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Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance

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Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance Task Force

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1.0 Introduction

Moist Heat Sterilization is a process that uses moist heat as the lethal agent to render liquid and porous/hard goods items free of viable microorganisms. There are two main types of processes used in moist heat sterilization: saturated steam sterilization and air overpressure sterilization. Saturated steam sterilization is used primarily for porous, hard goods loads, while air overpressure is used for liquid loads.

Sterilizers are used to sterilize many types of articles, including:

- Porous/hard goods, e.g., equipment, tools, laboratory glassware, product components, packaging, or devices
- Product components that are not part of a porous or liquid load, e.g., vials and syringes
- Cleaning materials and product intermediates
- Product in final containers (terminal sterilization)
- Heat labile media
- Biological solutions and products, equipment, tools

Air over-pressure applications are used to minimize destruction or distortion of plastic containers or syringes containing liquids.

The primary objective of the task force was to develop a science-based technical report on moist heat sterilizers that may be used in all regulatory environments and can be used by organizations to develop their own program for equipment qualification. To this end, prescription has been avoided, and region-specific regulatory expectations are not always addressed. This report should be considered a guide and is not intended to establish standards for sterilization systems. It is intended to be a single-source overview that complements existing documents listed in the reference section. References to appropriate and up-to-date scientific publications, international regulatory documents, journal articles, technical papers and books are used where more detail and supportive data can be found.

The task force was composed of European and North American industry professionals to ensure the methods, terminology and practices of sterilization science presented reflect sound science and can be used globally. This technical report was disseminated in draft for public review and comment.

1.1 Purpose / Scope

This Technical Report addresses moist heat sterilizers intended for use in the pharmaceutical, medical device and biotechnology industries. This technical report focuses on the design and operation of moist heat sterilizers, from the development of User Requirements Specifications (URS) through equipment qualification (Installation Qualification (IQ)/Operational Qualification (OQ)) and culminating with ongoing maintenance requirements. The focus of this report does not include Performance Qualification (PQ). The reader is directed to *PDA Technical Report No. 1: Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control* for discussion of load cycle development and process Performance Qualification. ***(1)***

This technical report addresses:

- Setting User Requirements and Specifications
- Design Qualification (DQ)
- Equipment and Control System Design
- Functional Requirements for the moist heat sterilizer and expectations for utilities supporting the sterilizer

- Equipment Operation, including calibration and maintenance
- Equipment Qualification, which may include Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), and commissioning
- On-going control requirements
- Cycle Development

This Technical Report will not address, and considers outside the scope of its content, steam-in-place, which will be covered in a subsequent PDA technical report. Several aspects described within this document may be useful for consideration when developing these types of systems; however the content of the Technical Report has been prepared specifically for moist heat sterilizers. A life-cycle approach is recommended for the specification, design, testing and qualification of moist heat sterilizer systems, and the reader should consult *Technical Report No. 1* in this regard. ***(1)***

The sterilizer life cycle approach to validation activities (see **Figure 1.1-1**) should include a Change Control Program and a Quality Risk Management (QRM) Program. A Change Control Program would encompass the requirements for documenting and verifying all changes made to the sterilizer that would affect its validated state. The QRM program would provide the end-user with the tools required to make intelligent risk-based decisions with respect to the design of the sterilizer, the sterilization process itself, and the operation of the sterilizer. QRM may be used during qualification and validation to prioritize and develop test requirements and acceptance criteria, and may also be used in conjunction with Change Control to determine the appropriate requalification interval for the sterilizer. *PDA Technical Report No. 44: Quality Risk Management for Aseptic Processes* outlines an approach that can be adopted. ***(2)***

Points to consider for equipment qualification activities are provided in this report. However, when to conduct these activities and the personnel who will perform them is determined by the user. Activity overlap or gaps should be avoided where possible. Personnel performing these activities should have the suitable skills and qualifications commensurate to their assigned responsibilities.