⁴ In addition, it will contain the facilities' sterility criteria, the preventive maintenance program and schedule, a system to evaluate any changes in either operating procedures or items to be sterilized, and will also contain a program for auditing of operations and records on an annual basis.⁵

The ISO sterilization process standards do not attempt to provide all of the information and requirements for the quality system, rather, they refer to another ISO standard that focuses only on this topic. The referenced standard is ISO 13485:2003 *Medical devices – Quality Management systems – Requirements for regulatory purposes*. This document provides detailed information for key areas such as management responsibility, resource management, measurement, analysis, and improvement, and purchasing controls.

A well designed and well maintained quality system is a fundamental requirement for industrial sterilization processes, and any process that will utilize parametric release. This is because consistency and control of the process is crucial, and this requires a broad and detailed documentation system. Development and maintenance of this type of quality system requires significant resources, including highly trained personnel and initial as well as on-going funding.

Product and process definition

The ISO sterilization standards require that the facility define many aspects of the system that will be used to process (industrial) or re-process (hospital) medical devices. "Definition" includes understanding, documenting, and ultimately controlling multiple variables of the process and equipment.

The definition of the product is important as the design, materials, and packaging of the devices can have a significant impact on key factors such as sterilant penetration to all surfaces of the device. A significant level of product understanding is also required by the standards, some examples of which are listed below:²

- Product to be sterilized shall be specified (i.e. documented)
- Product packaging systems shall be specified and shall conform to ISO 11607-1 and 11607-2
- The criteria for assigning the product family shall be specified
- If a process challenge device (PCD) is used to represent the product and packaging system, it shall be defined
- A system shall be specified to ensure that the condition of the product and/or its packaging system presented for

sterilization will not compromise the effectiveness of the sterilization process. This system shall include at least the following elements:

- effective cleaning and disinfection including reusable packaging systems, when used
- integrity of the packaging system before and after exposure to the sterilization process
- environmental control in areas that could have an impact on product bioburden

The definition of the process is just as important as that of the product. The actual process conditions will have a major impact on the result of the overall process. Naturally, the standards require a significant level of process understanding as well. Some examples of the requirements for process understanding include:²

- The sterilization process, including process parameters and their limits, shall be defined.
- The minimum level of sterility assurance (SAL), to be achieved by the sterilization process and/or within a product shall be specified.
- If a product is to be sterilized by saturated steam, the level of residual air and non-condensable gas at the commencement of the holding time shall not prevent the contact of saturated steam on all surfaces of the product, including the surfaces in cavities, lumens, and tubing.

Validation

Perhaps the most important requirement for a parametric release system is *validation* of the sterilization process. The standards define validation as the "documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification"¹. A process such as sterilization is considered to be "special", in that the results of the process (i.e. sterile product) cannot be effectively verified by testing after the completion of the process. So, if the final release of the devices is to be based only on a check of physical process parameters, rather than obtaining additional process information from devices such as biological and chemical in-

See **SELF-STUDY** on page 32

SELF-STUDY from page 31

dicators, the overall process must be validated and controlled.

The information required to complete process validation is quite extensive. The standards provide guidance on the overall validation process, which includes the following steps:¹

1. Installation Qualification (IQ): process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.
2. Operational Qualification (OQ): process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.
3. Performance Qualification (PQ): process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

So, the validation of the process requires evidence (data) that *all* equipment to be used in the overall sterilization process is

installed properly, that the equipment operates as intended, and, in the most important and complicated step, that the overall process is effective in consistently producing sterile product. The majority of this test data to support the validation process must be generated at the facility itself.

Additional considerations

A validated process must have systems in place to ensure that the process remains stable and controlled. Change control is a very important aspect of a validated system. The possible effect of any "change" must be assessed, and may require re-validation. This assessment must also be documented. Examples of changes that would require such an assessment:

- Addition of new devices that were not part of the original validation process
- Changes in the design or materials of any device
- Changes in sterilization load configuration or load mix
- Any change in packaging materials or design
- Any changes in materials used in the process, such as detergents or steam source
- Any change to the operating conditions of the process

Even without an identifiable change, the overall process must be revalidated on an ongoing basis, to assess the effects of any unintended changes. This revalidation is typically done annually.

Sterilization assurance in U.S. hospitals

The rigorous testing and documentation requirements required by the ISO standards would present a significant challenge for the vast majority of health care facilities in the U.S., and indeed, the world. While some countries or regions (e.g. Europe) claim to follow these guidelines in their hospitals, the reality is that true compliance to these standards is a relatively rare occurrence.^{5,6}

While the ISO standards have been adopted by the U.S. for industrial applications, health care facilities in the U.S. typically follow the recommended practices developed and published by AAMI, such as ANSI/AAMI ST79:2006⁷ and ANSI/AAMI ST41:2008⁸. These documents outline requirements for quality systems and process controls that are better suited for

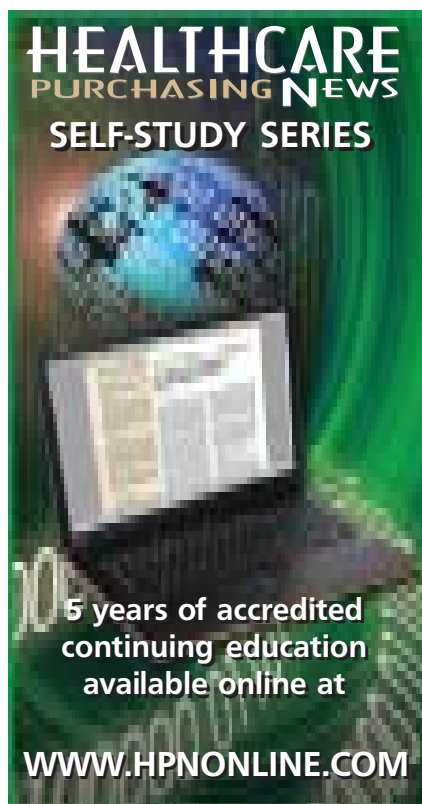
hospitals and clinics. The current practice in U.S. health care facilities relies on the integration of physical, biological, and chemical indicators in combination with recommended practice guidelines for device reprocessing to provide appropriate sterility assurance for load and pack release. Parametric release is not currently recommended because of the validation and documentation requirements.

Parametric release requires the highest level of documentation and control for all steps in the overall sterilization process. The documentation and validation requirements presented in the ISO sterilization process standards are intended for application in both industrial and health care settings. However, the stated requirements for documentation, a quality system and on-going validation are not realistic for the majority of health care facilities at the present time. **HPN**

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References

1. International Standards Organization (ISO) *Sterilization of health care products – vocabulary*. AAMI/ISO/TS 11139:2006.
2. International Standards Organization (ISO) *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. ANSI/AAMI/ISO 17665-1:2006.
3. International Standards Organization (ISO) *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. AAMI/ISO 11135-1:2007.
4. Cofield, A and Hancock, C.O. "An introduction to Process Validation, Purdue University/International Association for Central Service Material Management," Self Study Series Lesson No. 41, 1998.
5. Schneider, P.M. "Parametric Release of Steam Sterilized Items – Where We Are and Why," *Managing Infection Control*, April 2002, pp. 56-61.
6. Van Doornmalen, J.P.C.M, Dankert, J., "A validation survey of 197 hospital steam sterilizers in The Netherlands in 2001 and 2002", *Journal of Hospital Infection* (2005) 59, 126-130.
7. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, Amendment 2, ANSI/AAMI ST79:2006/A2:2009. Arlington, VA: AAMI 2009.
8. Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*. ANSI/AAMI ST41:2008. Arlington, VA: AAMI 2008.



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The facts about parametric release

Can it work in your facility?

Circle the one correct answer:

1. Parametric release simply replaces the use of biological and chemical indicators for sterile load release with a review of the physical parameters of the sterilization process. Nothing else is required.
A. True
B. False
2. A rigorous quality management system is a basic requirement for parametric release.
A. True
B. False
3. The Operational Qualification process documents that equipment operates according to specification.
A. True
B. False
4. A change to a new packaging supplier may require re-validation in a parametric release system.
A. True
B. False
5. The design and materials of a medical device can have a significant impact on how effectively it can be sterilized.
A. True
B. False
6. Parametric release can only be used for steam sterilization
A. True
B. False
7. Parametric release is commonly used in health care facilities around the world
A. True
B. False
8. From the perspective of the ISO standards, the sterilization process only involves the sterilizer itself.
A. True
B. False
9. Process validation is a fundamental requirement for use of parametric release
A. True
B. False
10. A validated process must be revalidated on a routine basis
A. True
B. False

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