Technical Report No. 48

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

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1.0 Introduction 引言

Moist Heat Sterilization is a process that uses moist heat as the lethal agent to render liquid and porous/hard goods items tree 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.
湿热灭菌是一种采用湿热作为灭菌手段来杀灭液体和多孔/坚硬物品中活微生物的工艺。湿热灭菌采用两种主要的工艺：饱和蒸汽以及空气超压（用空气加压条件下）灭菌。饱和蒸汽灭菌主要用于多孔/坚硬物品的灭菌，而空气超压灭菌则用于液体产品。

Sterilizers are used to sterilize many types of articles, including:
灭菌柜可以用来给很多类型的物品灭菌，包括：

- Porous/hard goods, e.g., equipment, tools, laboratory glassware, product components, packaging, or devices
  多孔/坚硬物品，如设备、工器具、实验室玻璃器皿、产品组件、包装材料或器具
- Product components that are not part of a porous or liquid load, e.g., vials and syringes
  不属于多孔或液体装载的产品部件，如小瓶和针筒
- Cleaning materials and product intermediates
  清洁材料和产品中间体
- Product in final container (terminal sterilization)
  在最终容器中的产品（最终灭菌产品）
- Heat labile media
  热稳定性差的培养基
- Biological solutions and products, equipment, tools
  生物溶液及产品、设备、工器具

Air over-pressure applications are used to minimize destruction or distortion of plastic containers or syringes containing liquids.
空气超压的湿热灭菌用于减少装有液体的针筒或塑料容器的损坏或变形。

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.
特别工作组的主要目标是编写一个有科学依据的关于湿热灭菌柜的报告,这个报告适用于所有法规环境，也可供组织开发自己的程序用于设备确认。为此，已经避免了法规，到地区性法规的期望也不是一直考虑。本报告无意去建立灭菌系统的标准，而应将它看作一个指南。它作为一个专

题性的综述，对所列参考文献进行补充。本文参考了有关最新的科技出版物、国际法规、科技文章、技术论文及书籍，在这些参考文献中，可查得更多细节和支持性数据。

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.
特别工作组由欧洲及北美专业人员组成，以确保灭菌科学的方法，术语及做法能够完整地体现其科学性并在全球范围内使用。本技术报告的草案曾公布征求公众的审核及建议。

1.1 Purpose/Scope 目的/范围

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)
本技术报告专注于制药、医疗器械及生物技术行业所采用的湿热灭菌柜。它将重点放在湿热灭菌柜的设计和运行上，从用户需求说明（URS）的编写开始，经设备确认（安装确认、运行确认）并以日常的维修要求告终。本报告没有包括性能确认（PQ）。读者可查阅注射剂协会第一号技术报告（湿热灭菌工艺的验证：灭菌程序的设计、开发、确认以及日常监控）中关于装载程序的开发和工艺性能确认的讨论。(1)

This technical report addresses:
本技术报告主要讨论如下内容：

- Setting User Requirements and Specifications
  设定用户需求及技术标准
- Design Qualification
  设计确认（DQ）
- Equipment and Control System Design
  设备及控制系统的设计
- Functional Requirements for the moist heat sterilizer and expectations for utilities supporting the sterilizer
  湿热灭菌柜的功能要求以及灭菌柜对公用系统的要求
- Equipment Operation, including calibration and maintenance
  设备运行，包括校准及维护
- Equipment Qualification, which may include Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), and commissioning
  设备确认，包括工厂验收测试（FAT），现场用户验收以及调试
- On-going control requirements

持续控制的需求

- Cycle Development
  程序的开发

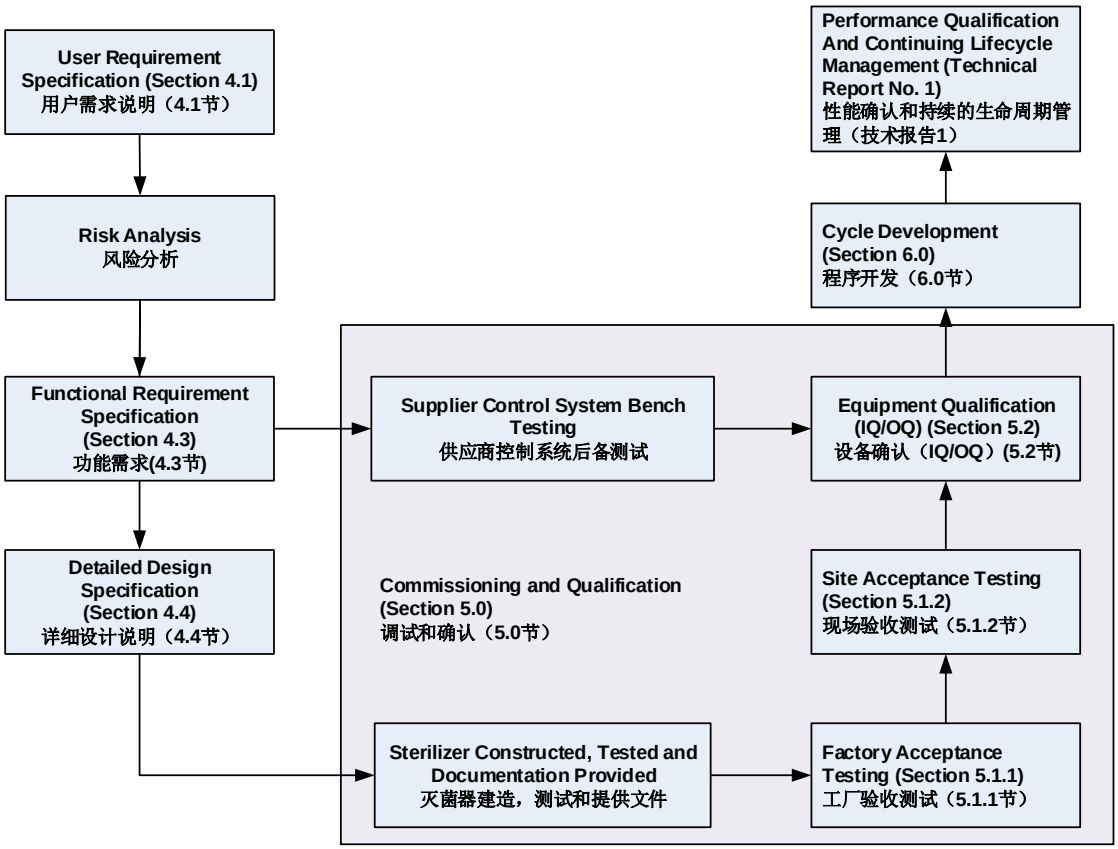
This Technical Report will not address, and considers outside the scope of its content, steam-in-place, which will be covered in a subsequent PDA technical report. Several aspects described within this document may be useful for consideration when developing these types of systems; however the content 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)
本技术报告不阐述并考虑此范围以外的内容，在线灭菌（SIP），这将包含在注射剂协会后续的技术报告中。当开发这类系统时，本报告所阐述的一些方面可能有助于考虑；然而，本技术报告的重心还是在湿热灭菌柜上。建议湿热灭菌系统的标准、设计、测试及确认采用生命周期的方式，在这方面，请读者参考第一号技术报告。（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)
灭菌柜生命周期的验证活动（**见图 1.1-1**）应包括变更控制计划以及质量风险管理（QRM）计划。变更控制计划包括记录并检查对灭菌柜所作的所有变更，而这类变更将影响灭菌柜已验证的状态。质量风险管理（QRM）计划给最终用户提供了一个必要的工具，以致用户能够就灭菌柜的设计，灭菌工艺本身以及灭菌柜的运行做出明智的基于风险的各种决定。在确认和验证过程中，质量风险管理（QRM）可用于优化和制订测试要求及可接受标准，还可以结合变更控制用以决定灭菌柜的再确认周期。注射剂协会第四十四号技术报告：无菌工艺的质量风险管理 概述了一种可供采用的方法。（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.
本报告中阐述了设备确认活动需考虑的问题。然而，何时，由谁来完成这些活动，应由用户确定。可能的话，应避免这类活动的重复或脱节。从事这些活动的人员应有适当的技能和资质，以履行他们的职责。

Figure 1.1-1 Validation Life-Cycle Activities

图 1.1-1 验证生命周期的活动



2.0 Glossary of Terms 术语

Current FDA. ICH. ISO and other regulatory definitions are used except when more clarity is added by the Task Force. In some instances two definitions used in current guidances are provided where both are considered applicable. Regulatory guidelines offer other definitions that may be considered.
除了那些需要特别工作组添加更多说明的，本报告采用了当前 FDA、ICH、ISO 和其它法规中的定义。有些情况下，提供当前指南中使用的两种定义，认为这两种均适用。也可考虑法规提供的其它定义。

Variations in the usage of some terms may differ from company to company, and some may be subject to change in the future. However, the terms used must be clearly defined and well understood within the company and clearly defined in internal Standard Operating Procedures (SOPs), standards, and in regulatory filings. For the purposes of this technical report, the following definitions are used.
在术语的采用上，不同企业之间存在差异，有些定义在将来可能产生变化。然而，在企业内部，必须对术语明确定义并有统一的理解，并在内部的标准操作规程（SOP）、标准及提交给监管机构的文件中应有明确的定义。本技术报告收载的术语如下：

Acceptance Criteria 可接受标准
The pre-defined specifications, standards or ranges that must be met under stated test conditions.
在规定的测试条件下必须满足的预先设定的要求，标准或范围。

Air Detector 空气检测器
An instrument that may be fitted to a saturated steam sterilizer that detects the presence of gas other than steam in the chamber.
可安装于饱和蒸汽灭菌器上用以检测灭菌器腔室中空气（不是蒸汽）的仪器。

Air Overpressure (AOP) Sterilization Process 空气超压灭菌程序
A moist heat sterilization process that operates at a controlled pressure greater than saturated steam pressure and typically uses compressed air to bring the chamber to the desired pressure.
指在大于饱和蒸汽压的控制压力下运行的湿热灭菌程序,通常用压缩空气使灭菌腔室达到所需的压力。

Air Removal Test 空气去除试验
A test used to evaluate air removal and steam penetration in an empty sterilizer that is used for porous/hard goods load sterilization (e.g., Bowie-Dick Test, DART^{TM}, Lantor Cube, Browns' Test).
用于评估灭菌器空载条件下空气去除和蒸汽穿透的一种试验(例如,Bowie-Dick 测试法,DART^{TM}, Lantor Cube，Browns 测试法)，此类灭菌柜用于多孔/坚硬物品类装载的灭菌。

Calibration 校准

The demonstration that an instrument or device produces results within specified limits when compared to those produced by a reference standard or a standard that traceable to national or international standards, over an appropriate range of measurements (calibration range).
在适当的度量范围（校准范围）以内，采用与相关标准或可溯源至国内或国际的标准进行比较，以证明一项仪器或设备所得结果符合规定限度标准的活动。

Calibration Tolerance 校准公差
In metrology, the maximum permissible range around a specified value that applies to a properly functioning measuring instrument. [Synonym: calibration uncertainty, error]
在计量学中，适当的功能性测试仪表给定值周围允许的最大范围。[同义词：校准误差，误差]

Chamber 腔室
The primary component of a sterilizer, contains the items to be sterilized. The chamber is a pressure rated vessel.
灭菌器用以放置被灭菌物品的主要组成部分。灭菌器腔室是一个有额定压力的容器。

Chamber Leak Test 腔室检漏测试
A test conducted to evaluate possible air infiltration to the chamber under vacuum. [Synonym: Vacuum Leak test, Air Leak Test]
一项评估在真空条件下空气可能渗入腔室的测试。[同义词：真空检漏试验，空气渗漏试验]

Commissioning 调试
A prescribed number of activities designed to take equipment and systems from a static, substantially complete state to an operable state. (3)
经设计使设备和系统从一个基本完成的静止状态成为一个可运行状态所需的一系列活动。（3）

Computerized System 计算机化的系统
Collective application software, data and hardware platform that provides functionality, control and data to a user or other system.
指向用户或其它系统提供功能、控制和数据的应用软件、数据及硬件平台的集成系统。

Control Valve 控制阀
A device that modulates the flow of fluid (e.g. gas, steam, water) in a conduit in response to a signal from a process measurement control system. (4)
一个响应工艺测试控制系统测试信号，用以调节管道中流量（如气体，蒸汽，水）的装置。（4）

Discrete Valve 控制总阀
A device designed for on/off operation; fully opened or fully closed.
一个设计用于运行启动/关闭的装置：有全开或全关二种状态。

Proportional Control Valve 比例控制阀
A device that is designed for precise positioning and continuous movement, typically in response to a varying analog signal. [Synonym: Modulating Valve]
一个设计通常用于响应一个可变类似信号，可精确定位并可连续调节的装置。[同义词：调

幅阀]

Cool-Down Phase 冷却阶段

The phase of a sterilization cycle that occurs after completion of the exposure phase. [Synonym: post-conditioning phase, slow exhaust phase, drying phase, equalization phase]
指灭菌周期中灭菌阶段完成后的阶段。[同义词：灭菌后的阶段，缓慢排放阶段，干燥阶段，平衡阶段]

Cycle Phases 程序阶段

A discreet series of sterilizer process steps (such as, heat-up, exposure and cool down) performed sequentially that represent a complete sterilization cycle. [Synonym: Cycle Steps]
灭菌柜灭菌过程中依次完成代表灭菌周期的各个步骤（如加热、灭菌和冷却）。[同义词：程序步骤]

Decommissioning 退役

A planned and orderly removal of a facility, operation or system from use.
将一个设施/设备或系统按计划和程序移除出使用的状态。

Design Qualification (DQ)设计确认

Documented verification that the proposed design of the facilities, equipment, or system is suitable for the intended purpose. (5)
确认所建议的设施、设备或系统适用于预期目的并有文件和记录的一系列活动。

Dryness Fraction 蒸汽干度

An absolute measure of actual latent heat of a sample of steam relative to the theoretical latent heat of saturated steam.
一个蒸汽样品中，实际潜热与饱和蒸汽理论潜热之比（绝对度量）。

Dryness Value 干度值

A dimensionless quantity, derived to approximate the Dryness Fraction that is a measure of the amount of liquid-phase water carried by steam.
近似蒸汽干度且系无因次的量值，它是蒸汽所带液相水量的测试值。

Eductor 喷射泵

A device that produces vacuum by means of the Venturi effect. [Syn.: Aspirator, ejector pump]
一种采用文丘里管效应来获得真空的装置。[同义词：抽气泵，喷射器]

Electronic Record 电子记录

A record used for GMP purposes or for regulatory submission that is stored electronically for the purposes of reproduction, retrieval or archival.
一种用于 GMP 目的或递交法规监管机构以电子方式贮存可供复制、恢复或归档的记录。

Equilibration Time 平衡时间

The period that elapses between the attainment of the minimum exposure temperature at the

reference measurement point (typically the drain) and the attainment of the sterilization temperature at all points within the load.
指从灭菌柜参照测试点（通常是排水口）达到最低灭菌温度开始，至装载所有测温点均达到灭菌温度之间所需的时间。

Exposure Phase 灭菌保温阶段
The phase of the sterilization cycle in which the appropriate parameters are maintained within defined ranges for the time (exposure time or dwell period) and temperature determined to be necessary to achieve the desired lethality. [Synonym: dwell period]
系指灭菌周期中，为获得设定杀灭效果，保持设定灭菌温度的持续时间（保温时间或保温阶段）。[同义词：保温期]

F-Value (lethality Factor)F 值(杀灭因素)
A measurement of sterilization effectiveness. $F_{(Tref, Z)}$ is the calculated equivalent lethality (using a specified z value), in terms of minutes at a reference temperature (T_{ref}), delivered by a sterilization cycle to an item.
系灭菌效力的度量值。$F_{(Tref, Z)}$ 是在规定的 Z 值下，一个灭菌程序赋予一被灭菌物品在参照温度 T℃下的等效灭菌时间。

$F_{physical}$
A term used to describe the delivered lethality calculated based on the physical parameters of the cycle. The $F_{physical}$-value is the integration of the integration of lethal rate (L) over time. The lethal rate is calculated for a reference temperature (T_{ref}) and z-value using the equation: $L = 10^{(T-Tref)/z}$
系按物理参数计算，用以描述灭菌周期赋于装载杀灭力的术语。它是灭菌率 L 对时间的积分值。当 z 值及参照温度为 T_{ref} 时，灭菌率 L 用公式：$L=10^{(T-Tref)/z}$ 计算。

F_0
A term used when the specific reference conditions of T_{ref} = 121.1℃ and z=10℃ are used to calculate the equivalent lethality. For example, when the z-value of the BI is 10℃ a cycle with an For $F_{(T=121℃, z=10℃)}$, equal to 8 minutes is equivalent (in terms of delivered lethality) to a square wave cycle of 8 minutes at 121.1℃. A square wave cycle that provided an exposure of 25.9 minutes at 116℃ would also yield an F_0 of 8 minutes.

F0 值（标准灭菌时间 ），是指参照温度 Tref =121.1℃，Z 取 10℃时计算的等效灭菌时间。例如，当生物指示剂的 z 取 10℃，$F_{(T=121.1℃, z=10℃)}$ 赋予产品 8 分钟的程序，或 F0 为 8，与一个 116℃灭菌 25.9 分钟方形灭菌波是等效的，F0 均 为 8 分钟。

注意：参照温度 121.1℃在数学上近似 250°F，为简化计算，本文此后将采用 121℃。

Factory Acceptance Test (FAT)工厂验收测试
A test typically conducted by the sterilizer manufacturer after the system has been assembled and before the system is shipped to the installation site.
在系统装配并在发往安装地点前通常由灭菌柜制造厂进行的测试。

Good Engineering Practices (GEP)良好工程管理规范

Documented proven and accepted engineering methods and practices that are applied throughout the project life-cycle to deliver solutions that are cost effective, are compliant with regulations and meet the requirements of the user.

在整个项目生命周期的全过程中，为提供经济、符合法规要求和用户需求的各种解决方案而采用的有文件证明的公认的设计方法和实践。

Gravity Displacement Process 重力置换程序

A sterilization based on the principle that air within the chamber is cooler and heavier than steam, and will sink to the bottom of the chamber.

以冷空气比进入腔室的蒸汽重而沉降在腔室底部的原理而运行的灭菌工艺。

Heat Transfer 传热

Energy that is transferred as a result of a temperature difference between an object and its surroundings.

指因一个物体与其环境之间存在温差所致的能量转移。

Heat Penetration 热穿透

Heat penetration testing uses temperature measurement obtained inside a load item to evaluate the amount of energy has been transferred to the materials that are to be sterilized.

为评价已传给被灭菌品能量而进行的装载测温试验。

Heat-Up Phase 加热阶段/升温阶段

The phase of the sterilization cycle that occurs prior to the exposure phase.

系指灭菌程序达到灭菌温度的前一个阶段。

Installation Qualification 安装确认（IQ）

Documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations. and/or user requirements. (5)

指检查、确认已安装或改造的系统或设备符合经批准的设计、供货商的建议及/或用户需求的有文件证明的相关活动。

Leak Rate 泄漏率

A measured quantity of air that enters the sterilizer chamber during a specified lime.

在一个规定的时间内，测得进入灭菌柜腔室空气的量。

Liquid Load 液体装载

A load consisting of containers of aqueous solutions. The sterilization of the combiner contend is achieved through transfer of energy through the container into the aqueous liquid.

指由装药液容器组成的装载。能量透过容器传给药液，以实现产品的灭菌。

Load Zone 装载区

Area within the sterilization chamber where materials to be sterilized may be placed.

指灭菌柜腔室内可放置被灭菌物品的区域。

Maximum Load 最大装载

The maximum quantity or mass of items permitted in a sterilizer load.

一个灭菌柜内允许的最大装载量。

Minimum Load 最小装载

The minimum quantity or mass of items permitted d in a sterilizer load. The minimum load may consist of item(s) that are the greatest heat-up and/or air removal challenge.

一个灭菌柜内允许的最小装载量。最小装载有可能面临去除空气（最长升温阶段）的挑战 。

Moist Heat 湿热

Steam, steam-air mixtures, and superheated water used for sterilization.

指用于灭菌的蒸汽、蒸汽-空气混合物以及过热水。

Moist Heat Sterilizer 湿热灭菌柜

Equipment (e.g., a pressure-rated vessel and associated controls) used to achieve sterilization through time, temperature and pressure. [Synonym: Autoclave, Steam Sterilizer]

通过温度、压力和时间来实现灭菌的设备（如带相关控制的压力容器）。[同义词：高压灭菌器，蒸汽灭菌柜]

Non-condensable Gases 不凝性气体

Air and other gas that will not condense to liquid state, thereby not releasing latent heat under the conditions of sterilization.

系指在灭菌条件下不会冷凝，因此不会释放潜热的空气和其他气体。

Operating Parameters 运行参数

Controlled and/or measured values (e.g., time, temperature, pressure) that collectively define each phase of a sterilization cycle (e.g. heat-up. exposure, and cool down). [Synonym: process parameter]

用来定义每一个灭菌阶段（如加热、灭菌和冷却）且需要加以收集和测试的参数（如时间、温度和压力）。[灭菌工艺参数]

Critical Parameters 关键参数

Values that arc controlled and/or measured and arc linked to safety and efficacy of a product.

需要控制和/或测量且与产品的安全和功效相关的参数。关键参数不合格时，被灭菌产品不得放行。

Key Parameters 重要参数

Values that are controlled and/or measured and are used to assure the on-going "stale of control of sterilization runs.

需控制/和测试以保证灭菌在“受控状态”正常运行的参数。

Operational Qualification 运行确认 (OQ)

A documented demonstration that equipment, facilities and operations function as specified in the design qualification.
Documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges. (S)
证明设备、设施及运行符合设计确认所规定的要求并有文件和记录的活动。
证明所安装或改造的设备、系统在整个运行的范围内符合预期要求并有文件及记录的活动。 (5)

Performance Qualification 性能确认 (PQ)
Documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications. (5) [Synonym： Process Performance Qualification]
证明一个已连接好的设备及辅助系统能根据批准的工艺及技术要求有效并重现性运行且有文件和记录的相关活动。(5) [同义词：工艺性能确认]

Piping and Instrumentation Diagram (P&ID)管道仪表流程图
A schematic diagram that shows the relational arrangement of piping, components, instruments, and equipment connections of the system. It also illustrates the control and functional relationship.
指显示系统设备连接、管道、部件、仪表相互关系并在图中说明控制和功能的相关性的示意图。

Porous/Hard Goods Loads（P/HG）多孔/坚硬装载
A porous/hard goods load consists of items in which the bioburden is inactivated through direct contact with saturated steam. Porous/hard goods load items include: items likely to contain air like: filters, stopper's, tubing (hoses), garments, cleaning equipment, or machine change pares.
系指通过与饱和蒸汽直接接触而杀灭其中微生物的被灭菌物品。多孔/坚硬装载包括：很可能包含空气的装载：过滤器、胶塞、软管、拖把、工作服、清洁器具或设备的更换部件。

Pre-vacuum Process 预真空程序
A sterilization process in which air is removed from the chamber using a vacuum pump or other mechanical system before the exposure phase begins. This method is particularly suited to load items that can trap such tubing, filters and filling machine assemblies.
一个需要用真空泵或其它机械系统去除空气后才开始灭菌的灭菌程序。此方法尤其适用于夹带空气的物品，如软管、过滤器和灌装机的部件。

Programmable Logic Controller (PLC)可编程序逻辑控制器
A digital electronic apparatus with a programmable memory tor scoring instructions to implement specific functions, such as logic, sequencing, timing, counting and arithmetic, to control machines and processes.
指一个数字式带可编程存储器的电器装置，此装置储存各种指令，以执行如逻辑、程序、定时、计数和自动化等操作。

Proportional, Integral, Derivative (PID)比例-积分-微分控制，简称 PID 控制
Control action in which the output is proportional to a linear combination of the input, the time

integral of input, and the time rate-of-change of input. (6)
输出正比于时间，输入积分时间以及输入走时变化时间线性组合的控制行为。(6)

Quality System 质量系统
Formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill produce/service requirements, customer satisfaction, and continual improvement (7)
系指正式的经营方式，它确定满足产品/服务要求、让消费者满意及持续改进所需组织机构、过程、程序及资源的管理者责任。 (7)

Resistance Temperature Detector(s) (RTDs)电阻温度检测器
Resistance temperature detector are temperature sensors in which the electrical increases with the element increases with increases in temperature. This electrical resistance is then translated into a temperature value (expressed as a resistance versus temperature curve).
电阻温度检测器系测温探头，其中的电阻值随着温度升高而增加，随后按电阻-温度曲线的方式转化为温度值。

Site Acceptance Testing 现场验收试验
The SAT is a series of tests that are performed as part of commissioning after the unit has been installed in the final location.
在设备最终地点安装后完成的作为试车组成部分一系列试验。

Saturated Steam 饱和蒸汽
Steam that is at a temperature and pressure chat corresponds to the vaporization curve of water. It is in a state of equilibrium between being a liquid and a gas with no entrained liquid water. [Synonym: Dry Saturated Steam]
指处于水蒸发曲线对应点压力及温度的蒸汽。它是蒸汽中不夹带液态水，处于汽液平衡状态的蒸汽。[同义词：干饱和蒸汽]

Steam 蒸汽

Plant Steam 设备蒸汽
Steam of undefined chemical or biological quality produced from a boiler，usually containing boiler additives, without further treatment. [Synonym: Factory Steam, House Steam. Industrial Steam]
由锅炉生产通常含有锅炉添加物不作进一步处理且无化学及生物学质量要求的蒸汽。[同义词：工厂蒸汽，民用蒸汽，工业蒸汽]

Process Steam 工艺蒸汽
Process steam is similar to plant steam, except the steam is generated using a controlled feed water source to which no volatile additives (amines or hydrazines) have been introduced. Process steam may be appropriate for moist heat sterilization of liquid loads where the containers filled and sealed prior to sterilization.
工艺蒸汽与工业蒸汽相类似，不同点在于工艺蒸汽采用受控的水源中无挥发性填加物（胺或肼）。工艺蒸汽可适用于容器灌封后液体产品的湿热灭菌。

Pure Steam 纯蒸汽/清洁蒸汽

Collected condensate that complies with the Compendial requirements tor Water for Injection (WFI). (Synonym: Clean Steam)

其冷凝水符合美国药典“注射用水”（WFI）专论要求的蒸汽。[清洁蒸汽]

Steam-Air Mixture process（SAM）蒸汽-空气混合气体的灭菌程序

A sterilization process typically used tor liquid loads in which the heating medium used to heat the load is in a mixture of air and steam. This addition of air results in an air overpressure condition.

一个以蒸汽和空气混合物为加热介质的灭菌程序，它通常用于液体灭菌。引入空气的结果是造成空气加压的条件。

Sterilization 灭菌

A process used co reader an item free of viable organisms with a specified probability.

指用以使一个产品达到规定微生物存活概率的工艺过程。

Sterilization Cycle 灭菌周期

A sequence of defined operating parameters (e.g., time, temperature and pressure) and conditions required to render an item sterile.

指使物体成为无菌的一系列运行参数（例如时间、温度、压力）和条件所组成的程序。

Sterilization Run 灭菌运行

The execution of a sterilization cycle.

指执行灭菌周期

Temperature 温度

Temperature is the measure of thermal energy.

温度是热能的度量。

Temperature Distribution 热分布

Temperature measurement of the heating medium across the chamber load zone.

指对腔室中整个装载区域加热介质温度的测试。

Temperature Probe/Sensor 温度探头/传感器

A generic term used to describe any type of temperature measuring device that works through contact with the material or atmosphere to be measured. [Synonym: Load Probe, heat penetration probe, temperature distribution probe, drain probe]

一个描述任何一种通过与物料或大气接触测试温度装置的通俗术语。[同义词：装载探头，热穿透探头，温度分布探头，排放口探头]

Terminal Sterilization 最终灭菌

A process whereby produce is sterilized within its sterile barrier system. (8)

系指产品在其无菌密封系统中的灭菌。 (8)

Validation 验证

A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting predetermined acceptance criteria. (5) The proof of validation is obtained through rational experimental design and the evaluation of data, preferably beginning from the process development phase and continuing through the commercial production phase.

一个能够可靠地保证特殊的工艺、方法或系统能始终如一地获得预期结果的有文件和记录证明的程序。（5）验证的证据应通过验证方案的合理设计并对数据资料进行评估获得，这些数据资料最好始于工艺的开发阶段，直至商业化生产。

Sterilizer Specification 灭菌柜规格说明

Documents that define sterilizer system attributes and how they should be met.

详细阐述灭菌柜系统的属性及如何实现这些属性的文件。

Design Specification (DS)设计说明：

A set of specifications and information related to the installation features (including equipment, hardware and software) of the system that will ensure the realization of the user requirements. (Synonym Detailed Design Specification (DD5))

保证实现设施要求（包括设备、硬件及软件）所需的一整套标准及信息。[同义词：详细设计标准/DDS]

Functional Specification (FRS)功能说明：

A description of functional attributes and operational characteristics of the system that will ensure fulfillment of the user requirements. (Synonym; Functional Requirement Specification, Functional Design Specification)

为保证实现用户需求而对系统功能及运行特性的描述。[同义词：功能要求标准，功能设计标准]

用户需求说明 User Requirement Specification (URS)：

A description of features and performance requirements of a system that will fulfill the needs of the end user.

为确保满足最终用户需求而对一个系统特点及功能要求的描述

Superheated Steam 过热蒸汽

Steam whose temperature, at a given pressure, is higher than chat indicated by the equilibration curve for the vaporization of water.

在一定压力下，其温度高于水蒸发曲线所指示温度的蒸汽。

Superheated Water 过热水

Water in a liquid phase at a temperature above 100°C requiring overpressure to maintain this state.

指在 100℃以上并需一定压力才能保持液态的水。

Superheated Water Process 过热水程序

A sterilization process in which the heating medium is superheated water that is continuously circulated with air overpressure. This process requires air overpressure to keep the water in a liquid state. [Synonyms: water cascade, water spray process, water immersion process, water submersion process, raining water process, steam-air-water process]

在空气加压条件下，以不断循环的过热水为灭菌介质的灭菌工艺。此工艺需要空气超压，以保持水的液体状态。[同义词：水喷流，水喷淋灭菌工艺，水浸泡工艺，水淋式工艺，蒸汽-空气-水工艺]

3.0 Sterilization Processes 灭菌过程

Sterilizer design is primarily based upon the types of cycles the sterilizer is intended to perform. Most moist heat sterilization cycles rely on direct contact with saturated steam, which is water vapor in equilibrium with liquid water. Saturated steam can exist only along the phase boundary; that is, the relationship between its temperature and pressure is fixed. (9) Saturated steam is the most effective for the sterilization process.
灭菌器设计从根本上是依据预期灭菌周期的类型，大多数湿热灭菌循环依赖直接接触的饱和蒸汽，饱和蒸汽是与液态水保持平衡的水蒸汽。饱和蒸汽只能存在于（液态和气态）的相分界线上，也就是说，温度和压力的关系是固定的。饱和蒸汽对灭菌过程是最有效的。

Sterilization is accomplished by the heat transfer from the steam to the load and by the hydrating effect of the resultant condensate that forms as a result of the change in state from vapor to the lower energy liquid state. This phase change requires the transfer of the latent heat of the steam (that heat which was required to change it from liquid to vapor 39.6 kJoule/mole at 121°C) to the surroundings, thus heating the sterilizer and its load.
灭菌通过热量从蒸汽转移到装载物和通过生成冷凝液的水合作用影响而实现(水合过程将放出热量)，冷凝是从蒸汽状态转变到低能量的液体状态结果的形成，这个阶段的改变需要蒸汽（从液态改变到蒸汽需要 39.6KJ/mol 的热量在 121°C 时）的潜热转移到周边环境，因而加热灭菌器和其内的装载物。所含的热能差异极大。

3.1 Saturated Steam Processes 饱和蒸汽程序

Removal of air is a crucial element in the design of many sterilizers. An air-steam mixture will have less latent heat than air-free steam at the same pressure, thus reducing the efficiency of heat transfer from steam to the load. Vacuum air removal cycles are designed to remove air out of the chamber and load more efficiently than gravity displacement cycles. However, all of the air in the sterilizer may not be removed depending upon process capability. The sterilizer load affects the quantity of air removed. For example, a load with items such as gowns, filters and hoses will retain more air than a load lacking such items; however, it must be demonstrated through the qualification effort that such low levels of air will not adversely affect the sterilization cycle.
在大多灭菌器设计里面，空气去除是一个关键的要素，在相同压力下空气-蒸汽的混合气体比不含空气的蒸汽（纯蒸汽）所含有的潜热少，因此其会降低热量从蒸汽转移的装载物的效能。被设计为去除腔体和装载物内空气的抽真空法比重力置换法更有效，然而，基于工艺能力灭菌器内所有空气不可能全部被移除，灭菌器装载（类型/量）影响空气去除的数量。例如一个含有诸如衣服、过滤器和软管的装载比没有这些物品的装载保留更多的空气，然而，这必须通过确认措施被证明此类低水平的空气残留将不会对灭菌循环产生不利影响。

The heat transferred by the condensation of saturated steam is many times greater than that which would be transferred from steam above its saturation point; a condition called superheated steam. Sterilization with superheated steam is a dry-heat phenomenon, a process that is less effective than a saturated steam process. A 1°C change in superheated steam temperature has only 1.5 kJ/mole°C of energy. Whereas, saturated steam releases 39.6

kJ/mole°C making it a more efficient process. Superheated steam is also referred to as “dry steam,” as it does not form condensate immediately upon contact with a cold surface. Thus, the important hydrating effect is not present when superheat is present. In order to maintain a saturated steam condition, sudden pressure reductions should be avoided. (10) Superheat may be avoided by maintaining steam in equilibrium with water at the steam generator. A steam filled jacket around a sterilizer chamber may be used to reduce heat-up time and increase chamber temperature uniformity, but the jacket should be controlled at or below the chamber temperature during heat-up and exposure to avoid generation of superheated steam in the chamber.
饱和蒸汽通过冷凝传递的热量是从高于饱和点的蒸汽（即过热蒸汽）转移热量许多倍。用过热蒸汽灭菌是一种干热现象,效率低于饱和蒸汽工艺。过热蒸汽温度改变 1℃只有 1.5KJ/mol 的能量，而饱和蒸汽释放 39.6KJ/mol 的热量使之成为更有效的工艺。过热蒸汽也被称作“干蒸汽”，因为它一旦接触冷的表面不会立即形成冷凝水,因而,当过热出现时重要的水合作用影响将不会发生，为了维护一个饱和蒸汽条件，应避免突然的压力降低。过热能通过维持蒸汽发生器中的蒸汽与水相平衡进行避免，灭菌腔体周围注蒸汽的夹套可能被用于降低升温时间和提高腔体温度均匀性，但该夹套在升温和灭菌暴露阶段应该被控制在或低于腔体温度以避免腔体中过热的产生。

Condensation to water will cause a volume decrease in excess of 99% for saturated steam cycles. (11) This would normally result in a substantial pressure decrease if the condensed steam were not immediately replenished with additional steam to the sterilizer. It is this condensation/replenishment cycle that allows the steam to rapidly heat the surface of load items until they reach an effective sterilization temperature. Sterilizers and their corresponding cycles are designed to ensure that the sterilizing medium reaches all of these surfaces.
对饱和蒸汽循环来说冷凝成水将导致体积压缩超过 99%，如果冷凝的蒸汽没有立即用额外的蒸汽填充到灭菌器中，这通常将导致一个实质性的压力降，这是允许蒸汽快速加热装载物表面直到达到一个有效灭菌温度的冷凝/补给循环。灭菌器和它们相应的循环被设计以确保灭菌介质达到所有这些表面。

When an aqueous liquid filled container is terminally sterilized, the sterilizing effect inside the sealed container will result from the heating effect of steam and/or superheated water on the outside of the container. The heat transferred from the external source will heat the internal liquid and convert a portion of it to steam that will permeate the headspace of the container. Conditions in the headspace will respond to this internally developed steam (air-steam mixture) as well as the heating effect on the container exterior on the headspace. The steam/superheated water in the sterilizer chamber is only significant as a source of energy to the container exterior. Steam saturation is not a primary concern as long as heat transfer to the container proceeds at the required rate.
当灌装有水溶性液体的容器被最终灭菌时，密封容器内灭菌效果将起因于容器外部的蒸汽和/或过热水的热效应，来自于外部的热源转移的热量将加热内部液体并转换一部分液体蒸发，蒸发后气体将进入容器顶端空间中。顶端空间内条件将响应（随其变化）容器内部发展形成的蒸汽（空气-蒸汽混合气体）以及容器外部顶端空间的热效应。灭菌器腔体中蒸汽/过热水仅仅是容器外部重要的能量源，蒸汽饱和度不是一个主要的问题只要热转移给容器以要求的速率进行。

3.1.1 Gravity Displacement Process 重力置换程序

The gravity-displacement cycle is based on the principle that air within the chamber is cooler and heavier than the steam and will sink to the bottom of the chamber. As the steam enters the chamber, air is pushed out the bottom drain and exits (with the condensate) through an open drain valve, and/or steam trap which is designed to effectively permit the passage of large volumes of air. The success of the cycle in removing air depends on the correct operation of the trap and the proper distribution of steam. Steam is injected into the sterilizer chamber through a baffle or spreader bar (such as a perforated pipe). The rate of steam injection is critical: steam must be added so that its natural buoyancy will carry it upward, forcing the colder air down. If steam is added too rapidly, or not distributed properly, air pockets may be trapped near the top of the load. If steam is added too slowly, the air can be heated, diffuse into the steam, and become more difficult to remove.
重力置换程序是基于灭菌器腔体内空气比蒸汽更冷更重而将下沉腔体底部的原理。由于蒸汽进入腔体，空气被排挤底部排水沟并且连同冷凝水一起从排水阀和/或疏水阀排出腔体外，疏水阀是被设计为有效地允许大量空气通过的通道。该循环（重力置换程序）排除空气的成功与否取决于疏水阀的正确运行和蒸汽的适当分布。蒸汽通过导流板或散流器（例如多孔管）注入灭菌器，蒸汽注入的速率是关键的:如果蒸汽进得过快或分布不合理,装载的顶部或周围可能会夹带空气层。如果进汽过于缓慢，空气受热而扩散入蒸汽中，从而使排除空气更加困难。

The effectiveness of air elimination from the chamber is determined by measuring the drain line temperature since air and condensate gravitate to the bottom of the chamber. As air is eliminated, it is first replaced by hot condensate and eventually by saturated steam. The change in temperature, from that of the cooler air and condensate to that of the hotter steam, causes the steam trap to close. As the cycle progresses, the sterilizer chamber gradually reaches the pressure coinciding with the desired temperature set-point.
从腔体中去除空气的有效性通过测量排水沟处温度进行确定,因为空气和冷凝水下沉到腔体底部,由于空气被消除，它首先被热冷凝水取代，最后被饱和蒸汽取代，该处温度从冷空气和冷凝水的温度变化到更热的蒸汽，导致疏水阀关闭。随着工艺循环进展，灭菌器腔体逐渐达到符合期望温度设置点对应的压力。

A variance of the gravity displacement cycle is a gravity/forced air removal cycle. Forced air removal ensures removal of air from the chamber and is faster, more reliable and more efficient than gravity air removal methods. It is designed to remove air from the chamber for liquid loads in vented or non-vented containers by introducing steam to force the air out through the drain line. A vacuum pump attached to the drain line is in simultaneous operation to assist in removing the air from the system. Both the chamber pressure and temperature are controlled during the phase.
一个重力置换循环的变化（改进）是一个重力/强迫空气去除的循环。强迫空气去除确保空气从腔体快速去除，比重力空气去除方法更可靠更有效，它被设计为在通气或不通气容器中的液体装载通过引入蒸汽强迫空气从排水管出去达到从灭菌腔体去除空气。一个附在排水管的真空泵同时运行帮助从系统中去除空气，在该阶段腔体压力和温度被控制。

Since air removal through gravity or forced air displacement is less efficient for sterilization of porous loads than other methods, use of these cycles is not recommended.
由于空气去除通过重力或强迫空气置换对多孔装载灭菌来说相对其他方法效率较低,因而不建议使用此类循环

3.1.2 Pre-Vacuum Process 预真空程序

In pre-vacuum process, air is evacuated from the chamber using a mechanical pump or steam eductor before the sterilization portion of the cycle begins. This method is suited to load items with internal volumes such as tubing, filters, wrapped packs, and fill assemblies. The steam pulses serve to rapidly fill the voids created by the vacuum pulses, causing incremental decreases in the amount of residual air. Large pressure differentials between the steam and vacuum pulses increase the air removal. The number of pulses required should be determined during cycle development. Alternating steam vacuum pulses are more effective for air removal than a single deep vacuum and will ordinarily result in either shorter cycle times or less residual air in the chamber. They allow the use of a smaller, less expensive vacuum pump. Vacuum pulsing cycles are used most frequently in the pharmaceutical industry to sterilize loads that contain items from which air removal can be difficult. The greater the differential pressure between the steam pulse and vacuum levels, the greater the amount of air removal. Examples of such load items include coiled hoses; filter cartridges and housings; densely packed containers of stoppers and packages of clean room garments. Vacuum may displace liquids in unclosed containers, hence its use should be risk evaluated.
在预真空程序，在灭菌开始之前用一个机械真空泵或蒸汽喷射器将空气抽走，该方法适宜于带有内部体积的装载物诸如管道、过滤器、缠绕的灭菌包以及灌装组合体。蒸汽脉冲则是用来快速填充由真空脉动创造的空间，使得残留空气减少。蒸汽和真空脉冲间大的压力差提高空气去除，需要脉动的次数应该在灭菌工艺开发时确定。蒸汽和真空交替脉冲对去除空气比单一的一个深度真空更有效并且通常会导致要么更短的循环时间要么更少的空气残留。它们允许使用一个更小、更便宜的真空泵，真空脉动工艺在制药工业中用于灭菌去除空气较困难的装载物是最常用的方法，蒸汽脉动和真空水平间的压差越大，空去去除能力越强，此类装载物包括例如盘绕管、滤芯以及外壳、包装紧密的塞子和洁净服的包装容器。真空可能取代一个未密封容器中的液体，因而真空脉动的使用应该有一个风险评估。

3.2 Air Overpressure Processes 空气加压程序

Although air is generally considered a potential problem that reduces the efficiency of steam sterilization processes, there are times when its presence is required. Liquid loads of parenteral drugs are often terminally sterilized in sterilizers. In this case the major function of the condensing steam is to provide rapid heat transfer to the wall of the product container, which may be either rigid or flexible wall. In nearly all containers there is air (nitrogen or other inert gases will behave similarly) in the headspace above the liquid. As the solution is heated, this gas expands and adds to the pressure increase resulting from the evolution of water vapor within the container. Thus, the pressure within the container will exceed the chamber pressure.
尽管空气通常被认为是一个会降低蒸汽灭菌工艺效率的潜在的问题,但有的时候空气又是被要求（需要）存在的。注射液体制剂经常在灭菌器中被最终灭菌，在这种情况下蒸汽冷凝的主要功能是提供快速的热量转移到刚性或柔性的产品容器壁上。几乎在所有容器内溶液上方的空间中有空气（氮气或其它惰性气体），由于溶液被加热，气体膨胀并加入到因容器内水蒸汽演变而压力上升之中，因而，容器内压力将超过灭菌器内压力。

Glass vials can be sealed with special closures to withstand this pressure. As long as the pressure differential does not become too great during the steam exhaust portion of the cycle,

the vials will not break or burst. In those cases where rapid cooling of the load is desired, the pressure differential might become significant enough to cause container breakage or loss of closure integrity.
玻璃小瓶用专门的密封盖进行密封以能承受这压力，只要在排气过程中压力差不变得太大，玻璃小瓶将不会破裂或爆炸。在那些情况下装载物快速冷却时期望的，压力差可能变得非常关键足以能导致容器破裂或密闭性损坏。

Pre-filled syringes, plastic bags and semi-rigid containers present a greater problem. Because they do not have the inherent strength of glass, they have a tendency to burst or open as the pressure differential increases. To prevent this, air must be injected into the chamber to raise the pressure to user defined levels, e.g., to prevent movement of a syringe plunger. This is particularly important during the cooling cycle, when the chamber pressure is reduced at a rate greater than that within the container. This is commonly referred to as “air overpressure”.
预灌封注射器，塑料袋和半刚性容器表现出一个较大的问题，因为它们没有玻璃那种固有的强度，它们随着压力差的上升而有爆炸或打开的趋向，为预防这种情况，必须向灭菌器腔体中注入空气以增加压力直到用户确定的压力水平，例如预防注射器活塞移动，当灭菌器腔体压力以一个比容器内容更大的速率降低时，这是在冷却循环过程中尤其重要的，这通常被称为“空气加压”。

The presence of air, although necessary, does reduce the heat transfer efficiency. Therefore when an air overpressure cycle is used, it is necessary to maintain a well-mixed chamber environment to assure that the heat transfer to the load will be uniform. Mixing may be accomplished in several ways. There are two principal methods by which this is accomplished: Steam Air Mixture Process and Superheated Water Process.
空气的存在，尽管必要，但会降低热传递效率，因此，当一个空气加压循环被使用时，维持一个良好的混合腔体环境以保证热传递到装载物是均匀的非常重要，混合有几种方法达到，两个主要方法是：蒸汽空气混合工艺和过热水工艺。

3.2.1 Steam Air Mixture Process and Superheated Water Process 蒸汽空气混合气体工艺 & 过热水工艺

It is important to understand the physical principle involved in a mixture of air and steam. The relationship between temperature and pressure differs from that in the steam saturation table. Mixing may be accomplished in several ways:
理解空气与蒸汽混合的物理原理是非常重要的，混合气体的压力和温度之间的关系不同于饱和蒸汽表中的规定，混合可通过几个方法完成：

- Steam-air sterilizers may use fans or another means of continuously circulating and mixing air and steam.
  蒸汽-空气可能用风扇或另一种持续循环手段，混合空气和蒸汽。
- Steam-water-air sterilizers use an external pump to circulate superheated water from the floor of the chamber through a series of distribution nozzles located on the top or sides of the sterilizer and thence over the load items. This “raining” effect serves to mix the air, water and steam. When utilizing this process with a closed loop cooling design (i.e., a heat exchanger is used to cool the recirculating water) the recirculating water that will be used to cool the product is also sterilized during the exposure phase of the process.

蒸汽-水-空气灭菌器用一个外部泵循环过热水，从腔体底部通过一系列分布于灭菌器顶部或侧面的喷嘴使水循环到装载物上方淋下来，这“雨淋“作用用来混合空气、水及蒸汽。当在一个封闭的冷却回路中利用该工艺时（例如，一个热交换器被用于冷却循环水），被用于冷却产品的循环水也在工艺的暴露阶段被灭菌。

Both of these designs have an additional application in the cooling of terminally sterilized products. Circulation of air or water through a heat exchanger serves to cool the containers more rapidly thereby increasing sterilizer throughput. This rapid cooling may also be necessary to enhance product stability. 这两种设计在最终灭菌产品冷却时都有一个额外的用途,水或空气通过一个热交换器循环有助于更快冷却容器从而提高灭菌器生产能力，这快速冷却对加强产品稳定性是必要的。

Immersion cycles may be used for sterilization of plastic containers. This type of sterilization cycle is similar to a water spray sterilization cycle, except that instead of a spray of water, the sterilizer chamber is filled with water. The pressure exerted upon the container from the outside is the same as the pressure exerted within the container.
浸入式循环可用于塑料容器的灭菌，这种灭菌类型类似于水喷淋灭菌循环，除了代替喷淋水，灭菌器腔体用水灌满，容器外部受到压力同于内部。

3.3 Decontamination Processes 净化程序

Sterilizers are also used for decontamination applications such as laboratory or manufacturing waste prior to disposal. Sterilizer systems in these areas should be designed appropriately for the Biosafety/ Category rating of the hazard that may be present in biological loads. The equipment design must incorporate the required safety controls to contain hazardous organisms and to prevent their release to the area outside of the sterilizer envelope. Biological materials and the waste associated with them should be first assessed in terms of their biological safety. These biosafety levels (BSL) are described in Table 3.3-1. 灭菌器也被用于去污染，例如实验室或生产废弃物在处理前净化。这这些区域的灭菌系统应该针对生物安全/生物装载中存在的伤害分类评级而进行适当设计，设计必须包括必须的安全控制，包括有害微生物以及防止它们释放到灭菌器之外的区域。生物材料及与其有关的废弃物应该首先根据它们的生物安全性进行评估，生物安全等级（BSL）描述在表 3.3-1.

Effluent decontamination sterilizers are designed to prevent potentially harmful organisms from leaving the unit prior to sterilization. In a typical sterilizer, steam flow is from the top or sides of the chamber and flows past the drain RTD (Resistance Temperature Detector) through the drain bleed. With an effluent decontamination sterilizer, a method should be used to prevent harmful organisms from escaping until sterilization is completed. Methods available include the use of sterilizing grade filter, hold tank, or thermal decontamination. During the exposure phase, steam is bled through the sterilizing grade filter past a controlling RTD to ensure the filter is also sterilized during the cycle.
污水净化灭菌器设计应防止潜在的来自于灭菌前残留下来的有害有机体,在一个典型的灭菌器中,蒸汽来自于腔体的顶或侧面并流经排水沟处的 RTD(电阻温度检测器)。使用污水净化灭菌器，应该使用一个方法来防止逃脱（溢出）的有害生物直到灭菌完成，可用方法包括除菌级过滤器的使用，保持罐或热能去污染。在暴露阶段过程中，蒸汽从经过一个控制 RTD 的除菌级过滤器泄漏

出以确保过滤器再循环过程中也被灭菌。

Table 3.3-1 BioSafety Levels and Sterilizer Requirements 生物安全等级和灭菌器要求

Biosafety/Category Level 生物安全/分类等级	Sterilizer Requirements (12,13) 灭菌器要求
1.	No sterilization of waste is required 无废物灭菌要求
2.	A sterilizer with a make-safe (effluent decontamination) cycle must be readily accessible, normally in the same building as the laboratory 有带有安全（废液净化）循环的灭菌器可方便利用，通常与实验室在同一建筑物里。
3.	A sterilizer with a make-safe cycle should be preferably situated within the laboratory, but one must be readily accessible in the laboratory suite 在实验室内有净化灭菌器（带安全循环），但必须在实验室
4.	A double-ended sterilizer with interlocking doors with entry in the laboratory and an exit in a clean area must be provided 一个双扉灭菌器带有连锁装置，在实验室端进，在洁净区出必须被提供。

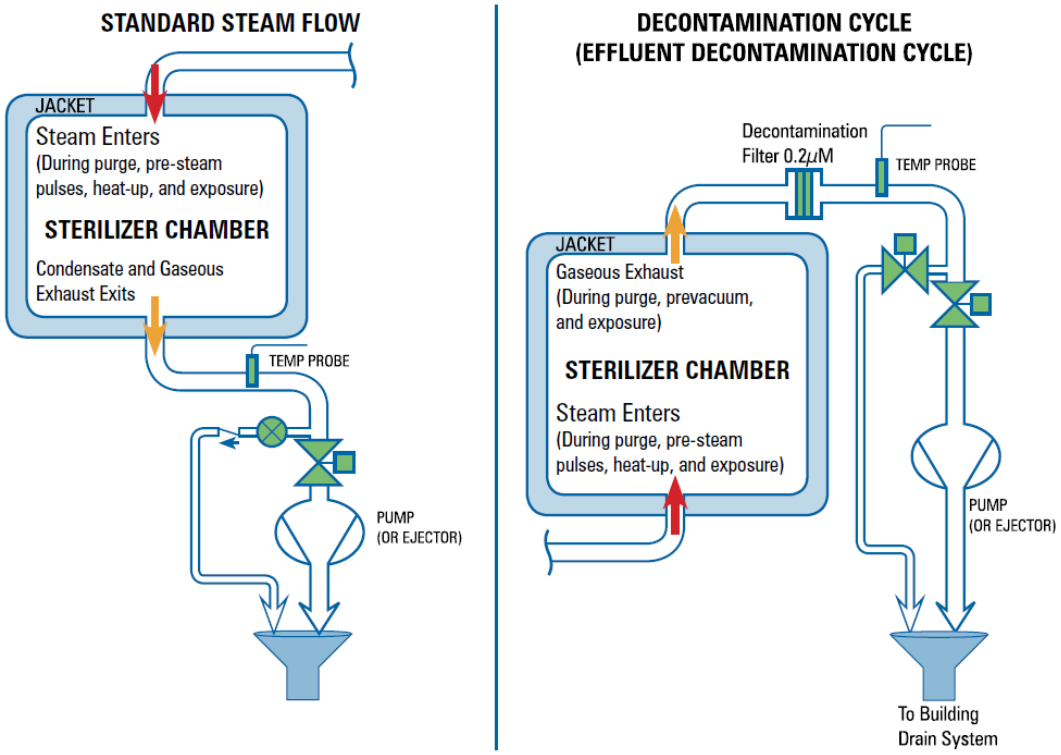
Figure 3.3.1 illustrates an example solution of the difference in the design of a sterilizer with normal steam flow versus that for an effluent decontamination sterilizer. The steam is fed through the drain line of the sterilizer and condensate is not drained until the end of the cycle. This is to ensure all effluents are exposed to the sterilization conditions prior to discharge. The filter configuration is a common effluent decontamination process. It should be noted that alternative methods are available such as steam-air high pathogen process or pulling air and effluent through an inline incinerator.

图 3.3.1 列举了正常的蒸汽流灭菌器与污水净化灭菌器在设计上差异的解决方案的一个例子，蒸汽通过灭菌器的排水管进入且冷凝水直到灭菌结束才从排水管排出，这是为确保所有的污水排放前暴露在灭菌条件下。过滤器配置是一个通常的污水净化工艺，应该注意的是可利用的替代方法诸如蒸汽-空气高病原体工艺或通过一个在线的焚化炉回收空气和污水。

Where a sterilizer is used to decontaminate hazardous waste, other considerations should also be made (e.g., wall seals, drain connections, filters, and decontamination for maintenance) and may be found in reference literature. Regional regulatory agencies should also be consulted.

当一个灭菌器被用于净化危害废物时，也应该考虑其它因素（例如壁密封性，排水管接头、过滤器以及起维护保养目的的净化）以及在参考文献里发现的，地区性法规管理机构也应咨询(区域性法规要求也应遵守)。

Figure 3.3-1 Decontamination and Standard Steam Flow Cycle Comparison 图 3.3.1 净化和标准蒸汽流循环比较



3.4 GMP and Non-GMP Sterilizers/GMP 和非 GMP 灭菌器

The term “GMP sterilizer” has no official definition or specific requirements for pharmaceutical manufacturing. However, it is commonly understood that a “GMP sterilizer” is a unit designed for moist heat sterilization, and built in accordance with current pharmaceutical industry sanitary design standards.

术语“GMP 灭菌器”没有官方定义或说对药物生产无明确要求，然而，对“GMP 灭菌器”通常理解是一个设计为湿热灭菌的单元，且符合当前制药工业卫生设计要求。

“Non-GMP” sterilizers are generally used for sterilization of items not used for processing product, product contact items, microbiological test items or items contacting primary product packaging. These sterilizers may include some “GMP” features, but may not have the precise control or recording of temperature and pressure that “GMP” sterilizers provide. Typical features of both types are depicted in **Table 3.4-1.**

“非 GMP”灭菌器一般用于 不用于工艺产品的物品、产品接触物品、微生物测试用品或接触产品初级包材的物品的灭菌，这些灭菌器可能包括一些“GMP”的特征，但可能没有 GMP 灭菌器需要的精度控制或温度及压力记录，两种类型典型特征描述在**表 3.4-1** 里面：

Table 3.4-1 GMP and Non-GMP Comparison Chart/ GMP 和非 GMP 对比表

GMP	NON-GMP
Typical applications include sterilization of products used in the testing or manufacturing of drug products, and terminal sterilization of liquids in sealed containers. 典型应用包括用于测试或药物生产的产品的灭菌，以及灌封在密封容器中液体产品的最终灭菌。	Typical applications include sterilization of products used for laboratory work (not supporting a production area or product testing) or sterilization of waste materials prior to disposal. 典型应用包括用于实验室工作（不支持生产区域或产品测试）的产品的灭菌或废物处理前灭菌。
Piping and chamber are designed to accommodate clean utilities such as pure or clean steam and process air. This includes stainless steel clamped and welded designs, proper slopes and deadlegs. 管道和腔体被设计以适应清洁设施诸如纯的或洁净蒸汽以及工艺气体。这包括不锈钢腔体和焊接设计，适当的倾斜度和死角。	Piping and chamber are designed as appropriate (e.g., copper piping) for the sterilizer's intended use. 管道和腔体为灭菌器的预期使用进行适当设计（例如铜管）。
Materials of construction are compatible and appropriate (e.g., non-particle generating) with products and processes ensuring no contamination (e.g., product or environmental). May be supported by certificates of inspection and traceability. 结构材质适合并兼容（例如，不产生颗粒）与产品和工艺以确保无污染（例如产品或环境），可能被检查证书和可追溯性支持。	Materials of construction appropriate (e.g., ensure no adverse reaction with load items to be sterilized) for the sterilizer's intended use. 针对灭菌器的预期使用有合适的结构材质（例如，确保没有与待灭菌的装载物没有不良反应）。
Product contact utilities (e.g., water, steam, air) supplied to the sterilizers are suitable for its intended use and meet applicable Compendial expectations. 提供给灭菌器的与产品接触的公用设施（例如，水、蒸汽、空气）适合于其预期使用以及符合适用的药典期望。	Load contact utilities (e.g., water, steam, air) supplied to the sterilizer are suitable for its intended use. 供给灭菌器与装载物接触的效用设施（例如水、蒸汽、空气）适合其预期使用。
Control and monitoring systems meets regional regulatory expectations for data security and integrity 数据安全性和完整性的控制和监控系统符合地区法规期望。	Control and monitoring systems data security and integrity meets internal organization requirements 数据安全性和完整性的控制和监控系统符合内部组织要求。
Temperature monitoring and control devices (e.g. drain probes) are independent of one another. 温度监控和控制装置（例如排水沟处探头）相	Temperature monitoring and control may be from a single device. 温度监控和控制可能来自于一个装置。

互独立。	
Performance meets requirements and specifications with Quality Unit oversight is expected. 性能符合质量部门监督的要求和标准。	Performance meets requirements and specifications. Quality Unit oversight may not be required. 性能符合要求和标准，质量部门监督可能不需要。

Aside from the designation of some sterilizers as “GMP” and other as “Non-GMP,” the validation of steam sterilization can be accomplished in any steam sterilizer according to its intended use and functional specification.

除了指定一些灭菌器作为“GMP”而另外一些作为“非 GMP”外，蒸汽灭菌的验证能在任何蒸汽灭菌器内按照它的预期使用目的和功能规格完成。

4.0 Comprehensive Sterilizer System Design 灭菌器系统全面设计

Design Qualification (DQ) provides documented verification that the proposed design is suitable for the intended purpose and conforms to User, Functional, and Regulatory Requirements.
设计确认：预定设计符合预期用途、用户、功能和法规要求的书面证明。

The conduct of a formalized Design Qualification (DQ) for new facilities and systems is becoming increasingly commonplace in the global healthcare industry. The execution of a DQ for a steam sterilizer is certainly possible however as the design expertise ordinarily lies with the sterilizer manufacturer, the benefits of a formalized DQ effort may be somewhat limited. Aspects of design qualification that might be more useful would be a critical review of the vendor's design compared with user requirements.
新厂房和系统的正式设计确认在全球健康产业中逐渐成为常规做法。进行蒸汽灭菌柜设计确认是可行的,因为设计技术一般取决于灭菌器制造商的水平,进行正式设计确认的作用可能是有限的。对于设计确认，更有价值的做法是通过与用户需求的比较对供应商的设计进行评审。

Design of a sterilizer system begins with the end use in mind and leads to the creation of a User Requirement Specification (URS). It is the responsibility of the end user to define the process outputs relevant to the intended operation of the sterilizer. Features and functions deemed important by the end user should be specified. Any specification that may impact the process output and therefore product quality should be approved by the Quality Unit. See Appendix A for examples of design considerations that may be included in the URS.
灭菌器系统的设计首先要考虑最终使用要求，并形成用户需求（URS）。最终用户有责任确定与灭菌器操作相关的工艺输出。应制订最终用户认为重要的特性和功能。任何可能影响工艺输出以及产品质量的指标应得到质量部门的批准。参见附录 A URS 中应包含的设计点示例。

These specifications are used to develop a Functional Requirement Specification (FRS) that outlines how the URS objectives may be achieved and is normally provided by the intended vendors.
这些指标是用来建立功能需求（FRS），说明如何达到 URS，通常由供应商制订。

Functional requirements may then be translated into a Detailed Design Specification (DDS) which may be produced by a collaborative effort between vendor and customer. The detailed design stage produces the document for construction bidding and contracting, system and equipment purchase, fabrication, installation and testing. (14)
功能需求可进一步转换成详细设计需求，详细设计需求可由供应商与客户共同完成。详细设计阶段应制订建造招投标和合同、系统和设备采购、装配、安装和测试文件。

To illustrate the intent of each primary phase of Design Qualification, an analogous example is presented in Table 4.0-1 below. Risk Analysis is presented here as a subset of the primary requirements and not portrayed in the example.
为了说明设计确认的每一基本阶段的目的，表 4.0-1 列举了一个类似的例子。这里风险分析作为

基本要求的一部分，每一包含在例子中。

Table 4.0-1 Design Qualification Example 设计确认示例

User Requirement 用户需求	I must be able to drive in the rain while seeing the road clearly 我必须能够在雨中开车，清楚地看见道理
Functional Requirement 功能需求	A mechanical wiping system will be implemented that does not cause damage to the windshield and can accommodate differing weather related rain roads. An area of the windshield will be cleared providing adequate forward viewing. 需要一个机械雨刮系统，不得损坏挡风玻璃，并能适应不同天气状况下雨中行车。能够清洁挡风玻璃的特定区域，提供充分的前视条件。
Detailed Design 详细设计	Manufacture a flexible carbon steel wiper blade, 20 inches in length, clad in EPDM rubber and shaped to match the profile of the windshield. The blade will be attached via a movable hinge to a carbon steel driver arm 24 inches in length protected from the elements by powder coated paint and attached to an oscillating motor of adjustable speed causing the arm and blade to traverse across the windshield through a 180°arc. Contact between the rubber blade and the windshield must be maintained throughout the full range of motion and a minimum effective clearance path of 80% of the windshield area is required. The speed of the arc oscillation is controlled by the driver within the vehicle at variable speed up to 1 cycle per second. 制造一个弹性的碳钢雨刮器，长 20 英寸，覆盖 EPDM 橡胶，形状应与挡风玻璃的轮廓相适应。雨刮器通过活动铰链与碳钢驱动手臂相连，手臂长 24 英寸，粉末涂层保护，并与可调速的摆动电机相连，这样手臂和雨刮器可在挡风玻璃 180°弧度范围内来回移动。移动时橡胶雨刮器与挡风玻璃保持接触，雨刮最低有效清扫面积应达到挡风玻璃面积的 80%。摆动速度通过汽车内驱动器控制，速度可调，最高 1 个来回/秒。

Process knowledge determines the type of moist heat cycle that will best support the product. Influencing factors such as product type, process type, packaging and preparation should be considered in a risk assessment. For example, the configuration and packaging requirements of certain products is essential for the removal of air and penetration of moist steam heat. Other products and components may require an air over pressure cycle to effectively sterilize a contained liquid. Historical data is also useful in the design of a process; however, new processes may need to be developed to achieve the desired conditions.

对工艺的认识决定了最适合该产品的湿热灭菌方式。影响因素包括产品类别、工艺类别、包装和制备应在风险评估中予以考虑。例如部分产品的摆放和包装要求对于空气排出和湿热蒸汽灭菌穿透十分重要。其他产品和组件可能需要正压行程对密封的液体进行有效灭菌。历史数据在灭菌工艺设计中也是有用的，然而需要开发新工艺以达到所需灭菌条件。

Risk assessment is an important part of the moist heat sterilizer system design process. Assessment considerations are primarily product and process flow. The following are examples of additional items that may be considered during a risk assessment:

风险评估是湿热灭菌器系统设计过程的重要部分。评估首先要考虑产品和工艺过程。以下是风险

评估中需要考虑的额外事项：

- Sterilization temperature (high and low) 灭菌温度（高温和低温）
- Loss of utilities 设施的损失
- Loss of sterilization data 灭菌数据丢失
- Cooling requirements 冷却要求
- Steam requirements 蒸汽要求
- Air overpressure requirements 正压要求
- Critical instruments failures 关键仪表故障
- Drain water level 排水高度
- Door gaskets longevity and type 门垫圈寿命和类型

4.1 User Requirements Specifications 用户需求

The correct selection of a sterilizer requires a robust definition of what the requirements and expectations are for the performance of a steam sterilizer. Prior to selection, users should ascertain:
正确选择灭菌器需要确定对一个蒸汽灭菌器的性能要求和期望。在选型前，用户应确定：

- What are the area/ process requirements? 厂房/工艺要求是什么？
- How will the sterilizer be used? 如何使用灭菌器？
  - Hard goods? 是否为坚实的物品
  - Finished filled parenterals? 是否为已灌装的注射剂
  - Liquid loads? 是否为液体装载物
  - Decontamination? 是否用于去污染
- What are the sizes of the largest items and possible load density? 最大物品的尺寸和可能的装载密度是多少？
- What are specific requirements for the sterilizer (i.e., control / operation)? 灭菌器的特殊要求是什么（即，控制/操作的特殊掏钱）？

Failure to integrate appropriate requirements into the sterilizer purchasing process can deliver a unit that is unable to be qualified. Without sufficient direction, vendors will establish a cost estimate based on a general or standard sterilizer design. While this keeps the anticipated costs down, it will likely omit specific attributes that may appear as standard items on other vendor's units such as redundant air vent filters or 316L stainless steel piping.
如果不能在灭菌器采购过程中提出适当要求，将导致购买的设备无法进行确认。在没有充分指导的情况下，供应商将根据通用或标准灭菌器设计评估成本，这将降低预期成本，可能会忽略标准灭菌器设计中一些特性，如冗余的空气过滤器或 316L 不锈钢管路的设计要求。

4.1.1 Equipment Location, Installation, and Maintenance Access Considerations 设备位置安装、维护通道的要求

An important consideration for the sterilizer specification is the details of the physical environment in which the sterilizer will be operated. Before the selection of the sterilizer can begin, the user should note the maximum height, width and depth that the sterilizer can be to fit through doorways from the point where the sterilizer enters the building to the point of

installation. The weight bearing capacity of the floor where the sterilizer will be installed should also be considered. See Appendix A for further discussion of equipment location and installation considerations.
灭菌器指标中重要一点是要考虑灭菌器运行的物理环境的细节。在开始灭菌器选型前，用户应关注最大高度、宽度、深度，以便灭菌器可通过门到达安装点。还应考虑安装灭菌器房间的地面承重能力。关于设备安装位置和安装要求的进一步讨论见附件 A。

The area environmental classification (e.g., loading, uploading side) should be considered when preparing the URS. This specification should include a decision on whether the sterilizer will be a single door or a double door (pass-through) sterilizer and the loading/unloading requirements. The door type should be specified (i.e., hinged, vertical or horizontal sliding).
制订 URS 时应考虑到厂房的环境级别（如，装载一侧、卸载一侧）。用户需求应包括决定是单门还是双面灭菌器，以及装载/卸载要求。应指定门的类型（即，铰链型、垂直或水平移动）。

If the sterilizer is used for decontamination, proximity to an effluent decontamination tank may be a concern. The flow path for loading materials and for removal of decontaminated material should be considered. Other design considerations for decontamination have been addressed in section 3.3, Decontamination Processes.
如果灭菌器是用来去污染，应关注是否靠近去污染储罐。应考虑装载物品和已处理物品移走的流程。其他关于去污染的设计要求见 **3.3 节，去污染工艺**

A wall seal (e.g., biological seal, air differential seal) should be considered when trying to maintain areas of different classifications. The seal type is dependent on the type of space and biohazard specification; it should maintain pressure differential, prevent particulate count egress into the clean room environment, and / or prevent organisms from escaping a biologically contained environment. **Figures 4.1.1-1~4.1.1-3** show common seal configurations in a facility.
当灭菌器两端洁净级别不同时，应考虑墙密封（例如生物密封，气压密封）。密封类型取决于空间大小和生物危害防护要求，应保持一定压差，防止颗粒进入洁净区，防止微生物从一个密闭环境中扩散出来。**图 4.1.1-1~4.1.1-3** 为工厂常用密封构造。

Figure 4.1.1-1 Facility Design Example One 厂房设计，例 1

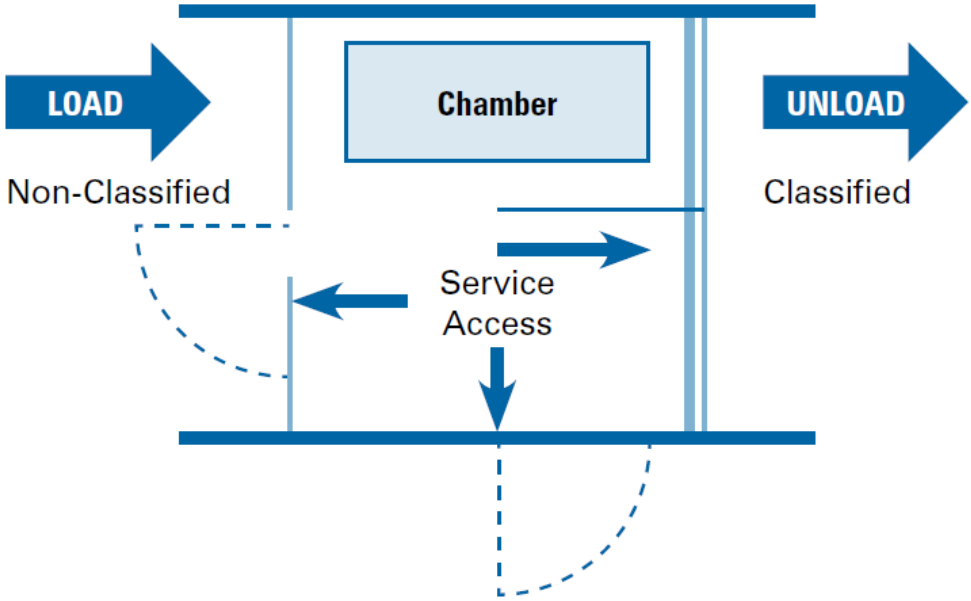


Figure 4.1.1-2 is an example where load and unload side area are classified. The wall seals on the load and unload sides maintain clean area space, separate from the maintenance area. Service access is from the top or side of the unit.

图 4.1.1-2 例中装载和卸载都在洁净区内。装载和卸载侧均维持洁净状态，并与维护区隔开。从灭菌器的上方或侧面进行维护。

Figure 4.1.1-2 Example of Dual Wall Seals 双墙密封设计

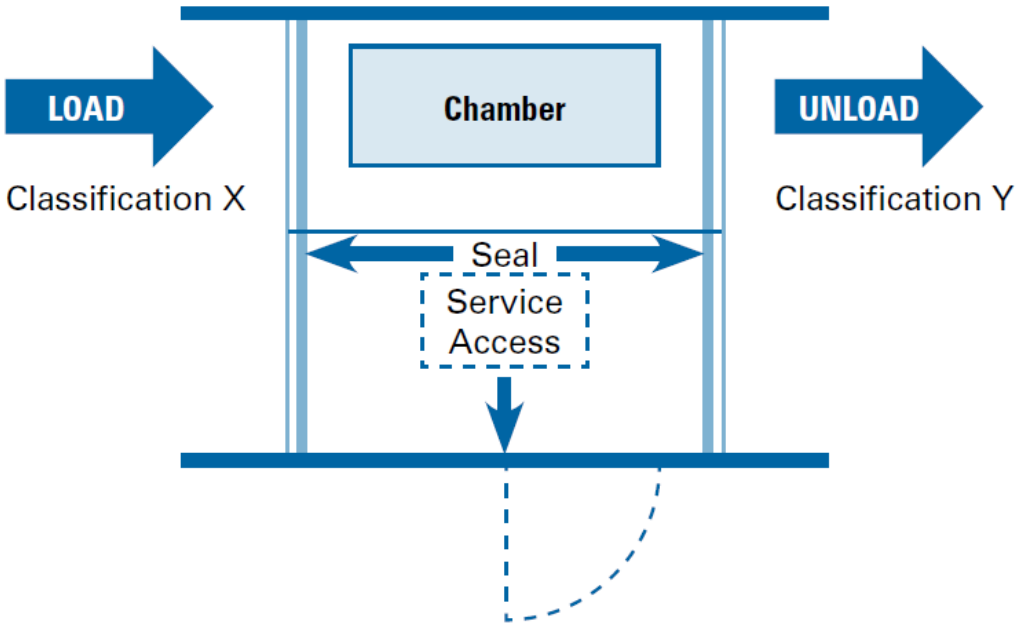
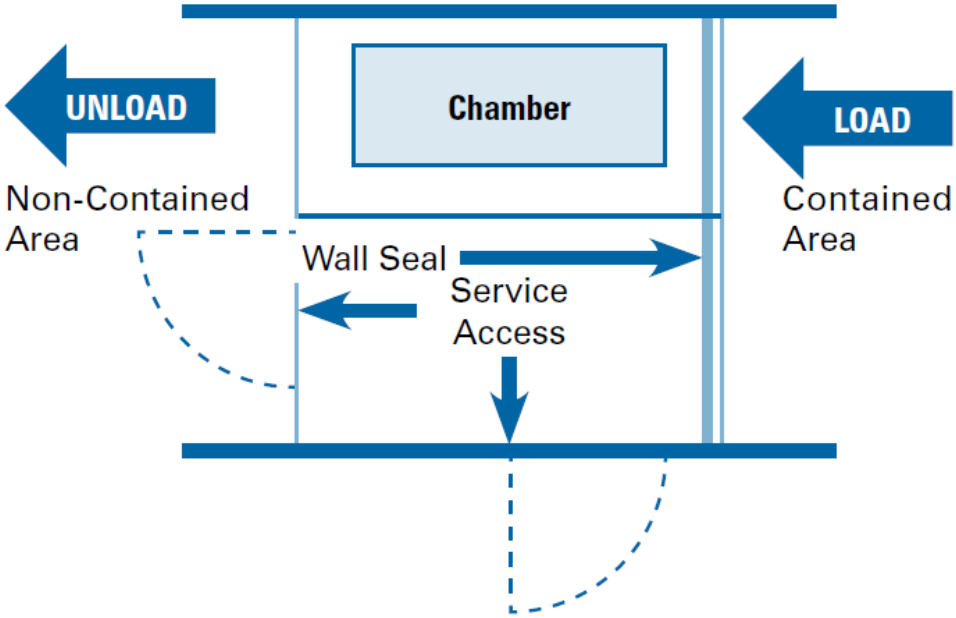


Figure 4.1.1-3 is an example where items are sterilized prior to removal from hazardous area. Seal is on the load or contained side to prevent hazardous organisms from escaping. Service area is on the unload side or side of the unit.

图 4.1.1-3 中物品从危险区域移走前进行灭菌。墙密封位于装载侧或受控区侧，防止危险性微生物逸出。维护区域在卸载一侧或设备的侧面。

Figure 4.1.1-3 Example of Wall Seal Facility Design 墙密封厂房设计



The sterilizer operation can impact both the temperature and humidity, so users must be aware of the area temperature and humidity requirements and consider the impact of the increased temperature and humidity during the sterilizer operation (e.g., unloading) on the clean room environment. Vents on the ceiling can be installed to remove excess moisture, and potentially higher temperature sprinkler heads and smoke detectors should be used. Excess steam can occur especially if cycles are aborted and the door is opened shortly after.

灭菌器的操作能够影响温度和湿度，因此用户必须了解所在区域的温度、湿度要求，在灭菌器运行（如卸载时）考虑温度、湿度提高对洁净厂房环境的影响。可在天花板安装排气口，排出过量湿气，可能需要高温喷水装置和烟雾感应器。当灭菌行程中止后不久就打开灭菌柜门时会产生大量蒸汽。

Consider the availability of utilities for the sterilizer operation (e.g., clean steam, plant steam, process air, water, electricity) and specify the available working conditions of the utilities (e.g., minimum and maximum pressure range for the clean steam and process air, water temperature, amperage and voltage for electricity). Location of valves (e.g., isolation and shut off), chamber validation ports, pressure gauges, steam traps and steam quality testing ports should be easily identified and accessible. The location of sample points (e.g., steam quality, WFI, process air) for routine monitoring and validation should be strategically placed, and the port designs should avoid any condensate storage.

考虑灭菌器操作所需设施（如清洁蒸汽、工业蒸汽、工艺气体、水、电），并说明设施工作条件（如清洁蒸汽和工艺气体的最低和最大压力范围，水温、电流和电压）。阀门位置（如隔离和关

闭)、灭菌器腔体验证口、压力表、蒸汽疏水阀和蒸汽质量检测口应有明显标识，并易于接近。日常监控和验证取样点应合理设置，取样口设计应避免任何冷凝水聚集。

The sterilizer effluent generated as a result of the sterilizer operation (e.g., volume and temperature of condensate) needs to be addressed, and, if needed, specify requirements for handling. For example, additional heat exchangers might be required to bring the temperature of the condensate to the allowable facility effluent discharge temperature. Also consider local regulatory requirements for final temperature and drained water in continuous flows if mixed cooling is allowed as opposed to closed loop cooling.
应考虑灭菌柜运行产生的排出物（如冷凝水体积和温度），需要时应指明处理要求。例如增加热交换器将冷凝水温度降至允许的排放温度。如果允许采用混合冷却的方式（与闭环冷却相对），还要考虑法规对最终温度和连续排水的要求

When operated, other equipment present in the area might interfere with the sterilizer. Identify types of wireless communication devices that might be used in the area where the sterilizer is to be installed.
运行时，现场其他设备可能与灭菌器相互干扰。应确定灭菌器安装区域内使用的无线通信设施类型。

Regarding the configuration of the area around the sterilizer, plan for sufficient space for the sterilizer maintenance area. Depending on the facility layout, the maintenance area can be located side by side with the sterilizer chamber or above the chamber in the interstitial area. Custom installations in tight spaces may require placement of steam regulators or control valve in alternate locations; check for the availability of adequate pipe length upstream of these control valves. Filters should be located where they are safely accessible. In addition, plan for enough floor space for storage and maneuvering of loading equipment; it is especially important to have enough clearance in front of the chamber.
对于灭菌器所处区域的设置，应有进行维护的足够空间。根据厂房平面布局，维护区可设在灭菌腔体侧面或上方。狭小空间安装灭菌器可能需要调整蒸汽调节阀或控制阀的位置，检查控制阀上游管路是否有足够长度。过滤器应安装在便于接近的地方。另外应有足够空间存放和操作装载设备，特别是灭菌柜前方应有足够空间。

4.1.2 Assessing Process Requirements 评估工艺要求

Along with the area requirements, the following equipment and process requirements should be considered:
除了对安装区域的要求，还应考虑以下设备和工艺要求：

- Temperature probes ports for validation studies. Specify the number, size, location, and type of port.
  温度探头验证口。指定接口的数量、尺寸、位置和类别
- Loading and unloading requirements (e.g., walk-in or reach-in).
  装载和卸载要求（如步入式或手伸入式）
- Door gasket medium (e.g., clean steam or pharmaceutical air) requirements. Determine if a backup door gasket is required.
  门密封介质（如清洁蒸汽或医用气体）的要求。确定是否需要备用门密封。

- Load configuration (e.g., item size, type and number of loads)
  装载物排放（如待灭菌物品的尺寸、类别和数量）
- Cycle time and throughput requirements
  完成灭菌行程所需时间、生产能力要求
- For porous / hard goods (equipment, tubing, gowns), air removal is critical to allow optimum heat transfer to the load. Air should be removed from the autoclave chamber and load prior to the sterilization exposure phase and minimized in the steam supply to the autoclave. Steam supplied to the autoclave should be saturated and not contain substances that would chemically contaminate the material with which it comes into contact
  对于多孔/坚实物品（设备、管道、衣服）的灭菌，空气排出效果对热传递至装载十分关键。在灭菌曝热开始前应将空气从灭菌柜和装载中排出，降低输送给灭菌柜的蒸汽。应使用饱和蒸汽，并不得含有可能污染与其直接接触物品的化学物质。
- For liquid loads, the steam acts principally as an agent for heat transfer. Therefore, air removal and steam attributes are not of equal significance as compared to porous / hard goods loads.
  对于液体装载，蒸汽主要是作为热传递介质。因此与多孔、坚实物品装载比较，空气排出以及蒸汽质量特性不是同等重要。
- For terminal sterilization of materials in their final packaging, the major concern is the identification of a sterilization cycle that ensures that sufficient lethality has been achieved in all location of the load without compromising item or product. Due to these factors, care must be taken to ensure that the temperature across the load is uniform and that the air over pressure (where utilized) is sufficient to minimize the breakage or distortion of containers.
  对于已包装产品的最终灭菌，重点要确定灭菌行程，在装载的所有位置都能获得足够杀灭效果，但不影响物品或产品质量。因此，必须保证装载的温度分布是均匀的，腔室正压（采用时）足以降低被灭菌容器的破裂或变形。

Consider the number of cycles to be available for the range of items being sterilized. Include additional cycles to be used with the sterilizer (e.g., chamber leak test, vent filter sterilization, air removal test).
考虑不同灭菌物品所需的灭菌行程数。应包括所需的额外行程（如腔体泄漏测试、排空滤器的灭菌、空气排除测试）。

Describe the requirements for the steps/phases that are required for the range of the sterilization cycles to be used. In each phase identify the critical control requirements and variables that are needed. For example:
描述灭菌行程所需的步骤/阶段要求。在每一阶段应识别关键控制要求和所需变量。例如:

- Heat-up phase, including: 升温段，包括：
  - Number of vacuum pulses 真空脉动次数
  - Time to attain vacuum 达到一定真空所需时间
  - Vacuum hold time 真空保持时间
  - Vacuum and pressure level 真空和压力大小
  - Charge phase, including the charge rate 排放阶段，包括排放速度

    - Temperature and pressure ramp rates 温度和压力上升速度
- Exposure phase, including the temperature and pressure ranges 灭菌阶段，包括温度和压力范围
- Cool-down Phase (if required), including: 冷却阶段（需要时），包括：
    - Evacuation level (if vacuum drying is used) 真空大小（如果采用了真空干燥）
    - Hold time 保持时间
    - Heat input (if drying is accomplished utilizing heat input) 加热（如果通过加热进行干燥）
- Exhaust Phase, including the exhaust rate 排气阶段，包括排气速度
- Pulse drying 脉动干燥
- Equalization 平衡时间
- Vacuum Relief Phase (if required) 去真空阶段（需要时）
- Liquid cooling temperature / method 液体冷却温度/方法
- Temperature and pressure ramp rates 温度和压力上升速度

4.2 System Control 系统控制

Good manufacturing practice with regard to the specification, build, testing and operation of a sterilization equipment requires a systematic approach to ensure that the equipment as designed meets specifications and is fit for intended use. Many choices may be evaluated during definition of the control system design. Some considerations are:
对于灭菌设备的技术要求、建造、测试和运行，GMP 要求采用系统的方法保证设备设计符合要求和预期用途。控制系统设计中可对多种选择进行评估。需要考虑的有：

- Possible interfaces of the control system with other systems available in the area
  控制系统与安装区域的其他系统可能存在的相互干扰
- Data collection should be based on company requirements (e.g., local printer report, network printer report, building control system report, historical trending).
  应根据公司要求进行数据采集（如本地打印报告，网络打印报告，建筑控制系统报告，历史数据趋势分析）。
- Controls provided with electronic data collection intended for use in the manufacture of pharmaceutical products are required to comply with regional regulatory expectations.
  用于药品生产，具备电子数据采集的控制系统应符合法规要求。
- Define the list of process variables to be recorded and frequency of recording (e.g., chamber pressure, chamber temperature, jacket temperature, run time)
  确定需记录的工艺变量清单，和记录频次（如腔体压力、腔体温度、夹套温度、运行时间）
- If the system provides a report, define the expectations for information to be included in the report
  如果系统能够提供报告，确定报告需保护哪些信息
- How complex or simple a control system is needed. Describe the control system requirements in terms of manual, semi-automatic and automatic operation.
  控制系统复杂或简单程度。根据手动、半自动和自动操作来描述控制系统要求
- Whether the operation and control of the system is to be performed at an operator interface panel on the sterilizer or at an external control system. State whether the access is provided through a date-communication link. Specify security access levels for

operation, cycle programming, and maintenance activities. Security access is typically local and may be server verified.
系统的运行和控制是在灭菌器上操作界面还是通过外部控制系统完成的。说明系统的进入是否通过数据通信连接完成的。指明操作、灭菌行程设计、维护确定不同安全访问等级。安全访问通常在本地确认，也可以通过服务器确认。

- Control type should be taken into consideration- on/off or analog. Digital (on/off) and Proportional (analog) valves are both successfully used in the establishment of steady state conditions within a chamber and load.
  应考虑控制类别-开启/关闭或模拟。数字（开启/关闭）和定量（模拟）阀门均可用于建立稳定状态
- Orifice plates and / or flow control valves positioned on the chamber inlet and /or outlet. Their settings or dimensions therefore become key control parameters.
  截留孔板和/或流量控制阀门位于腔体入库和/或出口出。它们的设置或尺寸也是关键控制参数

Consider the requirements for the following control systems:
以下控制系统的要求

- A temperature and / or pressure controlled system.
  稳定和/或压力控制系统
- A thermostatic steam trap (open when cool, closed when hot) to remove air and /or condensate form the chamber.
  用恒温的蒸汽疏水阀（当介质变冷时打开，当介质是热的时就关闭），来排出灭菌柜中气体和/或腔体冷凝水
- A cycle timer and (usually) a sequencing controller.
  灭菌周期计时和顺序控制器
- The ability to configure cycle parameters (e.g., add or subtract number of pulses, vacuum levels, exposure time)
  设置灭菌阐述的能力（如增加或减少脉动次数、真空度水平，曝热时间）

Define the interlocks that are to be supplied with the system. For example:
确定系统具有的互锁功能。例如：

- The door cannot be sealed before it is closed and locked.
  在关闭并锁死前，门没有完全密封
- The cycle cannot be initiated until the door is sealed.
  只有在门处于密封状态下，才能启动灭菌行程
- The cycle can be initiated only if there are no active alarms.
  只有当没有活动报警时才可启动灭菌行程
- The door cannot be unsealed before the sterilization cycle is completed and the chamber pressure has equalized to atmospheric pressure.
  在灭菌行程结束，以及腔体压力降至大气压力前，不得打开门密封
- In case the cycle is aborted but the exposure phase was not completed, only the loading side can be opened.
  当灭菌行程中止，但保温阶段尚未结束时，只能从装载侧打开

- The chamber steam valve cannot be opened by the controller if a door is open or unsealed.
  如果门是打开的或未密封，控制器不得开启腔体蒸汽阀
- Specify the placement of the Emergency Stop (E-Stop) button(s) according to local requirements. A double door sterilizer should have E-Stop buttons on both sides of the sterilizer.
  根据当地法规要求确定急停按钮的布置。双门灭菌器应在灭菌器两侧均有急停按钮。
- Requirements for the system response to an operator initiated cycle abort. Describe the final state the autoclave needs to be in at the conclusion of the abort sequence.
  操作者启动灭菌行程中止时，系统反馈的要求。描述在中止步骤结束后灭菌器所处的最终状态。
- System alarm requirements, both critical and informational.
  系统报警要求，包括关键报警和提示报警

Instruments identified in the risk assessment as critical and /or key to the process should be designed for calibration and should be easily accessible. Instruments should have the correct range, resolution, accuracy and precision for calibration and be designed to meet the needs of the process. Prior to qualification activities, instruments should be calibrated. See Section 7.2 for further discussion of instrument calibration.
风险评估中确定的关键仪表设计应便于接近并进行校准。仪表应具有正确的量程、分辨率、准确度和精密度，其设计应符合工艺的需要。在确认之前，应对仪表进行校准。仪表校准的详细讨论见 7.2 节。

4.3 Functional Requirements Specifications 功能需求

The intended use of the autoclave dictates the size, shape, construction materials, control system, required utilities, cycles available and accessories to be supplied with the unit. These attributes are defined in the functional requirement specification (FRS), FRS examples may include:
灭菌器预期用途决定了其尺寸、形状、材质、控制系统、所需设施、具有的灭菌行程和设备备件。这些特性应写入功能需求中，包括：

- If clean steam is required but not available at the installation site, a clean steam generator may be installed on the sterilizer skid.
  如果需要清洁蒸汽，但安装点没有清洁蒸汽，灭菌器单元应安装有清洁蒸汽发生器
- A decontamination cycle may be required for use in applications where chamber effluents may contaminate the sterilizer drain line or building drain system.
  当灭菌器腔体排出物可能污染灭菌器排水管路或厂房排水系统时，需要采用去污染行程
- A requirement to roll heavy tanks or equipment into the chamber may dictate a pit-mounted installation, in which the floor of the chamber aligns with the floor of the room.
  如需将很重的罐子或设备推入腔体中，则需采用基坑安装方式，使腔体底部与房间地面平齐
- Steam sterilizers used for decontamination of equipment may be manufactured from Ni-Clad material rather than stainless steel due to the corrosive nature of the effluent.
  考虑到排出物的腐蚀性，用于设备去污染的灭菌器可采用涂镍材料而不是不锈钢

Functions are defined first by the purpose of the system and then are defined in more detail as a series of individual functions. The FRS includes both manual and computer controlled functions for operation of the system. Requirements are described in terms of quality needs (i.e., instrument accuracy), hardware and software needs, system interfaces (i.e., particular programmable logic controller model should interface to particular distributed control system model), operator / product safety and performance. Refer to Section 4.3 for an overview of the FRS.
首先根据系统用途确定功能，再对一系列单个功能进行细化。功能需求包括手动运行和计算机自动控制两种操作模式。应从质量需求（即仪表准确度）、软硬件需求、系统接口（即特定 PLC 模块应与特定分配控制模块相连）、操作者/产品安全和作业需求来描述功能需求。

Specifications for utilities should also be included, and are dependent on the application and the manufacturer.
还应包括所需设施要求，这取决于灭菌器的应用以及药品制造商。

4.4 Detailed Design Specification 详细设计

The DDS will include basic elements common to all sterilizers, as well as specific requests intended to satisfy the operation requirements of a specific installation. Basic elements will include sterilizer description, size and configuration, sterilization cycle types required, and maximum load size or mass. Utilities available at the installation site may be provided as limiting factors. The type of control system desired for the sterilizer must be addressed including the validation requirements for that system. Typical options include: special cycle requirements, load probes for internal temperature measurement, loading carts, and spare parts.
详细设计应包括所有灭菌器通用的基本要素，以及满足特定操作的特定要求。基本要素包括灭菌器描述、尺寸和结构、所需灭菌行程类别和最大装载尺寸或重量。安装区域的设施可作为限制性因素。应涵盖控制系统的类别及其验证要求。典型的选择包括：特殊灭菌行程要求、内部温度测量的装载探头、装载推车和备件。

- The following milestones might be identified in the specifications:以下重要事件应在详细设计中说明：
- Proposal 建议
- Initial drawing review 初步图纸评审
- Manual availability 获得操作手册
- Factory acceptance testing (FAT) 工厂接收测试
- Delivery date 交付日期
- System start-up 系统启动
- Commissioning duration 调试持续时间
- Site acceptance testing (SAT)
- Training 培训
- Document turnover 文件交付

When complete, the specifications are approved and submitted to the selected vendors for their response.

完成后，详细设计应得到批准，提交给相关供应商，并获得其认可。

Consider the differences in cleaning for the different environmental classifications. Cleaning requirements for the difference area classifications may affect the materials of construction of the sterilizer panels, and possibly the design of the wall seals. The area classification would also affect the finish of the panels. Describe in detail the local procedural requirements such as local standards, which must be adhered to for the interior and exterior finishes. Describe materials of construction and requirements for material certification.
需要考虑不同洁净级别对清洁要求的不同,这将影响灭菌器面板材质,也可能影响墙密封的设计。所处区域的洁净级别也影响面板的装饰。应详细描述本地的程序要求，如当地标准，在进行内外部装修时必须符合这些要求。描述材质和材料证明要求。

Specify the utility piping requirements (e.g., stainless steel type, copper for non-sanitary utilities). Specify piping weld and slope requirements for clean steam, process air, sanitary chamber drain and sterile vent system (e.g., AISI, ASTM, ASME, or any local area requirements). List critical requirements for surface finish.
指定设施管路要求（如不锈钢、非卫生设施可采用铜)。指明清洁蒸汽、工艺气体、卫生腔体排水和无菌排空系统的管路焊接和坡度要求（如 AISI、 ASTM、 ASME 或任何本地要求)。

Prior to specifying detailed design requirements for the sterilizer, it may be a worthwhile endeavor to perform a Risk Analysis of the process(es) for which the sterilizer will be used. Once the intended and predicted uses have been identified, details of the design can be generated.
在确定灭菌器详细设计前，对灭菌工艺进行风险分析是非常值得的。一旦确定了预期用途，即可建立详细设计文件。

5.0 Equipment Verification & Qualification 设备验证或确认

Equipment qualification includes studies to assure the installation of a sterilizer and its associated utility systems has been performed, and the operation of the systems has been tested. Reproducibility of sterilization cycles is dependent on the controls, utilities and mechanics of the sterilizer operating according to their specifications. These critical items are verified as installed and set to their specifications as part of the qualification.
设备确认包括研究来确保一个灭菌器的安装和有关的公用设备已经确认以及系统的操作已经测试。灭菌循环的重现性依赖于控制，灭菌器操作的实用工具和技术细节根据他们的技术参数。当安装好时，这些关键条目被验证，并设置到它们的规范中作为确认的一部分。

Sharp distinction between the various activities is not essential. How verification and qualification activities are performed is up to the organization to determine. Some of the activities included in this section may be performed as part of cycle development, preliminary screening, or equipment acceptance. For the purposes of this report, these activities are addressed in the following sub-sections to provide an overall perspective to the reader.
各种活动间差异明显并不是最重要的。怎样执行验证和确认活动等待验证组织来决定。 包括在这节内的一些活动将被执行，见循环发展，初步筛选和设备接收部分。对于这份报告的目的，下面的章节写的这些活动给读者提供一个整体的观点。

Equipment documentation collected is useful for establishing maintenance spare parts inventories, preventative maintenance, and calibration schedules.
设备文档收集有助于建立维修备件库存,预防性维护和校准时间表。

Static and dynamic testings performed in commissioning may be leveraged for use in Installation Qualification (IQ) and Operational Qualification (OQ) respectively. However, in order to use the commissioning data changes should he documented via a change management system and the quality unit should approve the commissioning test methods and acceptance criteria prior to commissioning test execution.
在试机中执行的静态和动态测试可能分别利用在安装确认和性能确认中。 然而，为了利用试机数据变化应该通过变更管理系统记录，在试机执行前，质量部门应该批准试机测试方法和可接受标准。

During the sterilizer commissioning, or prior to Performance Qualification (PQ) devices are adjusted to optimize the process. The readings and/or settings of the adjustable devices and operational parameters are to be documented. Such devices may include:
在灭菌器试机期间或先前执行性能确认的设备是优化调整过程。读取或设置的可调节装置和操作参数应该被记录。这些装置可能包括

- adjustable bleed valves 调节排气阀
- gauge used to set a steam supply regulator
- flow control valve for cooling water 冷却水流体控制阀
- control parameters in a PID controller PID 控制器里的控制参数
- set points and alarm limits for time, temperature, and pressure 对时限、温度和压力设置点和报警限度

After qualification, records of these settings may be needed by operating and maintenance personnel for maintaining the qualified stale of the sterilizer. For example, while optimizing the control of chamber temperature, a steam supply regulator may be adjusted to a setting which differs from the value on the P&ID. This new setting should be documented in the qualification package, but in addition, it must be available where it can he referenced for ongoing control and verification of the equipment Assure that all adjustable device settings and operational parameters are noted in an SOP, equipment logbook, or as applicable for facility programs. Any proposed modifications or changes to the autoclave, the settings, or associated equipment must be evaluated through a change control program.
确认后，这些设置的记录可能需要操作，保养人员对不合格的灭菌器进行保养。例如，优化腔体温度时，蒸汽调节器可能不同于控制阀管道仪表图被调节设置。这些新的设置应该记录在确认程序包中，但除此之外，能参考的持续控制和设备确认必须有效，保证所有的调节装置设置和操作参数记录在 SOP、设备日志或可适用的工厂项目中，任何计划的改变或自动化、设置、有关设备的变更都应该通过变更程序评估。

5.1 Commissioning 试车

Commissioning is an important function that assures a well documented system is started up and turned over for development, verification, or qualification. Commissioning should be a sound foundation for subsequent qualification, and when a risk-based approach is employed, it may reduce some qualification testing. It verifies the range of functionality described by the vendor, such as pressure, vacuum, temperature. Commissioning also assures that sufficient system documentation is provided by the vendors and installers to enable subsequent protocol development and qualification.
试车是一个很重要的作用，来保证文件系统开始做起来以及后来的发展、确认、验证。试机应该对充分确认提供可靠的基础，当采用风险依据方法，它可能减少一些确认测试。它验证供应商描述功能的范围，比如压力、真空度、温度。试机也能充分保证供应商提供的系统文件和安装程序能使随后的草案开发和确认。

The primary purpose of commissioning is to assure that sufficient documentation is gathered to write the sterilizer qualification documents and to assure that the primary functions are operated and checked prior to attempting qualification. The unit is operated in a test mode by the installer or vendor. The installer or vendor follows a user approved commissioning document or checklist. The shakedown or commissioning process verifies that the unit's motors, valves, and controls function and operate properly. This confirms that the motors turn in the proper direction, valve operation is correct, and the controls activate the instruments as required.
试机的主要目的是确保可靠的文件集中于编写灭菌器确认文件和确保试图确认前主要功能能操作和检查。安装者或供应商用测试模式操作装置。安装者或供应商跟踪用户提供的试机文件或清单。调整或试机过程证明电机、阀门和控制功能和操作合适。这证明电机运转方向正确，阀门操作正确，仪器控制活动也按要求运作。

5.1.1 Factory Acceptance Testing 工厂验收测试

The Factory Acceptance Test (FAT) should be an integral part of the manufacturing quality assurance program of the vendor. The FAT activities are conducted at the vendor facility to

demonstrate that the equipment is constructed according to the design specifications and the performance is in conformance with the functional requirements and user requirements. A preapproved FAT lest plan is typically used to verify the construction and operation of the sterilizer against the requirements. This test plan may he provided by the vendor and/or user and approved by the user. Examples of sterilizer verification activities are outlined in **Appendix B**.
工厂验收测试应该成为供应商生产质量保证项目完整的部分。工厂现场验收测试是指导供应商工厂证明设备是根据设计说明和符合功能需求和用户需求的性能来建造的。提前批准的工厂现场测试通常以免用于灭菌器的核查结构和操作计划违背需求。测试计划应该被供应商批准和使用者批准。灭菌器确认活动的例子见 **Appendix B**.

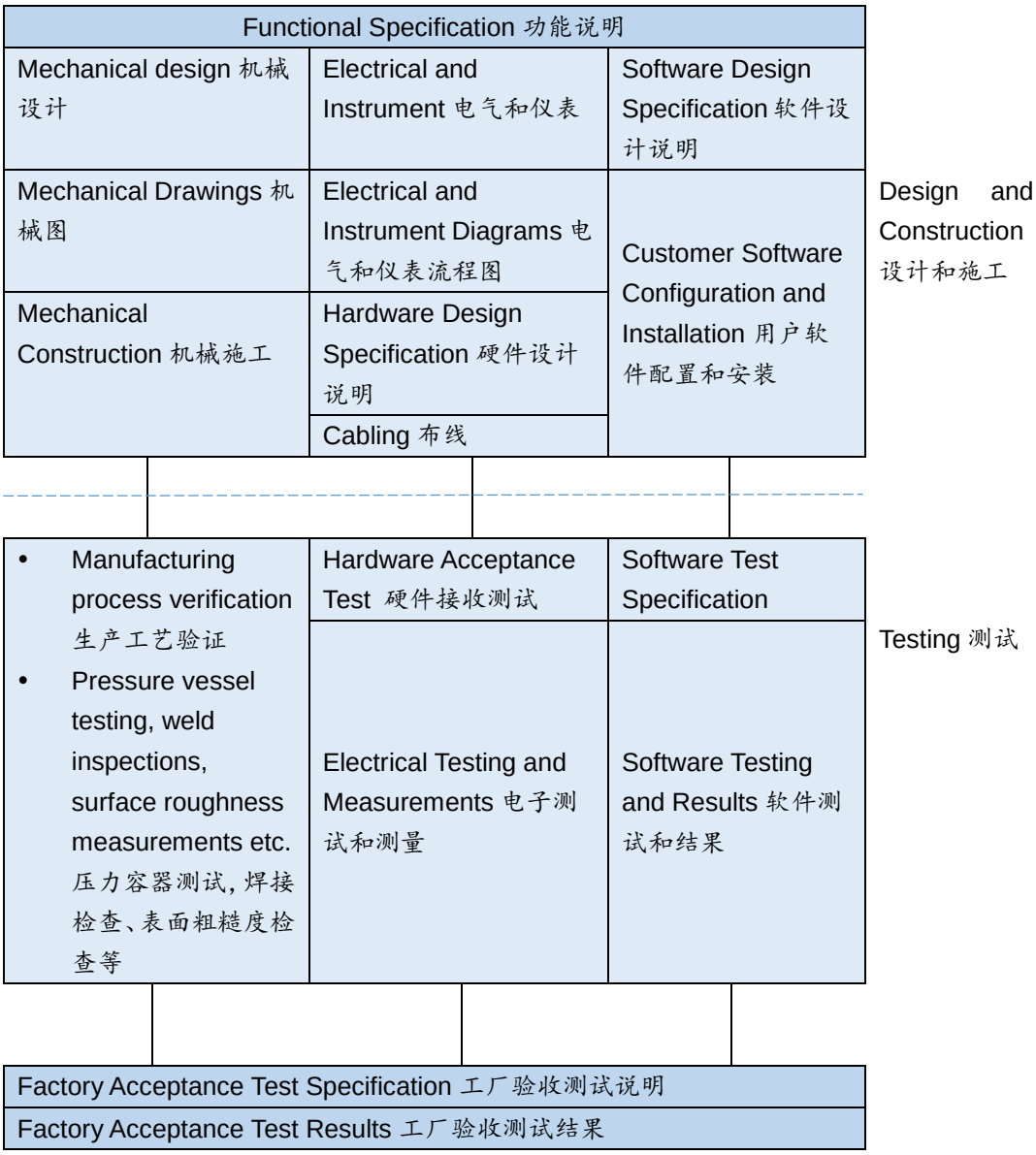
The FAT test results and documentation should be verified by the user prior to the shipping of the sterilizer. Objectionable findings should he noted and resolved prior to shipping to the user's site. If this is not possible, the owner and vendor should agree to an action plan to resolve any incomplete requirements.
工厂验收测试结果和文件应该运输灭菌器前被用户确认。在运输到使用者位置前有异议的发现用过被记录和解决。如果不可能，用户和供应商应同意一个行动计划来解决不完整的需求。

Utilities should be available to simulate the actual site utilities as much as possible e.g., electric, steam, cooling water and air, steam capacity and quality). Utilities used for FAT testing should be demonstrated to be of appropriate quality (e.g. steam should be free from chloride and iron, oil-free air) to prevent contamination of the sterilizer.
公用设备应该尽可能多的模拟真实现场，如电气、蒸汽、冷却水和压缩空气，蒸汽生产力和质量用于工厂验收测试的公用设备应该被证明合适的质量（如蒸汽应该不受铁、氯化物的影响，不含油的空气）来防止对灭菌器的污染。

The sterilizer should be ready and operational for the owner's FAT activities. Owner representatives should have the authority to authorize any changes required at the factory to prevent delays.
为了使用者工厂现场验收，灭菌器应该被准备和操作。使用方代表在工厂应该有权利来批准一些必要的改变来防止延期交货。

Some qualification activities may also be conducted and documented during the manufacturing process. In many cases, tests performed during the FAT are the same as those performed during the equipment qualification. To avoid repeating these tests or to leverage the FAT, documentation should meet requirements of qualification documentation and include oversight by the Quality Unit. To leverage tests performed during the FAT. Appendix A lists tests that apply to multiple qualification activities. Figure 5.1.1-1 outlines the manufacturing process 3nd testing of a sterilizer, including software development.
一些确认活动在生产过程中可能被指导和记录。在很多情况下，工厂验收测试和这些设备确认的执行是一样的。为了避免重复测试或利用工厂现场测试，证明文件应该满足确认文件的需求以及包括工厂现场测试期间质量部门对测试完成的监督。附录 A 列出了适合确认活动的测试项目。灭菌器的生产过程的 3 次测试，包括软件开发。

Figure 5.1.1-1 Sterilizer Manufacture and Testing 灭菌器生产和测试



5.1.1.1 Leveraging the FAT 工程验收测试的扩充

It is commonly recognized that testing executed according to Good Engineering Practice (GEP) can make a significant contribution to validation exercises. Where this is the case, the testing following GEP should be referenced within the appropriate validation plan, and the rationale for which testing will be performed clearly recorded.
一般认为测试执行根据良好工程质量管理规范可以为验证实践做贡献。在这种情况下，按照良好工程质量管理规范的这个测试应该在合适的验证计划内，执行测试额基本原理应该记录。

Where the validation approach indicates that GEP testing is to be used to reduce the onsite qualification effort, these GEP testing documents should h aw the same GMP requirements as site qualification. For example:

验证方法表明良好工程质量管理规范测试用于减少现场确认工作量,良好工程质量管理规范测试应该像 GMP 要求的现场确认那样记录。例如：

- The commissioning exercise and the overall approach to testing is approved within the validation plan.
  试机活动和全部测试方法应该在验证计划内被批准。
- Design documentation (e.g., functional, software and/or hardware) should be approved prior to approval of the test protocol.
  设计文件（如功能、软件、硬件）应该在测试方案前被批准。
- The equipment/software is required to be under change control. Use of the site change control system or the supplier change control system should be documented in the rationale.
  设备/软件需要变更控制。使用地点变更系统和供应商变更系统应该被用同一原理证明。
- The sections of the GEP testing used to reduce on site qualification have the same protocol test requirements as a qualification document, and approval includes the quality representative. This includes:
- 良好工程质量管理规范测试部分用于减少现场确认，像确认文件一样有同样的测试需求方案，一般也应该被质量部门批准。这包括
  - Acceptance criteria should he approved by the Quality Unit
    可接受标准应该被质量部门批准
  - The recording of test results and collection of test evidence is to the same documentation requirements.
    测试记录结果和测试依据收集同样需要存档
  - The recording and remedy of test deviations and failures follow the same requirements.
    补救的测试偏差和失败的记录同样要求存档

The acceptance of GEP testing to support on site qualification activity is based on effective demonstration of control of the system between the supplier and end user’s premises. Consideration should be given to repeating quality related functionality that could have been affected by the transportation, or is reliant upon connection to site services/utilities.
接受 GEP 测试来支持现场确认活动应基于供应商和最终用户之间对控制该系统的有效证明的前提。应考虑到质量相关功能的重现性，这些功能可能受到运输的影响，或依赖于现场服务/公用工程的连接。

5.1.1.2 Software Tests 软件测试

The software test procedures should be developed m accordance with the current guidelines. (15) In many eases a master software program for a sterilizer is created to accommodate multiple options. These software modules can be turned on or off depending on which items are selected. Each base program should be software (bench) tested. These tests are performed in a simulated environment and are used to verily basic functionality of the software and static aspects of the software design (functionality that is not changed when the software is configured). These tests typically include, but are not limited to:
软件测试程序开发应当与当前指导方针一致。很多情况下，灭菌器主要软件程序根据多种设置建立。这些软件模块取决于选择的项目开启或关闭。每个基本程序应该进行软件测试。软件测试应

该在模拟环境下执行，使用软件真实的基本功能和软件设计的静态方面。这些测试一般包括，但不限于以下方面：

- Screen navigation testing 屏幕导航测试
- Security testing 安全性测试
- Boundary testing for input values 输入值的边界测试
- Process sequence and transition condition testing 过程顺序和过度条件测试
- Alarm testing 报警测试
- Interlock testing 互锁测试
- Version verification & audit trail 版本确认和审计跟踪
- Configurable parameters 可配置的参数
- Data transfer to owner supplied hardware and software 数据传输到拥有者提供的硬件和软件

5.1.2 Site Acceptance Testing 现场验收测试

Site Acceptance Testing (SAT) is a series of tests that are performed as part of commissioning, after the unit has been installed in the final location. These documented tests establish the basic acceptability of the system as connected to the site utilities.
现场验收测试是在最后位置已经安装后的一些测试，并作为试机的一部分来执行。
这些备有证明文件的测试连接相应的公用设备建立基本可接受的系统。

During SAT, use is should ensure that no damage occurred during shipment and installation, that the installation was performed properly and that the unit is installed and scaled to maintain environmental conditions. In addition, users should evaluate the effects of environmental conditions (e.g.. elevation, temperatures) on the sterilizer and check final wiring (if wiring was required).
工厂现场测试期间，用户应保证在运输和安装期间没有危害发生，安装正常执行，已安装的部件处于正常使用状况。另外，用户应该评估环境条件（如海拔、温度）对灭菌器的影响和检查最后接线（如果需要接线）。

Utility Verification (water temperature, steam and air pressure), operational testing and final adjustments, and system orientation and safety training also should be conducted as part of SAT.
公用设备确认（水温、蒸汽、压缩空气）、操作测试和最后的调节、系统定位和安全培训也都应该扮演现场验收测试指导。

Successful completion of the SAT may be required before the owner assumes responsibility for its qualification and subsequent operation.
成功完成现场验收测试可能需要用户为确认和后来的操作承担责任。

5.2 Qualification 确认

The sterilizer specification establishes the equipment features and performance that are confirmed during the qualification of the sterilizer. The qualification phase of the validation verifies that the sterilizer operates according to design specifications tor performance, control

system function and computer system operation for PLCs and data collection systems associated with the sterilizer. Equipment installation and operation should be qualified prior to beginning performance qualification.
灭菌器的说明书立足设备特征和性能并验证灭菌器的性能。验证阶段的确认证明灭菌器操作根据设计说明执行，控制系统功能和 PLC 电脑操作系统、数据收集也与灭菌器有关。设备安装和操作确认应该在性能确认前。

Reproducibility of sterilization cycles is dependent on the controls, utilities, and mechanics of the sterilizer operating according to their specifications. Critical and key parameters and adjustments are verified as installed and sec to their specifications as part of the qualification. Failure to meet a critical parameter may result in rejection of the load. Failure to meet a key parameter could result in an investigation with a documented rationale for the disposition of the load. **Figure 1.1-1** outlines the lifecycle of a sterilizer.
灭菌循环重现性依靠控制，灭菌器的机械操作根据它的说明书。关键参数遇到失败可能导致负载的拒绝。关键参数遇到失败可能导致有记录负载处置的原理的调查。**Figure 1.1-1** 概述了灭菌器的生命周期。

5.2.1 Static Equipment Qualification or IQ 静态设备确认或者安装确认

The purpose of static equipment qualification is to verily and document that the sterilizer is installed as specified. Traditionally these qualification activities are considered part of an installation qualification (IQ).
静态设备确认的目的是确认和记录灭菌器的安装符合规定。一般这些活动被认为是一个安装确认的部分。

Qualification is performed to assure that the sterilizer has been installed according to user requirements and manufacturer's specifications. Verification of installed equipment may he leveraged from GEP activities or may be performed as part of the sterilizer qualification. Equipment documentation collected is useful for establishing maintenance spare parts inventories and preventative maintenance and calibration scheduler。The qualification phase of the validation verifies that the sterilizer operates according to design specifications for performance, control system function and computer system operation for PLCs and data collection systems associated with the sterilizer.
执行确认来保证灭菌器已经根据用户需求和生产厂家规定安装。已安装设备的确认可能利用工程质量管理规范活动或可能按灭菌器确认执行。收集的设备记录用于建立备件库存和预防性维护和校准时间表。验证阶段的确认证明灭菌器操作根据设计说明执行，控制系统功能和 PLC 电脑操作系统、数据收集也与灭菌器有关。

This documentation is used to maintain the system in a validated state during subsequent change control. For a pre-existing sterilizer, there may be no current specifications available. In this case, the IQ review documents the system's existing condition, as a basis for establishing on-going change control.
这些文件证明用于维持系统在后续变更控制期间处于验证状态。对于预先存在的灭菌器，可能当前没有的合适的规定。这种情况下，把 IQ 审核系统现有状态的文件作为建立持续变更控制的基础。

This testing may be leveraged from commissioning performed or other appropriate pre-approved procedure/testing. Appendix B contains a list of specific items that are typically verified during equipment qualification.

5.2.1.1 Steam Quality Testing 蒸汽质量测试

Steam quality testing should be conducted prior to Dynamic Equipment Qualification, also called Operational Qualification (See Section 5.2.2), as well as part of the ongoing monitoring program to ensure the delivered steam will sterilize as intended. Steam quality is determined through physical, chemical and endotoxin testing as described below Testing is conducted for non-condensable gases, super heat, and dryness fraction for porous load sterilizers.
蒸汽质量测试应该先于动态设备确认执行，也叫操作确认（见 5.2.2 节），和持续监控项目一样来确保传递的蒸汽如预期的将灭菌。蒸汽质量是通过物理、化学和内毒素测试如下所述测试是进行不凝结的气体,超级热,干燥部分多孔负载消毒器。

5.2.1.1.1 Prerequisites to Physical, Chemical and Endotoxin Testing of Pure Steam

Prior to performing physical, chemical and endotoxin testing, certain prerequisites should be established:
纯蒸汽的物理化学内毒素测试的先决条件是先执行物理化学内毒素测试,确定的先决条件应该建立:

- Personnel (operators) performing tests should he appropriately trained.
  执行测试的人员（操作者）应该适当的培训
- Point of use testing location should be representative of steam distribution into sterilizer
  用于测试位置的点位应有代表行的蒸汽分布进入灭菌器。
- Samples should be taken during the sterilizer cycle
  灭菌循环应该取样
- Multiple tests may be useful during the initial qualification of the sterilizer
  多种测试可能用于灭菌器的安装确认

5.2.1.1.2 Physical, Chemical and Endotoxin Testing 物理、化学、内毒素测试

Physical testing of steam quality for porous/hard goods sterilizers assesses non-condensable gases, dryness, and superheat. Required piping modifications, test methods and acceptance criteria may be found in available literature and guidances. (16) Steam quality testing may be conducted at the steam generator, at the distribution header for the sterilizer, oral the sterilizer to assure the supplied steam meets the requirements. However, the primary steam quality tests should he conducted at the sterilizer during empty chamber operation. For example, the superheat test is run when the steam valve first opens to test during maximum steam flow. During qualification and ongoing monitoring testing should be conducted at point of use to ensure quality meets engineering and regulatory requirements.
蒸汽穿透性质量物理测试。必要的管道的修改，合适的文献和指导方针提供测试方法和可接受标准。蒸汽质量测试可能由蒸汽发生器执行，分布在灭菌器管道，来保证提供的蒸汽满足要求。然而，主要蒸汽质量测试应该在灭菌器腔体内操作。
例如，过热测试运行时蒸汽首次打开测试最大蒸汽流量。确认和持续监控测试期间应在在用点执

行来保证质量满足工程和法规需求。

The purpose of chemical/endotoxin testing is to show that clean steam condensate from the steam generator and at the sterilizer meet compendial requirements. In addition, all condensate samples should be examined visually to assure that they are clear, colorless and odorless.
化学或内毒素测试的目的是展示来自蒸汽发生器的洁净蒸汽冷凝水和灭菌满足药典要求。另外，所有冷凝水取样应该目检确保他们是澄清、无色、无味。

5.2.2 Dynamic Equipment Qualification or OQ 动态设备确认或运行确认

Dynamic equipment qualification testing demonstrates that the steam sterilizer and ancillary components operate within pre-determined cycle parameters. Tests specific to the proper operation of the steam sterilizer should be completed before initiating cycle development studies. **Appendix B** contains a list of specific items that are typically verified during equipment qualification.
动态设备确认测试证明蒸汽灭菌器和配套组建按照预先确定的循环参数运行。在启动程序开发调研之前，蒸汽灭菌柜的合适的运行测试应完成。**附件 B** 包含一个特定条目的列表，这些条目在设备确认期间通常被确认。

5.2.2.1 Empty Chamber Temperature Distribution 空载温度分布

Empty chamber temperature distribution studies (temperature mapping) are intended to verity uniform distribution of the heating medium across the load zone. These studies may be used to adjust the bleed valves to obtain the desired chamber uniformity, and as a performance comparison tool throughout the life cycle of the sterilizer.
空载温度分布研究是为了证实热介质通过负载区的均匀分布。这些研究肯用于调节泄露阀来得到期望的腔体温度均匀性，作为性能比较工具贯穿于灭菌器的生命周期。

A sufficient number of sterilization inns should be conducted for each cycle type (porous/hard goods and liquid) to assure reliable results. Temperature probes should not be in contact with the internal surfaces of the sterilizer, nor closer to the chamber wall than load items would he with the chamber loaded. Some differences in sterilizer performance may be observed when evaluating empty chamber performance using sterilizer control parameters optimized for performance with a load.
足够数量的灭菌循环应该执行每个类型来确保可靠的结果。温度探头不应该接触的灭菌器表面，也不能接近腔壁，超过加载项目将被腔体加载。当用灭菌器控制参数优化负载性能时评估空载时，灭菌器性能的一些不同可能被注意到。

The allowable temperature range is considered acceptable if there is not more than a predetermined difference between the highest and lowest temperature after stabilization. A tighter range may be necessary, depending on intended use of the sterilizer. The cycle should utilize the same air removal methods as the production load cycles.
如果没有超过最大和最低温度后稳定，允许的温度范围是可接受的。更严格的范围可能是必要的，这取决于灭菌器的预期的使用。这个循环应该像产品负载循环一样利用同种空气消除方法。

6.0 Cycle Development 循环开发

Successful and efficient cycle development demands a thorough, detailed understanding of the load to be sterilized (including its intended use), the capabilities of the sterilizer, and the requirements for documented evidence of cycle suitability (may be influenced by regional regulatory requirements). This section leverages information provided in Technical Report NO.1 on cycle development and provides practical insight to cycle optimization once it has been developed.
成功而有效的循环开发需要对灭菌物品的装载（包括预期用途）、灭菌设备的灭菌能力，以及循环适用性文件证明的要求（可能受到地区性监管要求的影响），具有透彻而细致的理解。本章节采用技术报告 No.1 中关于循环开发的信息，并为优化已开发的循环提供实际而深刻的洞见。

Adjustments to sterilizer control parameters optimize the sterilization process. These parameters define heat up, exposure and cool-down cycle phases. The sterilization process used (e.g., gravity displacement, pre-vacuum. Steam-air mixture (SAM), superheated water) is determined by the load type.
调整灭菌设备的控制参数能够优化灭菌工艺。这些参数对加热、接触以及冷却循环阶段加以界定。所采用的灭菌工艺（如重力取代、预真空、蒸汽与空气混合物（SAM）、过热水）由装载类型决定。

6.1 Preliminary System Testing 初步系统试验

When starting cycle development, it is important to perform system suitability tests. The following activities (as applicable) should be conducted at intervals defined by the organization to assure chamber integrity:
循环开发开始时，执行系统适用性试验很重要。按照规定的时间间隔执行以下测试活动（如适用），以保证腔室完整性：

- Chamber Leak Test: A chamber leak test for sterilizers utilizing pre-vacuum cycles should be conducted prior to placement of the thermocouple wire to determine chamber integrity. Thermocouple wires should not cause an air leak during cycle development and validation. After the thermocouples wires are placed into the sterilizer chamber, the chamber leak lest may be repeated to confirm chamber integrity. Conduct pressure hold tests for decontamination sterilizers to ensure biosafety containment. The leak rate should not exceed a level that will inhibit the sterilization process during air removal or vacuum drying stages.
  腔室泄露测试：采用预真空循环的灭菌设备的腔室泄露测试，应该在放置热电偶线之前进行，以测定腔室的完整性。循环开发和验证过程中，热电偶线不应造成气体泄漏。继热电偶线放入灭菌设备腔室后，再执行一次腔室泄露测试，确认腔室的完整性。净化灭菌设备应执行保压测试，从而保证生物安全防护。泄漏率不应超出一定限度，从而在排气阶段或真空干燥阶段阻碍灭菌进程。

- Chamber Preparation: Warm up cycles for sterilizers utilizing jackets may be used lo preheat a cold or idle sterilizer chamber and should only he used according to standard operating procedures as part of the established practice.

腔室准备：如果灭菌设备采用夹套装置，则需要进行暖机循环（预热）对冷的腔室或处于闲置状态的腔室进行预热。暖机循环（预热）必须按照相应的 SOP 进行（作为已建立规范的一部分）。

- Air Removal Test: Air removal tests for sterilizers utilizing pre-vacuum cycles should be conducted prior to development or validation studies for a saturated steam pre vacuum process.
  排气测试：采用预真空循环的灭菌设备的排气测试，应该在饱和蒸汽预真空工艺的开发或验证研究之前进行。

6.2 Thermal Measurement Test Equipment 热量测量测试仪器

Instrumentation and peripherals selection is essential to ensure accuracy and precision of the resulting test data. The system selected to provide and record thermal measurement data should be adequate for the purpose. Consideration should be given to the following when selecting temperature and measurement instrumentation:
仪器和周边设备的选择是保证测试结果准确性和精确度的必要条件。选择用于提供并记录热量测量数据的系统必须充分满足使用目的。在选择温度和测量仪器时，需要注意以下几点：

- Use of an appropriate thermocouple (TC) wire
  使用合适的热电偶线（TC）
- TC wire routing should avoid electrical interference
  TC 线的布线应该避免电子干扰
- TC wire placement in the chamber or items should not impede steam flow
  腔室或物品内的 TC 线应避免对蒸汽流造成阻碍
- Quality and type of TC junction (e.g. crimped, welded, soldered, twisted)
  TC 结合处的质量和类型（如压接，熔焊、焊接、拧接）
- Use TC wire of the smallest practical diameter with consideration for application and risk to data integrity.
  使用实际直径最小的 TC 线，并考虑到应用于数据完整性及数据完整性风险的因素
- Recording device accuracy
  记录仪器精确度
- Number of available data acquisition ports
  获得可用数据接口的数量
- Data collection frequency (scan rate)
  数据采集频率（扫描频率）

6.3 Sterilization Cycle Optimization 灭菌循环优化

Sterilization cycles may use vacuum and pressure to remove air from the chamber and load to assure steam penetration. Adjustment of the heat up phase is important to optimize air removal, prevent undue stress on the load items/packaging and minimize the cycle time. The heat-up phase is dependent on the load and chamber characteristics. Variability in heat-up time can affect the actual accumulated lethality lo which the Biological lndicators are exposed and therefore should be considered when determining the worst-case load for validation.
菌循环中可能采用真空和真气压力去除腔室和装载物品的空气，以保证蒸汽穿透性。对加热阶段

的调整对于去除空气非常重要，能够防止对装载物品/包装造成压力过度，并将循环时间降低至最小。加热阶段取决于物品装载和腔室特性。加热时间的可变性会影响与生物指示剂接触的实际累积的杀死率，因此在确定用于验证的最差装载情况过程中，应考虑到这一点。

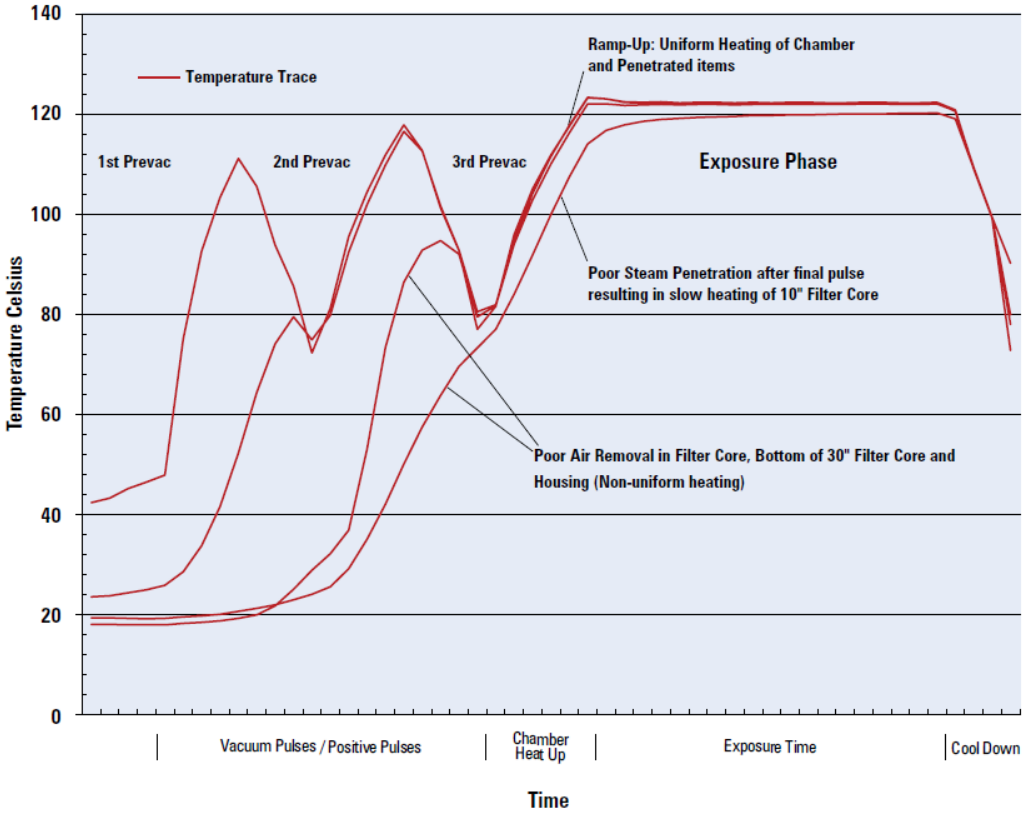
Temperature profiler are used to determine adequacy of air removal for cycle optimization. To analyze the sterilizer performance thermocouples are installed at representative and hardest to heat locations throughout the chamber and load. The result in temperature profiles can he used to determine if adjustments to the cycle parameters are effective. The goal is to have uniform heating by the end of heat-up time.
采用温度分布曲线确定循环优化中去除空气的充分性。为分析灭菌设备的性能，在腔室内和物品装载的具有代表性、以及最不易加热的位置放入热电偶。温度分布曲线的结果可用于判定对循环参数的调整是否有效。目的在于在加热时间结束时，腔室内及装载物品的温度分布均匀。

After collecting data the appropriate interval, graphing the entire cycle can reveal significant differences in heating of the various items and locations. These differences are generally caused by air remaining in the items that prevent steam penetration.
每间隔一段时间收集数据后,将整个循环制成图表,从而显示出不同物品和位置加热的显著差异。这些差异通常是由残留在物品中的空气导致蒸汽穿透受阻。

To illustrate the use of temperature profiles, the following three heat penetration profiles reflect incremental steps through a cycle optimization study. For the purpose of the study, a mixed load of porous/hard goods including, large sterilizing grade filters, tubing, open containers and diaphragm valves used.
为说明温度分布曲线的使用,下列三个热穿透分布曲线反映了通过一项循环优化研究的渐进式步骤。为达到研究的目的，采用能渗透的物品/硬质物品混合的装载模式，这些物品包括灭菌级过滤器、开口容器以及隔膜阀。

Figure 6.3-1 depicts a significant difference in the heating profile and the slowest to heat area lags significantly behind the other locations, which may be due to inadequate air removal. These differences are more pronounced earlier in the heat-up phase.
图 6.3-1 描绘了加热曲线的显著差异，以及升温最慢的区域明显滞后于其他区域，原因可能在于空气去除不充分。这些差异在加热阶段初期更为显著。

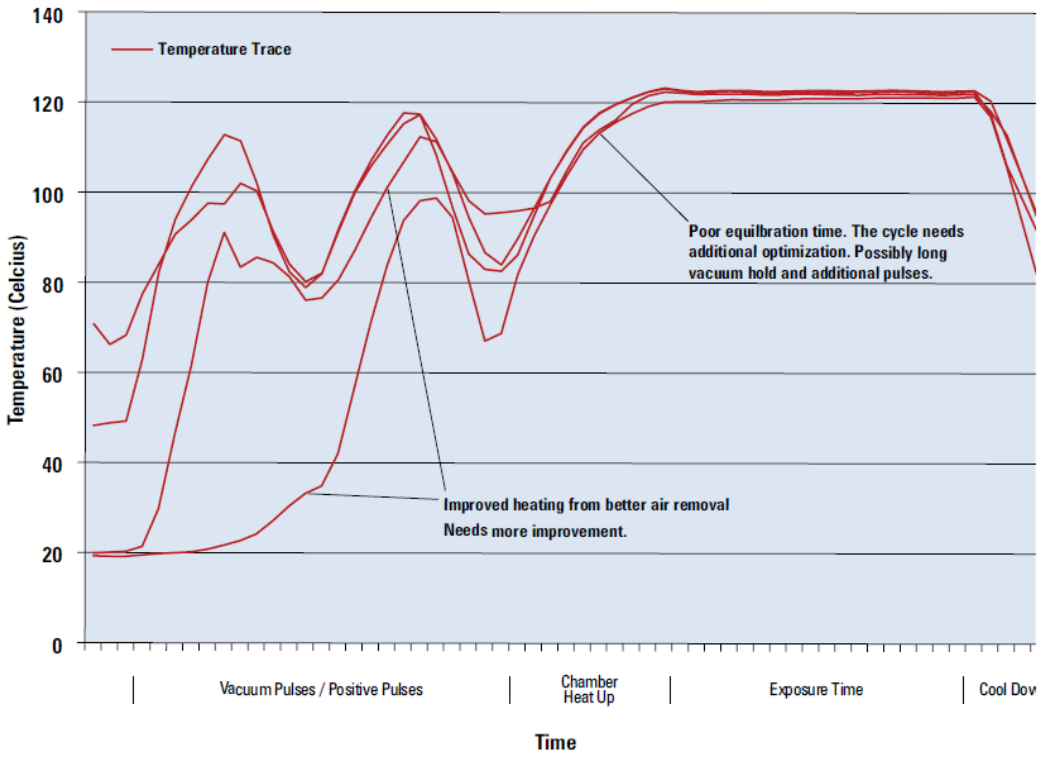
Figure 6.3-1 Example of Heating Uniformity Problem During Initial Development Study 图 6.3-1 初步开发研究过程中受热均匀度问题示例



Temperature trace: 温度追踪
Temperature Celsius: 摄氏温度
1st Prevac: 第一次预真空
2ndPrevac: 第二次预真空
3rdPrevac: 第三次预真空
Exposure Phase: 接触阶段
Vacuum Pulses/ Positive Pulses: 真空脉冲/正脉冲
Chamber heat up: 腔室升温
Ramp-up: Uniform Heating of Chamber and Penetrated items 上升：腔室和被穿透物品的均匀受热
Poor Steam Penetration after final pulse resulting in slow heating of 10” Filter Core
最终脉冲后蒸汽穿透性不足，导致 10”滤芯受热缓慢
Poor Air Removal in Filter Core, Bottom of 30” Filter Core and Housing (Non-uniform heating)
滤芯、30”滤芯底部和滤壳空气去除不充分（受热不均匀）
Vacuum Pulses/ Positive Pulses: 真空脉冲/正脉冲
Chamber heat up: 腔室升温
Exposure Time: 接触时间
Cool Down: 冷却

Figure 6.3.-2 illustrates the progression of the cycle development study. The vacuum level was increased and the profile shows the areas that were lagging in the previous profile are now heating more uniformly. However, the cycle still needs significant improvement.
图表 6.3-2 说明了循环开发研究的发展进程。真空度升高，温度曲线显示：之前温度曲线中滞后的区域现在受热更加均匀。然而，仍需要对循环进行显著提高。

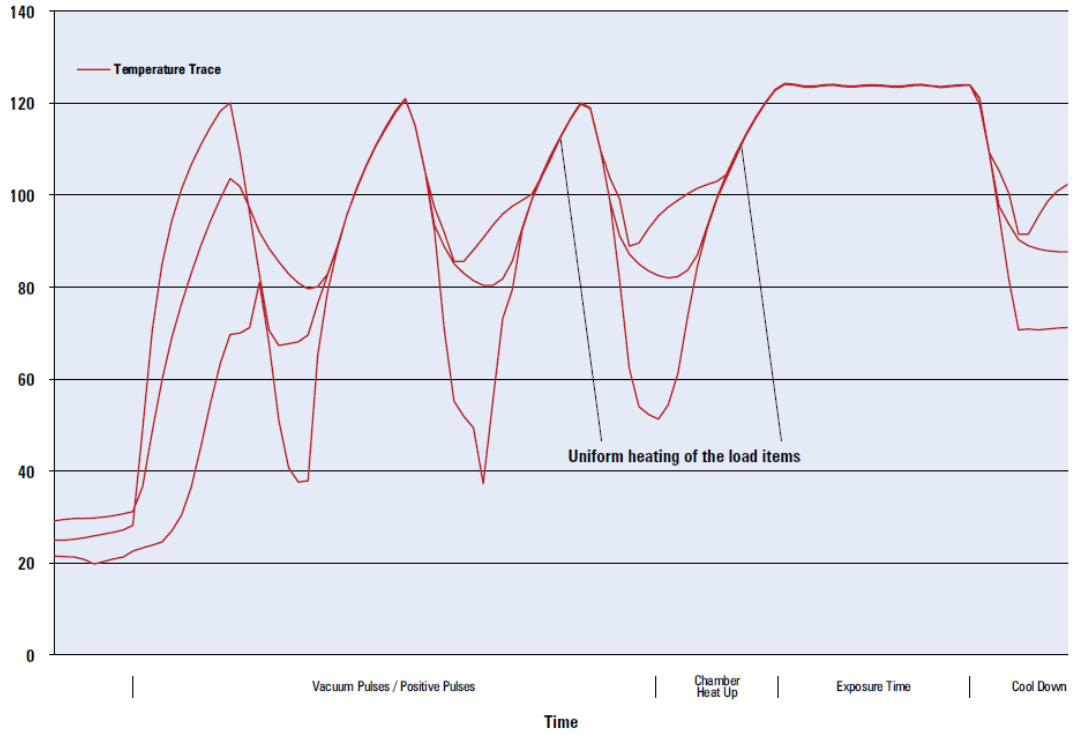
Figure 6.3-2 Example of Heating Uniformity Progression During Cycle Development Study 图表 6.3-2 循环开发研究过程中受热均匀性进程示例



Temperature trace: 温度追踪
Temperature (Celsius): 温度（摄氏度）
Poor equilibration time. The cycle needs additional optimization. Possibly long vacuum hold and additional pulses.
平衡时间不够。这一循环需要另行优化。可能需要延长真空保持时间并增加脉冲。
Improved heating from better air removal
空气去除改进后受热程度得以提高
Needs more improvement: 需要更大提高

As the pressure, vacuum and hold times are optimized the temperature difference decreases until the entire load is heating at the same rate as shown in Figure 6.3-3.
当压力、真空以及保持时间得以优化后，温度差异开始减少，直至整个装载受热速率相同。见图表 6.3-3.

Figure 6.3-3 Example of Heating Uniformity Progression During Cycle Development Study 图表 6.3-3 循环开发研究过程中受热均匀性进程示例



Temperature Trace: 温度追踪

Uniform heating of the load items

装载物品受热均匀

Load temperature uniformity is determined by the measurement of temperature range between the load thermocouples. Acceptance criteria for uniformity should be defined in the test protocol.

装载物品温度均一性根据放置在腔室内和装载物品中的热电偶之间的温度而测得。均一性的验收标准应在测试草案中加以界定。

Common adjustable parameters include, but are not limited to, the number and type of pulses, vacuum and steam pressure levels, exposure time, hold time, drying time and rates of change of pressure and vacuum. Table 6.3-1 provides examples of points to consider when optimizing cycles.

一般可调整的参数包括但不限于：脉冲的数量和类型、真空度和蒸汽压力级别、接触时间、保持时间、干燥时间，以及压力和真空的换气率。表格 6.3-1 提出了对循环进行优化过程中需要考虑的示例点：

Table 6.3-1 Cycle Optimization Considerations Table 表格 6.3-1 循环优化考虑因素表格

	Saturated Steam Processes **饱和蒸汽工艺**		**Air Overpressure Processes** **气体超压工艺**	
Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
HEAT -UP 加热	Vacuum assisted or Forced Air Purge: 借助真空或空气吹扫 Many sterilizers have a purge cycle programmed as the first step in porous/hard goods cycles. Pulses can be made more efficient by pre-empting them with a gravity purge. This may also reduce wear and tear of the pump system, as well as remove condensate in the load. 多数灭菌设备在可渗透物品/硬质物品循环中第一步设定为吹扫循环程序。可以通过预排空脉冲来提高脉冲的性能，同时还可以降低泵系统的磨损，去除装载中的冷凝物。 Pulses: Alternating vacuum pulses and steam charges are used to condition the load prior to the exposure phase of the cycle. The number of pulses are load type dependent, typically 1-3 pulses are	The rate of heat up and pressurization should be carefully controlled to prevent the liquid from boiling while removing the air from the chamber and head space of the container. 去除腔室内空气和加热容器过程中，需要小心控制加热和增压速率，防止出现液体沸腾。 Gravity purge: Time and pressure can be varied during development studies. 重力脉冲：开发研究中可以采用不同的时间和压力。 Large and numerous steam supply and drain ports will facilitate faster and more effective air removal. During development, determine at what temperature to close vent(s) but leave open as long as possible. 较大的、大量的蒸汽进气和排气接	The rate of heat up and pressurization should be carefully controlled to counter act internal container pressure developed as the liquid heats. This will prevent distortion and rupture of the container. In addition, the heat-up ramp rates should be set under worst case conditions (full load of largest mass) so that the steam valve opening can maintain the desired ramp rate. 小心控制加热和增压速率，对液体加热过程中容器内部实际产生的压力进行计数。这样可以防止容器出现扭曲和破裂。另外，应当根据最差条件（最大量满载）设置加热过程中的升温速率，从而蒸汽开度能够保持要求的升温速率。 Visual confirmation of	Since air overpressure is controlled, many are similar to the SAM process. The following parameters are those specific to this process 由于气体过压得以控制，且许多参数类似于蒸汽和空气混合工艺，下列参数为本工艺特有参数。 Chamber door is closed and sealed; water of appropriate quality enters the chamber to a preset level. Circulation system pumps water from the chamber floor through spray nozzles or water cascade grid located in the ceiling. Ensure spray nozzle placement covers the entire load configuration. 腔室门关闭并密封；适量的水进入腔室，至预先设定的水平。循环系统通过喷嘴或放置在腔

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	used for hard goods air removal; whereas, mixed or porous loads may require additional pulses. 脉冲：循环接触阶段前，交替使用真空脉冲和蒸汽交换来调节装载的空气。脉冲的数量取决于装载的类型，通常硬质物体的气体移除过程中使用 1-3 个脉冲，混合装载形式或可渗透物品的装载可能需要额外的脉冲。 Vacuum depth: This parameter directly affects the amount of air remaining in the load. To optimize air removal for porous/hard goods heat-up generally begins with a deep vacuum pulse followed by a steam charge. 真空程度：这一参数直接影响装载中剩余气体的含量。为优化可渗透物品/硬质物品装载中的空气去除效率，加热通常以一个高真空脉冲开始，后续进行蒸汽交换。 Liquid loads: Steam purge may be	口可以促进去除空气的速率和效率。开发过程中，确定在哪个温度下关闭排气但尽量保持打开状态。 Jacket Temperature: The jacket temperature should be set at or just below the chamber temperature to prevent excess condensate or additional radiant heat causing superheated steam. 夹套温度：夹套温度应该设置为腔室温度或更低，防止过度冷凝或多余的辐射热能，从而导致蒸汽加热过度。 If the jacket is set to far from the chamber set point chamber uniformity and temperature control may not as tight and can cause hot spots. This should also be a monitored operating parameter during operations. 如果夹套距离腔室设置点较远，腔室均匀性和温度控制可能控制不够	container pressurization during the cycle may be helpful in establishing parameters during development. 循环过程中对容器增压进行目检有利于开发过程中参数的建立。 Ensure any trays used are adequately perforated to ensure steam/air/water circulation. 确保使用的任何一种托盘均进行充分打孔，保证蒸汽/空气/水分循环。 Ensure uniform flow of the steam air sterilizing medium through the product zone by adjusting luevers (if equipped). 通过调节放气孔（如果配备）来确保蒸汽灭菌媒介通过产品	室顶部的倾注格，对腔室底部的水进行泵压。确保喷嘴的放置覆盖整个装载配置。 Time: Controlled based on the water and steam flow. 时间：基于水流和蒸汽流进行控制。

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	accomplished through alternating slight vacuum pulses and steam purges during the heat-up phase of liquid cycles to ensure even penetration between load items and within flasks/tubes. 液体装载：蒸汽吹扫可以通过在液体循环的加热阶段交替使用轻微的真空脉冲和蒸汽吹扫实现，从而保证装载的物品与烧瓶/管之间的穿透的均匀性。 Pressure: As more steam is forced into the chamber the amount of remaining air is diluted, displaced from the load, and removed in subsequent vacuum pulses. 压力：由于腔室中冲入更多的蒸汽，对装载物品的空气进行稀释，后续的真空脉冲则对空气进行替换和去除。 Rates: This parameter determines the rate of change of vacuum or pressure. A faster rate will minimize the cycle time but pressure differentials or rapid steam flow can	严格，并导致热点的出现。这一点应该在操作过程中作为监控的操作参数。	区域的均匀度。 Adjust air rates according to pressurization due to expansion of the contents of the container during heating of the product. The total pressure of the container is equal to the partial pressure of the liquid plus the partial pressure of the vapor. 由于产品受热过程中容器内内容物的膨胀，需要根据增压情况调整气流速率。容器总压力与液体部分压力加上水蒸气部分压力的总和相当。 Adjust air rates according to pressurization due to expansion of the contents of the container during heating of the product. The total pressure of the container is equal to the partial pressure of the liquid plus the partial	

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	damage items, packaging, and wrapping material. Pouches and bags can be damaged; syringes can lose liquid; wrapping material can be damaged due to overheating caused by rapid steam flow. 速率：这一参数决定真空或压力的换气率。速率越快，循环时间越短，然而压差或快速的蒸汽流会对物品、包装以及包装材料造成损坏。蒸汽流交换过快会造成包装袋破损，注射器出现液体泄漏，包装材料损坏。 Hold time: Vacuum and pressure hold times also serve to remove air. While the chamber is held in vacuum or pressure, air diffuses from the porous substrates into the chamber. Longer hold times can be used for membrane filter and items that must remain wetted. Hold time can be as short as possible for open containers and other items that do not challenge air removal. 保持时间：同时，真空和压力保持时间		pressure of the vapor. 由于产品受热过程中容器内内容物的膨胀，需要根据增压情况调整气流速率。容器总压力与液体部分压力加上水蒸气部分压力的总和相当。 Auxiliary fans, modified jets or air jets may be used to circulate air and steam in chamber to provide even distribution of heating medium and to prevent stratification. Steam will tend to stratify at the top of the chamber if not circulated properly. 可以通过辅助风机、改良的喷嘴或气体喷嘴对腔室内的空气和蒸汽进行循环，从而达到加热媒介分布的均匀性，防止出现层化。如果蒸汽循环不合理，则蒸汽可能会在腔室顶部造成	

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	也用于去除空气。当腔室处于真空或压力状态下时，空气从可渗透物品的底部扩散出来。膜式过滤器和需要保持润湿状态的物品可延长保压时间。敞口容器和其它不需要进行空气去除挑战的物品则可以采用尽可能短的保压时间。 First and second pulses: These have the largest affect on air removal from the chamber. These pulses normally have the deepest (maximum) vacuum level and greatest hold times. 第一次和第二次脉冲：第一次和第二次脉冲对去除腔室内的空气影响最大。这些脉冲通常具有最高的脉冲水平，保持时间也最长。 Additional pulses may be added based on the temperature profile curves. Examples of loads that may require additional pulses to achieve requirements for equilibration may include: tubing, densely packed loads, dense fabric loads and filters.		蒸汽层。 Overshoot/Overdrive: Use of over shoot/overdrive is mainly used for liquid loads. Overshoot is designed to shorten the heating-up time required for products which absorb large quantities of heat, i.e. large volume liquid containers. The heat-up step is accelerated by initially setting the set point temperature higher than the user configured exposure temperature. As the load temperature approaches the exposure set point the overshoot rate progressively approaches zero. 过调量/超载：过调量/超载的使用主要用于液体装载。过调量用于缩短吸收大量热量产品的加热时间，如大容量液体容器。在最初阶段将温度设置为高于	

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	根据温度分布曲线，可能需要增加额外的脉冲。需要额外脉冲来达到平衡要求的装载示例包括：管子、包装较多的装载、厚重织品装载和过滤器。 Once the load is uniformly heated the depth of latter vacuum pulses may be decreased to keep the load at a higher temperature to improve equilibration time. The deeper the vacuum pulse the more the temperature of the load is reduced from the previous steam charge. 当装载物品得以均匀受热时，可以降低后续真空脉冲的程度，以保持装载处于较高的温度，从而提高平衡时间。真空脉冲程度越高，装载的物品从上一次蒸汽交换后的温度降低越快。		使用者配置的接触时间，从而加速加热阶段。由于装载温度接近接触设置点，过调量速率逐渐接近于零。	
Exposure 接触	Equilibration Time: The equilibration time is the period that elapses between attainment of the minimum specified sterilizing temperature in the chamber (chamber reference temperature – typically the drain RTD) and attainment of the minimum	Utilize some steam bleeds to maintain a dynamic environment in the sterilizer as additional steam will need to be added to maintain the desired temperature set point. 由于需要增加额外的蒸汽来维持所	Stabilization Time: For liquid loads, this is the period at the start of the exposure phase of the cycle where there is some overshoot of the process temperature over the set point temperature. This	Set point: The exposure set point (dwell) should be set based on thermal impact to the product while assuring adequate lethality. 设定点：接触（保持）设定点

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	specified sterilization temperature in the load, as measured by the slowest-to-heat penetration probe. This period is an indication of the ability to properly condition the load through air removal and load heating. Equilibration coincides with the start of the Exposure phase of the cycle. 平衡时间：平衡时间是指达到腔室内最低规定灭菌温度（腔室参考温度—以排气 RTD 为代表）和达到装载最低规定灭菌温度之间的时间段，通过受热最慢的穿透型传感器测量而得。这一时间段是经过去除空气和装载加热过程的装载调节能力的指示剂。平衡时间与循环过程中接触阶段的开始时间相一致。 During exposure, the parameter of most importance is the fluctuation in chamber temperature and the differential temperature across the load. A sensitive product requiring finite control over applied heat means the establishment of criteria for fluctuation limits between and within	需的温度设定值，可以利用排空一定量的蒸汽维持灭菌设备处于一个动态的环境。 Set point: The exposure (dwell) set point should be set based on thermal impact to the product while assuring adequate lethality. 设定点：接触（保持）设定点应该在保证充足的杀死率的同时，根据热量对产品的影响进行设置。 Stabilization Time: Proportional Integral Derivative (PID) control valves normally require time to stabilize once the sterilization temperature band is reached. The use of overshoot and/or heating up transition pressure can delay the Proportional Integral Derivative (PID) program of the control value increasing stabilization time. As a result, the first few minutes of exposure can have higher variability. Therefore,	overshoot period is a function of the design and tuning parameters that affect the chamber temperature control loop. Temperature control eventually stabilizes to within the desired range. Duration is determined by the load and chamber size as well as temperature control loop response. 灭菌时间：针对于液体装载而言，灭菌时间是指循环过程中接触阶段的开始，此时工艺温度超出设定温度。这一过调量时间段是设计和调整参数的功能，对腔室温度控制回路有影响。温度控制最终稳定在所需的范围内。持续时间取决于装载和腔室大小，以及温度控制回路的反应。 Maintain pressure of air and steam in the chamber throughout the exposure	应该在保证充足的杀死率的同时，根据热量对产品的影响进行设置。 Superheated water provides the maximum heat transfer to the product. Continuous water circulation and load coverage should be ensured throughout the exposure phase. 过热水能够将最大的热量传递给产品。继续水循环，并保证接触阶段装载的覆盖范围。

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	individual thermocouples. 接触过程中，最重要的参数是腔室内温度与贯穿装载过程的温度差的波动。一个需要对受热进行有限控制的敏感产品意味着需要建立热电偶之间及各个热电偶的波动限值标准。 Set point: The exposure (dwell) set point should be set based on what the load will tolerate; In general a shorter time at higher temp may have the advantage to the load versus a longer exposure time at lower temperatures. 设定点：接触（保持）设置点应该根据承载的装载进行设置。通常时间越短、温度越高，相比于较长的接触时间和较低的温度而言，对于装载更有利。 Exposure Time: This parameter should correlate with the set point to deliver the required accumulated lethality to all parts of the load. 接触时间：这一参数应该与将所需的累	a stabilization time may be required prior to applying chamber uniformity acceptance criteria. 灭菌时间：达到灭菌温度带后，PID 控制阀通常需要时间稳定下来。使用过调量和/或加热转换压力能够延迟控制阀增加稳定时间的 PID 程序。因此，接触阶段的前几分钟具有较高的可变性。所以，可能在应用腔室均匀性验收标准前，需要一个稳定时间。 Overshoot/Overdrive: Use of over shoot/overdrive: Mainly used for liquid loads. Overshoot is designed to shorten the heating-up time required for products which absorb large quantities of heat, i.e. large volume liquid containers. The heat-up step is accelerated by initially setting the set point temperature higher than the user configured exposure temperature. As the load temperature	period. Continue to circulate the air steam mixture to prevent stratification. 接触过程中，维持腔室内空气和蒸汽的压力。继续循环空气和蒸汽的混合气流防止出现层化。	

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Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
	积致死率传递至装载的所有部分的设定点相关 Sterilization Temperature Band: The temperature tolerance range for the load and sterilizer control. The minimum of the band should assure that the sterilization evaluation temperature is reached and maintained. 灭菌温度带：即装载和灭菌设备控制的温度承受范围。灭菌温度带应至少保证达到并维持灭菌评估温度。 Jacket Temperature: The jacket temperature should be set at or just below the chamber temperature to prevent excess condensate or additional radiant heat causing superheated steam. If the jacket is set to far from the chamber set point chamber uniformity and temperature control may not be as tight and can cause hot spots. 夹套温度：夹套温度应该设定为腔室温	approaches the exposure set point the overshoot rate progressively approaches zero. 过调量/超载：过调量/超载的使用主要用于液体装载。过调量用于缩短吸收大量热量产品的加热时间，如大容量液体容器。在最初阶段将温度设置为高于使用者配置的接触时间，从而加速加热阶段。由于装载温度接近接触设置点，过调量速率逐渐接近于零。 During exposure, the parameter of most importance is the fluctuation in chamber temperature and the differential temperature across the load. A sensitive product requiring finite control over applied heat means the establishment of criteria for fluctuation limits between and within individual thermocouples. 接触过程中，最重要的参数是腔室内温度与贯穿装载过程的温度差的		

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Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
	度或更低，防止过度冷凝或多于的辐射热能，从而导致蒸汽过热。如果夹套距离腔室设置点较远，腔室均匀性和温度控制可能控制不够严格，并导致热点的出现。 This should also be a monitored operating parameter during operations. 这一点应该在操作过程中作为监控的操作参数。	波动。一个需要对受热进行有限控制的敏感产品意味着需要建立热电偶之间及各个热电偶的波动限值标准。 Set point: The exposure (dwell) set point should be set based on what the load will tolerate; In general a shorter time at higher temp may have the advantage to the load versus a longer exposure time at lower temperatures. 设定点：接触（保持）设置点应该根据承载的装载进行设置。通常时间越短、温度越高，相比于较长的接触时间和较低的温度而言，对于装载更有利。 Exposure Time: This parameter should correlate with the set point to deliver the required accumulated lethality to all parts of the load. 接触时间：这一参数应该与将所需		

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		的累积致死率传递至装载的所有部分的设定点相关。 Sterilization Temperature Band: The temperature tolerance range for the load and sterilizer control. The minimum of the band should assure that the sterilization evaluation temperature is reached and maintained. 灭菌温度带：即装载和灭菌设备控制的温度承受范围。灭菌温度带应至少保证达到并维持灭菌评估温度。		
Cool-down 冷却	Dryness Assessment: Leaving an environment conducive to microbial growth is undesirable. Also, there may be product or process reasons that moisture cannot be tolerated in the load. Assessment of dryness can be done visually on some types of items or gravimetrically. Test methods for this can be found in sterilizer standards or defined by user. 干燥度评估：不应出现适合微生物生长	Liquid loads: Slow exhaust or air overpressure may be used to slowly cool the load preventing boil over. Time, pressure rate and jacket cooling can be adjusted. 液体装载：可能使用较慢的排气或空气过压缓慢降低装载的温度，防止沸腾而溢出。时间、压力速率和夹套冷却均可以调节。	Air overpressure during cooling is used to prevent the closure from lifting, vial or flexible bag rupture. Cycle adjustment should be made based on product type and container size. Smaller sizes have a larger surface area to volume ratio than larger sizes and may be the worst case. 冷却过程中的空气过压用于防	The superheated water passes through an external-heat exchanger where it is cooled at a controlled rate. This water removes heat from the product as it circulates over the load. A point to consider during cooling is the chamber overpressure set point. It is

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Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
	的环境。同时，装载中可能包含不能受潮的产品或因为工艺原因不能出现水分。一些物品的干燥性评估可以通过目测或比重法检测。测试方法见灭菌设备标准或用户自行制定。 To achieve the desired load dryness the options available during cool-down of a porous/hard goods cycle include deep vacuum, jacket heating, and pulsing. 为了达到所需的装载干燥度，可渗透行物品/硬质物品循环的冷却阶段中可用的选择包括：高真空、夹套加热和脉冲。 Vacuum: The deeper the vacuum the lower the boiling point of the condensate remaining in the load. Therefore, the vacuum can be maximized based on what the load items will tolerate. However, wet pouches may burst and other sensitive items may be damaged. Vacuum depth and hold time are generally user programmable and	For Liquid loads in sealed glass containers, Air overpressure (AOP) and cooling water can be utilized to cool the load in the same manner as a Superheated water spray cycle. 针对装入制定容器的液体装载而言，可以利用空气过压（AOP）和冷却水对装载进行冷却，采用与过热水喷淋循环相同的方式。 Prior to introducing cooling water into the saturated steam environment, the AOP should be added first as the steam will be collapsed quickly along with the chamber pressure. 在将冷却水引入饱和蒸汽环境前，应首先加入空气过压，原因在于蒸汽会随着腔室压力迅速消散。 Cool the load before door opening 打开腔室门前对装载进行冷却。	止在上升过程中瓶子密封掉落或可收缩包装破裂。应该基于产品类型和容器大小对循环进行调整。较小的容器与较大容器相比，容积比表面更大，可视为最差条件。 Reduce chamber pressure to atmospheric pressure using similar parameters as those applied during the heat up phase. 使用那些加热阶段已经应用的相似参数来降低腔室压力到常压。 Continue to circulate the air to optimize the cool down phase. 继续循环空气以优化冷却阶段。 A point to consider during cooling is the chamber	important to maintain the chamber pressure with make up air (overpressure). 过热水贯穿外部加热换热器，此换热器在受控的速率下进行冷却。过热水在装载中循环会带走产品的热量。冷却阶段需要考虑腔室过压设定点。维持带有外气补给的腔室压力非常重要（过压）。 Air overpressure during cooling is used to prevent the closure from lifting (vial caps, blister lid, or flexible bag rupture). Air overpressure adjustments should be made based on product type and container size. Smaller sizes have a larger surface area to volume ratio than larger sizes and may be the worst case. 冷却过程中的空气过压用于防止在上升过程中瓶子密封掉落

	Saturated Steam Processes 饱和蒸汽工艺		Air Overpressure Processes 气体超压工艺	
Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
	can be adjusted based on the dryness assessment. 真空：真空度越高，装载中残留冷凝物的沸点越低。因此，可根据装载的物品将真空调节至最大。然而，润湿的包装可能发生破裂，其他敏感性物品可能会受到损坏。真空度和保持时间通常可由用户进行编程，并根据干燥度评估进行调节。 Pulsing: Vacuum pulses followed by pressurization with compressed air, rather than steam, enhance evaporation. The compressed air can also be heated with an inline heat exchanger for further drying. This is especially useful for porous/hard goods rubber loads. 脉冲：压缩空气增压后，使用真空脉冲而不是蒸汽，用于增强蒸发过程。压缩空气还可以通过在线换热器进行加热用于进一步干燥。这一点对于可渗透物品/硬质物品橡胶装载尤其有效。		overpressure set point. It is important to maintain the chamber pressure with makeup air (overpressure). 冷却阶段需要考虑腔室过压设定点。维持带有外气补给的腔室压力非常重要（过压）。	或可收缩包装破裂。应该基于产品类型和容器大小对循环进行调整。较小的容器与较大容器相比，容积比表面更大，可视为最差条件。

	Saturated Steam Processes 饱和蒸汽工艺		Air Overpressure Processes 气体超压工艺	
Phase 阶段 (Possible Load Type)（可能的装载类型）	**Pre-Vacuum 预真空 (Porous/Hard Goods Loads, Liquid Load Sealed Rigid or Non-Sealed Container)（能渗透的物品/硬质物品混合装载。装有液体的密封硬质容器或非密封容器）**	**Gravity Displacement 重力取代过程 Process(Porous/Hard Goods or Liquid Load (sealed/non-sealed))（能渗透的物品、硬质物品或液体装载（密封与非密封））**	**Steam Air Mixture Process 蒸汽与空气混合工艺 (Liquid Load sealed container)（装有液体的密封容器）**	**Superheated Water Spray/Cascade 过热水喷淋/倾注 (Liquid Load sealed container)（装有液体的密封容器）**
	Jacket Heating: Vacuum or pulsing combined with radiant heat from the jacket combine to speed evaporation. The jacket should be set to provide radiant heat to the load during vacuum to dry the load. If the jacket temperature drops during cool-down the load can remain wet. 夹套加热：真空或脉冲与夹套的辐射热量相结合可加速蒸发。夹套应该设置为能够为装载提供辐射热能，在真空阶段烘干装载。如果夹套温度在冷却过程中下降，则装载仍处于润湿状态。 Liquid loads: Slow exhaust or air overpressure may be used to slowly cool the load preventing boil over. Time, pressure rate and jacket cooling can be adjusted. 液体装载：可能使用较慢的排气或空气过压缓慢降低装载的温度，防止沸腾而溢出。时间、压力速率和夹套冷却均可以调节。			

6.3.2 Pressure Vacuum (Pre-vacuum) Cycle Development 压力真空（预真空）循环开发

Methods for evaluation of the cycle are important to determine how to adjust and optimize the cycle. An air removal calculation is useful to determine the theoretical air remaining in the chamber. Individual load items may retain more air than reflected in the calculation. All pressure units must be the same.
循环的评价方法对于决定如何调整和优化循环非常重要。对于去除空气的计算有利于测定理论上残留在腔室内的空气。与计算结果相比，单个装载物品可能保持更多的空气。所有的压力单位应该相同。

【Equation1 方程 1】

$$P = \frac{vp1}{sp1} \times \frac{vp2}{sp2} \times \cdots \frac{vpx}{ep} \times 100\%$$

Where 其中:

P =Percent Air Remaining 残留空气百分比
vp1=First vacuum press 第一次真空压力
vp2=Second vacuum press 第二次真空压力
vpx=Final vacuum press 最终真空压力
sp1=First Steam Press 第一次蒸汽压力
sp2=Second Steam Press 第二次蒸汽压力
ep2=Exposure Press 接触压力

Example 示例：

$$2\% = \frac{6\text{psia}}{20\text{psia}} \times \frac{6\text{psia}}{22\text{psia}} \times \frac{6\text{psia}}{25\text{psia}} \times 100\%$$

7.0 On-Going Control 持续控制

After completion of qualification for a CMP sterilizer, an ongoing program of sterilizer monitoring contributes to assuring a consistent validated state of control. The suitability of the sterilizer should be established as described in PDA Technical Report No.1. Requalification, maintenance, change control, and periodic verification of the cycle should also be considered as part of the life cycle control of the Sterilizer. Change control procedures should adequately address issues such as a load configuration change or a modification of a sterilizer. (1)
完成一个 CMP 灭菌器的确认后，灭菌器的持续监控项目有助于保证与验证状态的控制一致灭菌器的适应性应该像 PDA 技术报告描述的那样确定，确认、保养、变更控制和定期确认也应该作为灭菌器生命周期控制的一部分。变更控制程序应充分提出如灭菌器的装载结构改变或其他变化的问题。(1)

System suitability evaluations are physical evaluations that can be performed on a routine basis as a maintenance type of activity, and therefore can be defined and documented through SOP or PM Procedures. Physical evaluations (e.g., chamber integrity or air removal) may be conducted on a scheduled frequency to demonstrate ongoing control of the sterilizer system and may he performed by personnel other than validation personnel.
系统适应性评估是物理评估，能够执行像保养类型的活动，因此能通过 SOP 或程序手册被定义或文件化。物理评估也许预定频率的进行来证明灭菌系统的持续控制，它可能由除了验证人员外的人员执行。

Requalification indicates a procedural process that would require a written protocol before performance of a test. Requalification studies should also be performed on a periodic basis. Empty chamber studies may be performed to evaluate numerous locations throughout a sterilizing unit to confirm uniformity of temperature and pressure conditions. Although empty chamber mapping studies arc typically associated with initial qualification of a new sterilizer, the studies can also provide data to evaluate ongoing consistency. Requalification of the loads in the sterilizer is a topic addressed in Technical Report No.1. (1)
合格后再确认表明在执行测试前将需要编写草案的一个程序过程。专业学习也应该 在一定基础下执行。空载研究可能通过执行评估一个灭菌单元的许多分布点，来确认温度和压力条件的均匀性。虽然空载分布研究一般与新灭菌器的安装确认有关，这个研究也能为评估持续控制一致性提供数据。灭菌器确认的方法在技术报告 1 中是一个主要处理。

Control system settings should be reviewed at intervals defined by t h e internal requirements. The review should encompass verification of the controller PID parameters for the sterilizer and verification of the critical and key operational parameters on both the sterilizer control system and the internal operational SOPs/master production records. Any changes to the parameters should be investigated.
控制系统设置应该通过内部需要在确定的间隔时间内回顾。回顾应该包含灭菌器控制器参数的确认，灭菌器关键系统和内部操作 SOP 的主要产品记录的关键参数的确认。任何参数的变更应该研究。

Maintaining the sterilizer's computer system in the validated state includes change control for software and hardware, and continuing calibration of critical and key input and output devices. Written procedures must define system security, (17) storage and access to backup firmware and software, version control, and audit trail. If the system uses electronic records in place of paper records, assure applicable regulatory compliance.
在验证状态保养灭菌器的电脑系统包括变更软件和硬件，和继续校正关键输入和输出装置。编写的程序必须定义系统安全性，存储和进入备份固件和软件、版本控制和审计追踪。如果系统用电子记录代替纸质记录，保证符合法规的适应性。

7.1 Sterilizer System Maintenance 灭菌系统的保养

Preventive maintenance is important to ensure the equipment is maintained in its qualified state. Maintenance planning should include what, when, and how to perform preventive maintenance. Manufacturer recommendations, usage, and application of the sterilizer should

be considered when setting the maintenance schedule. It is recommended that maintenance should be performed in conjunction with calibration. Typical items for maintenance planning may include:
预保养对于保证设备处于我们合格的状态是很重要的。保养应该包括保养内容，时间，如何进行预保养。在设定保养计划时，应该考虑生产建议、用途和灭菌器的应用。建议保养应该结合校验一起执行。一般保养计划项目包括：

- Cleaning of the chamber, racks, shelving, and door 腔室、架子以及门的清洗
- Replace chamber exhaust filter 替换腔室排气过滤器
- Lubricate door gasket (if applicable)润滑门垫圈（如果合适）
- Replace door gasket(s)替换门垫圈
- Vent filter is sterilized and / or replaced periodically (Recommendations on sterilization and integrity testing of filters may be found in reference literature.) (I8)
  排气过滤器是消毒的或应该定期更换吧（建议根据建立的参考文献中的消毒和过滤器完整性测试）
- Replace compressed air inlet filter 更换压缩空气进气过滤器
- Steam traps cleaning and functional verification 蒸汽疏水阀的清洁和功能确认
- Verify chamber pressure switches and door interlock function 核实腔体压力转换器和门的互锁功能
- Cheek the compressed air / pneumatic system operation 检查压缩空气和气动系统运行
- Cheek the steam / clean steam inlet valves and pressure regulators
  检查蒸汽/洁净蒸汽进入阀和压力调节阀
- Rebuild vacuum pump as needed 当需要时更换真空泵
- Cheek water and cooling water pressure and level 检查水和冷却水的压力和水高度
- Check water control valve operation 检查水控制阀操作
- Flush heat exchangers 用水冲洗热交换器
- Cheek and replace valve seals/diaphragms 检查和替换阀门密封圈膜片
- Verify pressure relief devices function 核实减压装置功能
- Verify other safety switches 核实其他安全转换开关
- Check clean steam piping and chamber for rouging
  检查洁净蒸汽管路和腔室的红锈

There may be occasion when corrective maintenance must be performed due to malfunction. In this case, change control procedures should be followed to ensure the system remains in its qualified state.
当错误的保养发生时，一定会导致故障上演。在这种情况，变更控制程序应该服从保证系统处于合格的状态。

7.2 Calibration 校正

Calibration is the comparison of a measuring device of unknown tolerance to a measurement standard of known tolerance in order to detect and report all deviation from specified calibration tolerance limits. (19) Calibration may include adjusting the instrument, or a measurement loop, to bring the measurements to within specifications. (20) Equipment should be calibrated according to a documented program that includes establishing appropriate calibration intervals. Documentation should include sterilizer instruments such as temperature indicators, pressure indicators, transmitters, controllers, recorders and limit switches (e.g. high temperature and high pressure safety switches).
校正是将一个未知公差的将要的测量装置与一个已知偏差的标准装置比较，根据校正规定的公差限度，以便检测和报告所有偏差。校正可能包括对仪器的调整，或测量通路，包括技术参数的测量。设备应该根据包括建立有合适校正间隔时间的文件项目来校正。文件应该包括灭菌一起，比如温度指示器，压力指示器，信号传送器，控制器，记录和限定开关（如高温和高压安全开关）。

Device measurement tolerances are specified by the instrument vendor. That information is often used for determining the acceptable performance and accuracy of the measurement, but in actual practice, calibration can provide greater than slated accuracy. For example, an RTD

element (as delivered) may be specified to be within ±0.5 at 0℃. When the RTD is connected to an adjustable transmitter, the RTD tolerance can he eliminated, thereby providing an installed system accuracy that can be maintained within tighter specifications.
设备检测允许偏差被仪器供应商规定的。TK 信息通常用来可接受的性能和测量精确度，但实际操作上，校正能提供一个比一般精确度更高的数据。比如，一个电阻式温度计偏差可能被规定在 0.5 摄氏度内。当电阻式温度计与调节发射器连接，电阻式温度计的偏差能被消除，这样通过安装系统保证在一个更严格技术参数下保养。

Calibration of a single device is measured against a reference standard that is used to verify accuracy across the range of operation tor that device. For linear devices, it is common to perform at least a two-point calibration at the range of use low point and high point. Nonlinear devices may require additional calibration points throughout the range of operation.
单个装置校正测量违背参考标准，通常通过装置的操作来确认精确度。对于线性装置，在最低点和最高点范围内通常执行两个点的校正。非线性装置可能需要额外的校正点贯穿操作范围。

Each device can be tested to a reference standard and adjusted to within acceptable calibration tolerance. Calibration of a loop takes into consideration the individual characteristics of each device that comprises the loop. The collective calibration tolerance or acceptable tolerance of measurement for the loop should consider tolerances for all the devices in that loop.
每个装置在一个可参考标准下测试和调整在可接受校正偏差一个循环校正应该考虑包含这个循环的每一个装置的个别特性。集体校正偏差或对这个循环测量的可接受偏差应该考虑在这个循环的所有装置。

Instruments that control and monitor critical and key parameters on a CMP sterilizer must be maintained within specified limits in order to comply with regulatory and process requirements. (16) Each instrument should be assigned a unique identification n u m b e r that can be used to document its calibration and History of compliance. When purchasing a new sterilizer, determine if the manufacturer is willing to use your company's instrument numbering nomenclature m the documentation supplied with the unit, which would alleviate the need to translate instrument numbers upon entry into your calibration system. Assure that your purchase specifications address the instrument accuracy required to meet the needs of your particular processes.
为了遵守法规和过程需求，在一个 CMP 灭菌器的控制盒检测和关键参数的仪器应该在规定的限度内保养。每个仪器应指定一个唯一识别数码,可用于文档其校正和历史记录的文件中。当购买一个新的灭菌器,确定制造商愿意使用贵公司的仪器编号命名法命名该单位所提供的资料,这将缓解需要翻译工具的数字在进入你的校准系统。确保你的购买规格地址所需的仪器精度满足您的特定需求的过程。

7.2.1 Calibration Records 校正记录

Calibration activities and results should be recorded. This information is typically recorded on a form or may be maintained in an electronic database. The record should include basic information such as:
校正活动和结果应当被记录。这些信息一般记录在一个表格或存在一个数据库里。
这些记录应该包括这些基本信息：

- The device manufacturer, name, tag number, and location
  仪器生产商，名称，附属物数量、存放位置
- Operating range and calibration points 操作范围和校验要点
- Identification of procedure used to calibrate the device 用于校验仪器的识别程序
- Accuracy or allowed deviation from standard that triggers an adjustment
- Out-of Tolerance deviation that triggers an investigation
- The 'as found" data and "as left" data 校前测试数据和校后测试数据
- Identification of the reference standard(s) used to compare field measurements.认同参考标准，用于与同行业比较

- Identification of the person(s) that performed the calibration
  个人认同和执行校正
- Date of calibration, and date next due for calibration
  校正日期和下个校正到期的日期

The "as found" data are the measurements of the test device that are recorded and compared against a reference standard before any adjustments. The "as left" data is recorded to document results after adjustment.
调整前校正数据是在任何调整数前记录和与有关标准相违背的测试装置的尺寸。调整后数据是在调整后记录文件结果。

Calibration records should be reviewed and approved by a subject matter expert, and depending the organization's policies and practices, the Quality Unit. Documentation should be available that includes procedures to describe when and how to notify departments when "as found data is outside the stated accuracy specification, and how to evaluated the impact to product or process.
校正记录应该被一个有关主题专家回顾和批准，依靠这个组织的政策和实践、质量单元。文件应该成为有效的，包含程序描述当发现数据超出准确技术参数状态时怎样和如何通知有关部门。

8.0 Document/文件

Validation is a lifecycle process, which relies on the content, quality and up to dace documentation to enable the 'validated' status of systems to be demonstrated. The following section is intended to give a high level overview of the types of documents that would he expected to be generated for a moist heat sterilizer system, and the purpose that each document satisfies within t h e validation lifecycle.
验证是一个生命周期过程，依靠内容、质量直到文件是已经证明的系统验证状态成为可能。下接文件打算给我们对一般文件一个高水平概述，期望对于湿热灭菌系统的产生，包括验证生命周期的每个文件的满足因素。

It should be noted that although the general validation lifecycle is recognized, there is no universally agreed approach to validation. **Appendix C** provides typical documentation for design, cycle development, qualification and ongoing maintenance of sterilizer systems. In general, however, the following stages of the validation lifecycle should he documented, using good technical understanding of the product and process requirements as the basis for the development of a sound validation rationale:
应注意到虽然一般的验证生命周期普遍被接受了,但是没有普遍认同的方法来验证。**Appendix C** 提供的设计的一般文件，周期发展、确认和灭菌器系统持续控制。一般，一下验证生命周期应该被记录，用对产品良好的技术理解和过程需求作为基础来发展充分验证。

- Planning 计划
- Requirements 需求
- Verification of design
- Testing and Qualification 测试和确认

The validation strategy is defined in master plans and test plans. Specific activities with respect to design qualification (DQ), installation qualification (lQ), operational qualification (OQ) and performance qualification (PQ) arc described in standard operating procedures or protocols.
验证策略被定义在验证主计划和测试计划中。具体的活动对设计资质(DQ)。安装确认(lQ)，运行确认资格(OQ)和性能(PQ)中描述的标准操作程序或协议。

Validation activities are typically managed through approved protocols with acceptance criteria that arc related to the requirements. Test results are presented and discussed in reports and should include any conclusions and recommendations.
验证活动通常通过相关要求的有可接受标准的批准文件来管理。在报告中被提出和讨论的测试结果应该包括一些结论和建议。

The content of the documentation generated for a CMP system would be expected to be more detailed than for a non CMP system. The use of supplier documentation may be considered as suitable to support the end users validation requirements provided good documentation practices are followed and the CMP requirements of the user are satisfied. This may include a quality review and approval of the supplier-generated documentation.
对于一个 GMP 系统产生的文件内容比一个非 GMP 系统预期更详细。这可能包括一个质量回顾和供应商生成文件的批准。

Historical documentation related to system performance (e.g.. maintenance), as well as quality systems management data (e.g. deviations, CAPAs and change control) should be periodically evaluated. Periodic quality review ensures t h e sterilizer performance remains consistent with user requirements, specifications and previously validated conditions. Any compliance gaps that arc observed can be appropriately addressed. Lifecycle concepts ensure that the sterilizer is maintained in a continuous state of control.
有关系统性能的历史文件和高品质的系统管理数据（如偏差，纠正与预防措施，变更）一样，也应该被定期评估。周期的质量回顾保证灭菌器性能和用户需求、说明书、前验证条件保持一致性电弧观察到的任何合规的差异能够被适当处理。生命周期概念保证灭菌器在继续控制状态下被保养。

A list of typical documentation for design, cycle development, qualification and ongoing maintenance of moist heat sterilizer systems is shown in Figure C-1 Documentation.
典型的设计文档的列表，循环开发、确认和湿热灭菌器系统的持续维护是图 C-1 文档。

9.0 Appendix 附录

Appendix A Design Considerations 设计考虑事项

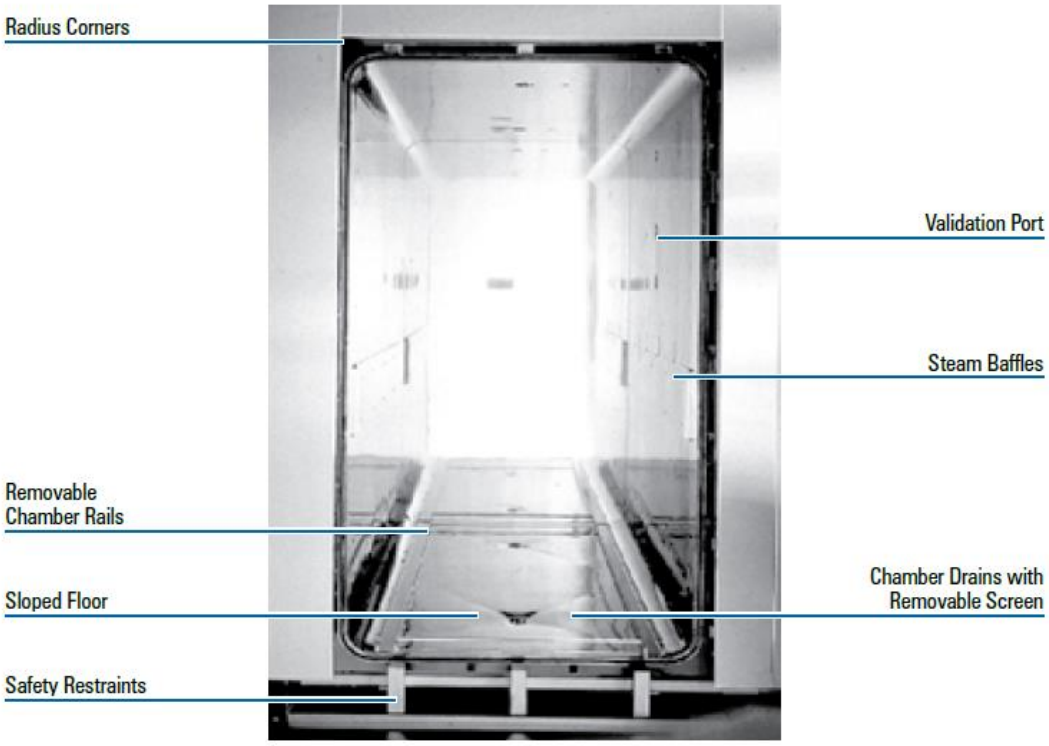
The following are elements of a moist heat sterilization system that may be used as guidelines for design and testing this system. These descriptions are points to consider and may not necessarily be all inclusive.
可以用作湿热灭菌系统设计和测试指南的原理如下。这些描述都是需要考虑的要点，并不一定完全包括。

Chamber and jacket Considerations:
腔体以及夹套考虑事项：

- The chamber is typically a rectangular pressure vessel with radius corners or cylindrical construction. The autoclave should be positioned so that condensate flows towards the drain.
  腔体通常是一个弧形内角的矩形压力容器或圆桶形结构。高压灭菌柜应合理放置以便于冷凝水排放。
- The chamber should have sloped floors and penetrations to minimize condensate pooling. Baffles may also be required to deflect condensate to the chamber wall and provide even temperature distribution. The chamber drain should have a debris screen to prevent broken glass or other materials from entering the drain line or vacuum system.
  腔体的板层应当倾斜以及可渗透以最大限度的减少冷凝水聚集。同样需要导流板将冷凝水转移到腔体壁面以及提供温度分布。腔体排水口应当有一个碎片挡板来保护整个排水管路或真空系统不被碎玻璃或其他材料损坏。
- A single or multiple validation ports should be on the chamber to insert thermocouples or load probes as required.
  腔体上应当安装一个或多个验证口，需要时方便插入热电偶或装载探头。
- The chamber is typically insulated to prevent heat loss, provide better temperature distribution, and provide safety for operators and maintenance personnel. Figure A-1 is a typical rectangular chamber for a moist heat sterilizer.
  为了阻止热损失，提供更好的温度分布以及为操作和维护人员提供保护，腔体通常是隔热的。图 A-1 是一个湿热灭菌柜的典型矩形腔体。

Figure A-1 Example of Sterilizer Chamber
图 A-1 灭菌柜腔体实例

Figure A-1 Example of Sterilizer Chamber



- Steam sterilizers typically have a steam jacket to insulate the chamber and improve temperature distribution. When a steam jacket is present, it is ordinarily operated at lower steam pressure and temperature than the chamber to avoid superheat.
  蒸汽灭菌柜通常有一个蒸汽夹套来隔离腔体并提高温度分布。为避免过热，夹套的蒸汽操作压力和温度通常比腔体要低。

- • The contact part of the chamber for sterilizers is typically constructed from austenitic stainless steel such as 316L or 316Ti. The jacket if applicable is also an austenitic stainless steel such as 304, 316L or 316Ti. Carbon steel may be used for the jacket if plant steam is used for jacket heating. However, use of carbon steel in contact with stainless steel may result in corrosion of both the jacket and the chamber especially around the contact place. Other chamber materials include nickel clad carbon steel （used for highly corrosive media solutions). The chamber surface may be treated to remove weld discoloration, to facilitate cleaning and decrease the risk of corrosion.
- 灭菌柜腔体的接触部分通常由奥氏体不锈钢，例如 316L 或 316Ti 构成。如果可以，夹套材料也是不锈钢，例如 304,316L 或 316Ti。如果使用工业蒸汽为夹套加热，夹套也可以采用碳素钢。然而，在与不锈钢接触部位使用碳素钢会导致夹套以及腔体，特别是接触部位的腐蚀。其他材料包括含镍碳钢（用于高腐蚀性溶液）。腔体表面通过处理可以去除焊接褪色，易于清洁以及减少腐蚀的风险。

- Weld discoloration should be minimized by appropriate welding techniques and materials to minimize potential risk of corrosion
  通过适当的焊接技术最大程度的减少焊接褪色，采用合适的材料来减少腐蚀的潜在风险。

- Since sterilizers use saturated steam or heated water at a pressure higher than atmospheric conditions, the chamber and jacket are built to an acceptable pressure vessel code. Local regulatory expectations should be consulted for applicable pressure vessel requirements. The chamber and jacket should include a code appropriate safety relief device such as a rupture disk or relief valve. Safety valves should be piped to a safe location.
  由于灭菌采用饱和蒸汽或过热水，腔体和夹套应当按照压力容器的标准制造。适用于压力

容器的要求应参考当地监管的期望。腔体和夹套应当包括安全减压设备,例如防爆片或减压阀的合适标准。安全阀应当安装在一个安全的位置。

- Common pressure range for sterilizer chambers and jackets is full vacuum to at least 35-45 psig (2.4-3.1 barg). The pressure rating will depend on the cycle temperatures required and if air overpressure is used. Proper high pressure safety devices should be used.
  灭菌柜腔体和夹套的正常压力范围是全真空到至少 35~45 psig(2.4~3.1barg)。压力等级取决于需要的循环温度以及是否使用过压空气。应当使用合适的高压安全设备。

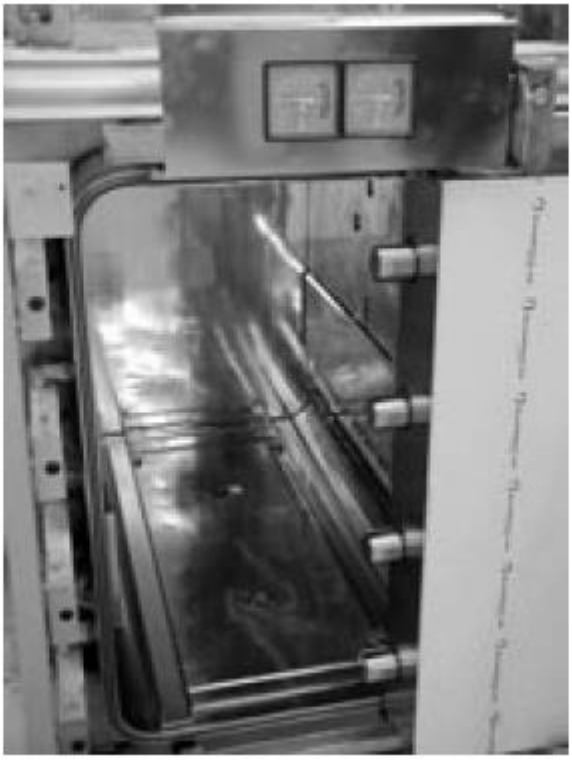
Chamber Door 腔体门

- Chamber door may be sliding type or swing type. Sliding doors arc the most common type in modern steam sterilizers. Below are features of each type door.
  腔体门应当是平移式或旋转式。现代蒸汽灭菌柜最常选用平移门。以下是每个类型门的特点。

Sliding Door 平移门

- Door slides on a track. Space should be maintained at the side, top or bottom of the sterilizer for the door to slide
  门沿着轨道平移。灭菌柜的侧面，顶部或底部应留够门平移的空间。
- • Door is typically automated using an air cylinder or door motor
  通常选用使用气缸或马达的自动门
- Door slides behind fascia and in front of wall seal. Provisions should be made to allow cleaning of surfaces between the fascia and the wall seal.
  门在仪表板后及密封墙前平移。应当有规定允许清洁仪表板及密封墙之间的表面。
- Door has a safety feature to prevent closure if obstruction is present when moving in either direction.
  门有一个安全装置，当向任一方向移动发生障碍时可以阻止门的关闭。
- An active (moved by steam of compressed air) door gasket is typically used with this design.
  这种设计通常用到一个活动（由压缩空气蒸汽推动）密封圈
- **Figure A-2** shows a typical sliding door with locking pins.
  图 A-2 展示一个典型的有锁销的平移门

Figure A-2 Example of Sliding Door 图 A-2 平移门实例



Swing Door 旋转门

- Door swings on a hinge. Adequate space should be allowed for the door to swing open.
  门沿一个轴旋转。应当有足够的空间允许门旋转打开。
- If a sterilizer is placed in a pit and a swing door is chosen, then a means of swinging and raising the door should be considered (e.g., hydraulic lilt)
  如果将灭菌柜放置在一个凹陷处并选用旋转门，应当考虑升高或旋转门的方法（如液压）。
- Door is typically manual although motorized doors are common on larger vessels. The door can use radial arms or mechanical closure to press the door against the gasket (static design).
  尽管自动门常见于大型容器，灭菌柜通常选用手动旋转门。门可以采用径向臂或机械关闭挤压密封圈实现关门（静态设计）
- Static gaskets may be changed less frequently than active gaskets and should be manually inspected.
  静态密封圈变形没活动密封圈那么频繁，需要手工检查。
- **Figure A-3** shows a typical swing door unit with locking handle.
  图 A-3 展示一个经典的拥有止动手柄的旋转门单元

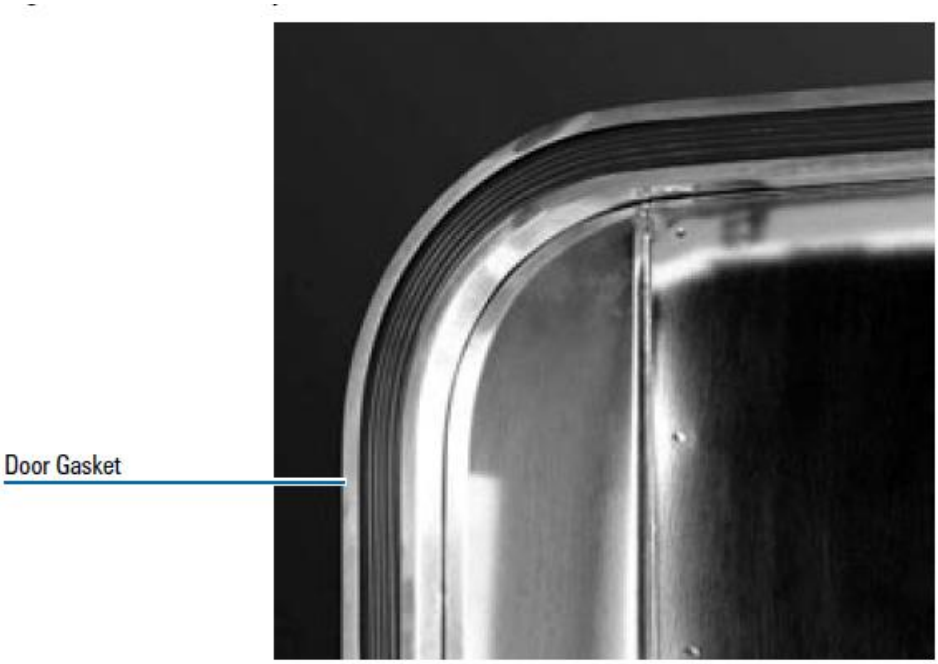
Figure A-3 Example of Swing Door 图 A-3 旋转门实例

Hardware and software interlocks should be designed to assure safe door functioning. This will ensure the door cannot move during normal or maintenance operations. A door should not be allowed to open if there is pressure in the chamber.
设计硬件及软件互锁以保证门的安全功能。这样将保证在正常操作或维护过程中门无法移动。如果腔体有压力，不允许开门。

Door Gaskets 门密封圈

- Door gasket typically extends against the chamber door by pressure or steam (dynamic seal).
  密封圈通常为了阻止腔体门在压力或蒸汽作用下发生扩展(动态密封)。
- Wear, loss of lubricant, or debris can impede movement of the gasket, which can cause an inadequate seal, or the gasket can become wedged between door and chamber when the door tries to move. Gaskets should be lubricated and/or changed as required to provide proper operation.
  密封圈破损，润滑油缺乏，或有碎片都会阻碍密封圈的移动，导致密封不充分，或者尝试移动门时，密封圈可能会被夹在门和腔体之间。根据操作需要润滑和/或更换密封圈。
- Active gaskets are easier to change and maintain and may be monitored for integrity using pressure devices.
  活动密封圈比较容易更换和维护，可以使用压力设备监控密封圈的完整性。
- **Figure A-4** depicts a typical active door gasket, which is a polymer suitable for contact with clean steam (i.e. silicone is a common material for door gaskets).
  图 A-4 为一个典型的活动门密封圈，由一种适合同洁净蒸汽接触的聚合物构成（硅树脂是密封圈的一种常见材料）。

Figure A-4 Example of Active Door Gasket 图 A-4 活动门密封圈实例



Clean steam and filtered air both have advantages and disadvantages when used with active door gaskets:
洁净蒸汽和无菌空气与活动门密封圈一起使用时有着各自的优缺点：

- The steam or air that drives the door gasket is not in contact with the product however a leak could occur into the chamber from this area. If either leaks into the chamber the sterilizer could have uneven temperature distribution.
  驱动门密封圈的蒸汽或空气不与产品接触；然而腔体的这个区域可能发生泄漏。如果泄漏到腔体会导致灭菌柜的热分布不均匀。
- In order to ensure a tight seal using steam, the steam pressure to the door gasket must be set higher than the chamber pressure creating localized superheat near the door gasket.
  使用蒸汽时为了确保密封，驱动密封圈的蒸汽压力必须设定的比导致密封圈附近局部过热的腔体压力要高。
- Depending on use, steam is more aggressive and can hasten the degradation of the gasket material and remove the lubricant, creating leaks and/or a jammed door. This is typically an issue on the sterile door where a seal is maintained for longer periods to maintain clean room pressure.
  依据使用，蒸汽更富有侵略性，可以加快密封圈材料的降解以及润滑油的流失，泄漏和/或卡门。无菌门通过保持较长时间的密封来维持洁净室的压力。

One alternative to minimize the impact of steam on the door gasket life and gain the benefits of steam in a leak situation is to use an air in stand-by system. With this system steam is used to activate the door gasket during the cycle and air is used when the unit is in stand-by to maintain the sterile side seal. This provides the benefits of using steam during the cycle by maintaining the sterility of the groove and preventing a potential air leak. It also minimizes steam contact to the gasket prolonging its useful life.
在泄露的情况下，减少蒸汽对门密封圈寿命影响的方式是使用备用系统的空气。通过这个系统，在循环中用蒸汽驱动门密封圈，空气用来保持无菌侧的密封。在循环中维持凹槽的无菌性,这样既能提供使用蒸汽的好处以及防止潜在的空气泄露。同时减少蒸汽同密封圈的接触，延长密封圈的使用寿命。

If filtered process air is used, concerns about gasket air leaking into the chamber may be alleviated in one or more of the following ways. 1) Air to gaskets should be operated at equal to or less than the chamber pressure during the sterilization cycle. 2) Monitoring the temperature/pressure relationship for saturated steam condition.
如果使用过滤的工艺空气，以下一个或多个方法可以减轻密封圈内空气泄漏到腔体的担忧：1）

灭菌循环中密封圈压力等于或小于腔体压力。2）监测饱和蒸汽的温度压力关系。

Piping Design Considerations 管路设计注意事项

- Materials of construction and internal surface finish should be specified to meet the needs of the process.
  材质以及内表面光洁度必须满足工艺需要。
- Piping should be sufficiently sized to provide adequate flow to meet process requirements and standards applicable to the process such as those found in literature. (16, 21)
  管道的尺寸应当能提供足够的流量，以满足工艺需求以及适用于文献（16,21）中工艺的标准。
- Valves should meet process requirements（e.g., air actuated stainless steel piston style for steam and sanitary ball, or sanitary diaphragm type for other connections)
  阀门应当满足工艺需求(例如，蒸汽选用活塞式不锈钢阀，其他连接选用卫生级球阀或隔膜阀)。
- • Steam piping should be insulated for safety and to minimize heat loss and condensate formation
  为了安全以及减少热损失及冷凝水形成，蒸汽管路应进行保温处理。
- Insulation should be non-shedding and chloride-free if stainless steel piping is used
  如果选用不锈钢管路，保温材料应当无氯无脱落。
- Pipe slopes should be adequate to promote drainage and condensate removal
  管路有一定的坡度以利于污水和冷凝水的排放。
- Deadlegs should be minimized
  盲管应当最少化
- If process requires WFI, deadleg piping should allow purging
- 如果过程需要使用注射用水，死角管路应当允许吹扫
- Utility cross contamination risk should be minimized
  公用系统的交叉污染风险最小化
- Welds should meet applicable materials and joining standards
  焊接应满足适用的材料以及焊接标准。
- If the incoming steam pressure is above the manufacturer's recommendations, additional valves (e.g., modulating steam, pressure reducing, pressure relief, shut-off) should he considered.
  如果进口蒸汽压力超出供应商的建议值，应当考虑使用其他阀门（如蒸汽调节阀，减压阀，泄压阀，截流阀)。
- An appropriate thermostatic steam trap combined with floating ball should be used to quickly remove large quantities of air and/or condensate from the chamber.
- 为了快速移除腔体中大量空气和/或冷凝水，应当选用一个合适的恒温式疏水阀以及浮球。

Sterile Air Filter 无菌空气过滤器

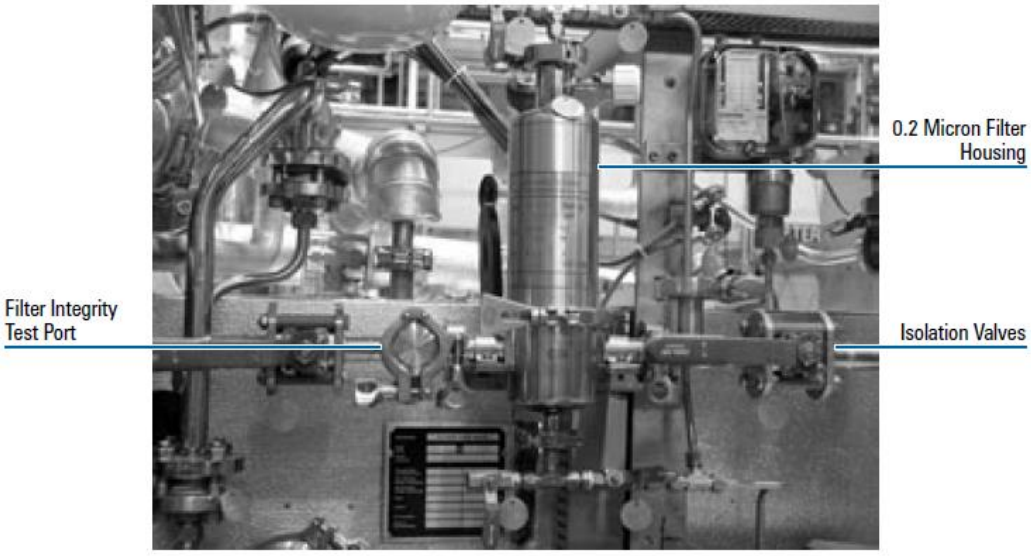
- Use of a sterilizing air filter for atmospheric vacuum break or overpressure cycles filtration may be determined through a risk assessment (2) for available tools to perform risk assessment.
  通过风险评估确定用于大气真空断路器的无菌空气过滤器或超压循环过滤的使用。
- Terminal sterilization processes typically do not require an air sterilizing filter
  终端灭菌工艺通常不需要无菌空气过滤器。
- Sterilizing air filters should be considered if unloading into an aseptic environment
  如果卸载到无菌环境应当考虑使用无菌空气过滤器。
- Filters should be integrity tested (method and frequency according to the manufacturers' recommendation)
  过滤器要进行完整性测试（方法及频率参考供应商建议)。
- Filter housings may be stainless steel or disposable
  过滤器外壳选用不锈钢或一次性的。
- Filters may be sterilized in place (in-situ) based on application
  过滤器可以在线灭菌。
- Redundant or serial filtration should be determined through a risk assessment

应当通过风险评估确定冗余过滤或多级过滤

- A separate filter should be used on the vacuum pump for the heat up phase of an effluent decontamination process
  真空泵废水处理过程的加热阶段应使用独立的过滤器。

Figure A-5 depicts stainless filter housing with ports and valves that allow in-situ sterilization and integrity testing.
图 A-5 描述装有阀门和端口的可以在线灭菌及完整性测试的过滤器外壳

Figure A-5 Example of Inlet Air Filter 图 A-5 进口空气过滤器实例



Vacuum Pump (if present)真空泵（如果存在）

- Vacuum pumps aid in efficient air removal mechanically
  真空泵可以有效的去除空气。
- Vacuum pumps are typically a liquid ring type
  通常使用液环式真空泵。
- A condenser may be used to decrease steam volume before the pump
  可能需要使用一个冷凝器来减少泵前的蒸汽体积。
- Closed water circuits with cooling reduces water consumption
  关闭冷却水回路来降低水消耗。
- Water temperature and elevation impacts vacuum depth and process efficiency
  水的温度和高度影响真空度及过程效率。

Figure A-6 shows a typical liquid ring vacuum pump
图 A-6 为一个典型的液环式真空泵

Figure A-6 Example of Typical Liquid Ring Vacuum Pump 图 A-6 典型液环式真空泵实例

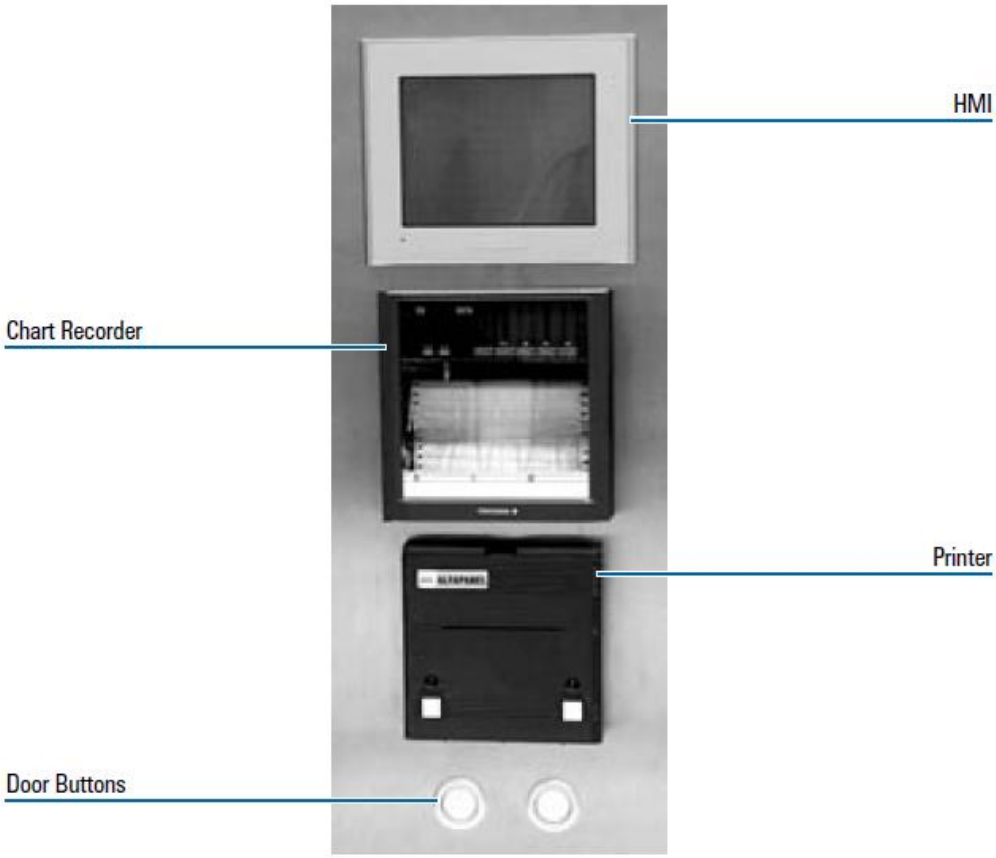
Instrumentation and Controls Considerations 仪器和控制事宜

A local control panel may include 本地控制面板包括:

- start/stop 开始/停止
- emergency stop 急停
- door control 门控制
- pressure indication (chamber, jacket) 压力显示（腔室，夹套）
- temperature indication (chamber, jacket) 温度显示（腔室，夹套）
- a local printer provides numerical data of the cycle
  一台本地打印机提供灭菌周期的数值数据
- a chart recorder that provides a graphical representation of the cycle
  一台图表记录器提供灭菌周期的图形显示
- audible/visible alarm indicator 声光报警显示器
- a local Human Machine Interface (HMI) that allows
  一台本地人机界面，允许:

  - selection and start of different type of cycles.
    选择并启动不同种类的灭菌周期
  - cycle programming 灭菌周期编程
  - maintenance functions 维护功能
  - Cycle status and alarms scanning 灭菌周期状态和报警扫描
  - a cycle report print initiation 打印灭菌周期报告

Figure A-7 Example of Sterilizer Control Panel with HMI, printer, chart recorder, and door open/close buttons
图 A-7 带 HMI、打印机、图表记录器，开/关门按钮的灭菌器的例子



- A programmable logic controller (PLC) is typically provided, to control and monitor valves, devices, and instruments. The PLC usually interfaces with:
  一般提供 PLC 用于控制监控阀门，装置和仪器。PLC 接口有：
  - Human Machine Interface
    人机界面
  - inputs and outputs via direct wire or field bus communication device 通过直线或现场总线通信设备输入和输出
  - integral printer to print cycle data
    内置打印机来打印灭菌周期数据

- The PLC may also communicate with an external control systems to PLC 也可以和外部控制系统通信，以：
  - confirm password verification. 确认密码查证
  - download cycle recipes. 下载灭菌周期配方
  - provide for data storage 提供数据存储

- Critical data should be controlled and documented (e.g., printout, electronic storage) according to applicable regulations. (22)
  根据适用法规要求关键数据要被控制并记录（例如打印，和电子储存）。
- This critical data may include
  关键数据可能包括：
  - date, time, load, lot number, batch information, program, temperature, pressure, cycle phases, duration, alarms
    日期，时间，装载，批号，批信息，程序，温度，压力，灭菌循环阶段，灭菌时间，报警

The unload side of a pass-through sterilizer should include:

对开门灭菌柜卸载侧需要包括：

- a cycle indicator 灭菌周期显示器
- an alarm indicator 报警器
- door control 门控制
- an emergency stop 急停
- chamber pressure indication 腔室压力显示

Functions of the sterilizer should include but not limited to:
灭菌柜的功能应包括但不局限于：

- automatic stop to a safe condition, on specific alarms
  遇到特定报警时自动停止以达到安全状态
- local display of alarms and acknowledgement
  本地显示报警和确认
- password control to different levels of access control such as:
  不同等级的密码控制，例如：

  - Administrator (e.g., parameter and password control, software programming)
    管理员（例如参数和密码控制，软件编程）
  - Supervisor (e.g., cycle programming)
    监管员（例如灭菌程序编程）
  - Technician (e.g., maintenance, calibration)
    技术人员（例如维护，校验）
  - Operator (e.g., cycle selection)
    操作者（例如选择灭菌周期）

- Temperature control system may include:
  温度控制系统可能包括：

  - Load probes 装载探头
  - Drain probes 排水探头
  - Pressure control system 压力控制系统

- Proportional steam control valve (optional) 成比例蒸汽控制阀（可选）

- Dual temperature probes 两种温度探头
  - Temperature Recording 温度记录探头
  - Temperature Control 温度控制探头

- Chamber pressure indicators on each door
  每个门上腔体压力显示器
- System valves and instruments should be accessible for maintenance and calibration
  系统阀门和仪器应易于维护和校验
- Utility (e.g., steam, air and water) pressure indicator and switches
  公用工程（例如蒸汽，空气和水）压力显示器和开关

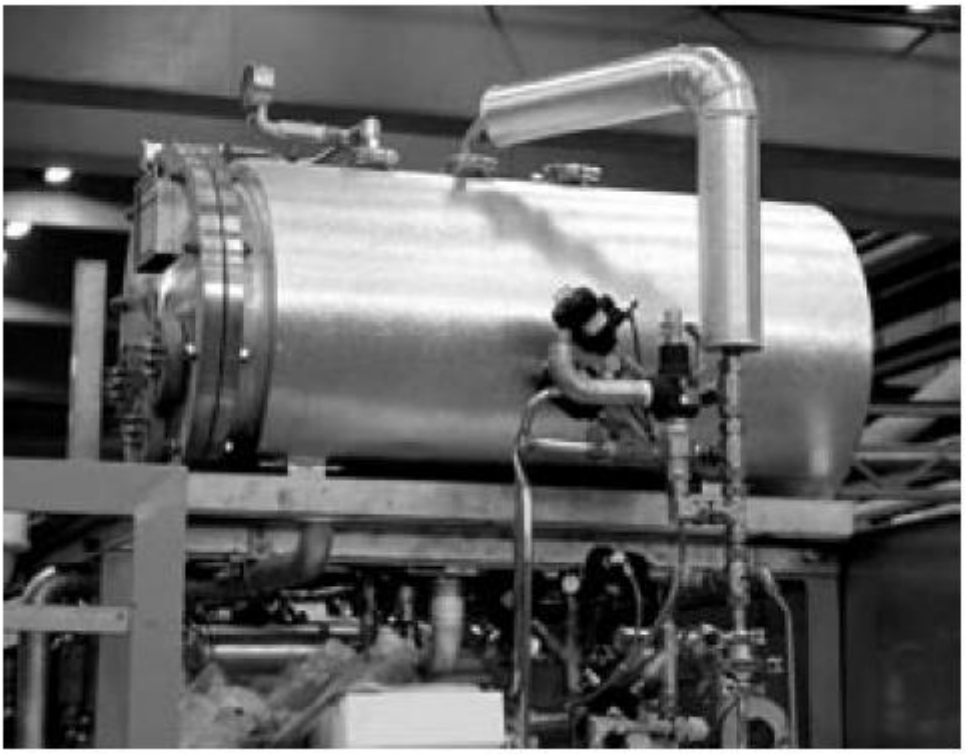
<u>Utilities Considerations公用设施事宜：</u>

- Steam 蒸汽：
  - Steam Quality (See Section 5.2.1.1) and type
    蒸汽质量（参照 2.1.1）和类型
  - Plant steam can be used for non-product contact sterilizers, heating jacket or integral steam generators.
    工业蒸汽可用于不接触产品的灭菌器，加热夹套或整体式蒸汽发生器
  - Process steam may be appropriate for moist heat sterilization of liquid loads

where the containers are filled and sealed prior to sterilization.
工艺蒸汽可用于液体的湿热灭菌，容器在灭菌之前装上液体并密封

- Steam condensate may be cooled or recycled hack to plant steam. 蒸汽冷凝物可以被冷却或回收到工业蒸汽
- Steam supply lines must be sized for peak demand
蒸汽供应线尺寸要满足高峰需求
- The steam supply to the sterilizer should have a local steam trap just upsteam of the sterilizer steam control valve(s) and pressure indicator.
供应给灭菌柜的蒸汽应在灭菌柜蒸汽控制阀门和压力表的上游有疏水阀
- Local steam generators may he used in lieu of a central steam system. **Figure A-8** shows a typical integral electric steam generator.
本地蒸汽发生器可以用于替代集中蒸汽系统。图 A-8 展示了一个典型的整合的电力蒸汽发生器。

Figure A-8 Example of Electric Steam Generator 图 A-8 电力蒸汽发生器的例子



- Electrical 电
  - Three phase power
三相电源
  - Control power from an uninterruptible power supply (UPS) or generator backed-up
使用不间断电源或备用发电机
  - Transformers for instrumentation (e.g., 24 VDC)
仪器变压器
  - Water tight enclosures on electrical control boxes
电控柜的防水密封

- Instrument Air 仪表用气
  - Sterilizers may use electrical actuated valve that may not require instrument air.
灭菌器可能使用电控阀门而不需要仪表用气
  - Instrument air should be separated from process air, before sterilizing grade filters to avoid contamination
仪表用气在进入灭菌级滤芯前应与工艺用气分开以避免污染

- Process air 工艺用气
  - process air when needed should be :
    如果需要工艺气体应该是：
    - dry 干的
    - oil free 无油
    - of sufficient pressure 足够压力

• Cooling Water 冷却水
  - Often city water, clean recuperated water, closed loop cooling systems is used for.
    常用生活用水，干净回收水，密闭循环冷却系统
    - liquid ring vacuum pump
      液环真空泵
    - jacket cooling
      夹套冷却
    - drain cooling
      排水冷却
    - cooling the load via heat exchanger
      通过换热器冷却负荷
  - When used for cooling of liquids in sealed container. (i.e., terminal sterilization), the primary quality attribute of the water used is the microbial content of the water.
    当用于密封容器中的液体冷却时（例如最终灭菌），使用的水的主要质量参数是微生物含量。

<u>Other Considerations 其它事宜：</u>

- Floor Drain 地漏
  - temperature resistant 耐热
  - Drain Air Break to prevent cross contamination
    空气隔断来防止交叉污染
  - Should be segregated from dean room
    与洁净室分开
- Exhaust hood/HEPA filter on the load and unload side
  装载和卸载侧的排气罩/高效空气过滤器
- Loading and unloading environment should meet requirements of the process as well as local applicable regulations
  装载和卸载的环境应满足工艺要求并符合当地法规
  - Sample ports for steam condensate and Steam Quality Testing should be accessible and safe to use
    蒸汽冷凝水和蒸汽质量测试的取样口要易接接且使用安全。
- Local steam generators may used in lieu of a central steam supply 本地蒸汽发生器可以替代集中蒸汽供应。

<u>Installation Considerations 安装事宜</u>

- Ingress and Rigging: 进入和索具
  - Ensure the sterilizer can be transported to and installed in the designated location. Installation considerations may include:
    保证灭菌柜能够转移并安装到既定位置。安装事宜包括主要以下内容：
    - Facility Wall and door modifications
      设施的墙和门的改造
    - Sterilizer modifications (split construction to transport to installation site)
      灭菌柜改造（拆分建造以运到安装现场）
    - seismic anchors
      地震锚

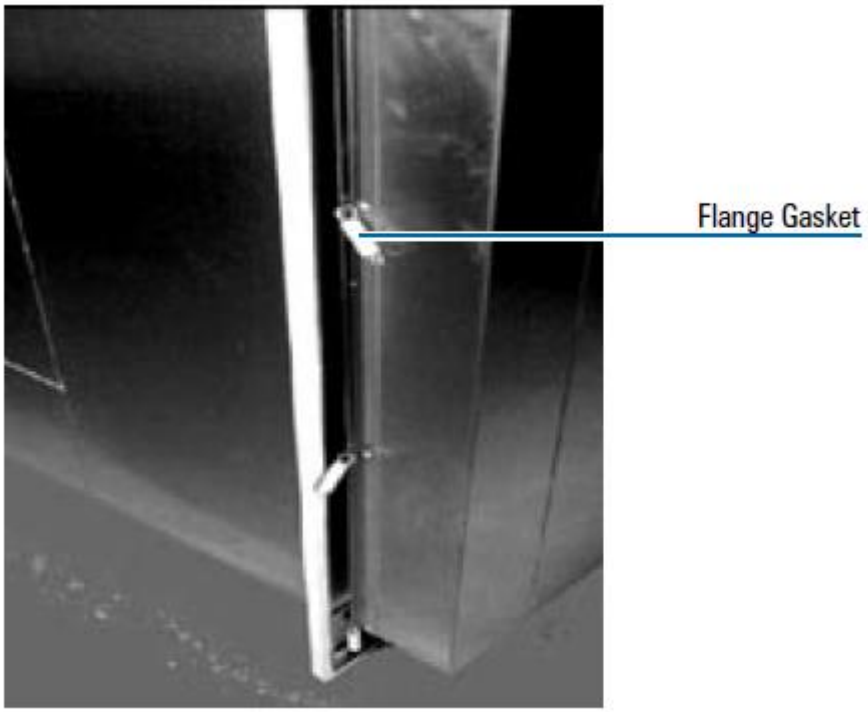
- Floor modification for pit mounting
  地面改造用于凹坑安装
- Floor reinforcement
  地面加固
- Floor drainage
  排水

- Facility wall thickness and form to accommodate different wall seals 设施的墙的厚度和形式适应不同的墙的密封
- Sterilizer fascia and trim panels
  灭菌柜仪表板和饰板

If separation of a classified space is required, wall seals should he provided (See 4.1.1). There are two main types of wall seals:
如果需要与分级的区域分开，要保证墙的密封性（见 4.1.1）。主要有两种密封：

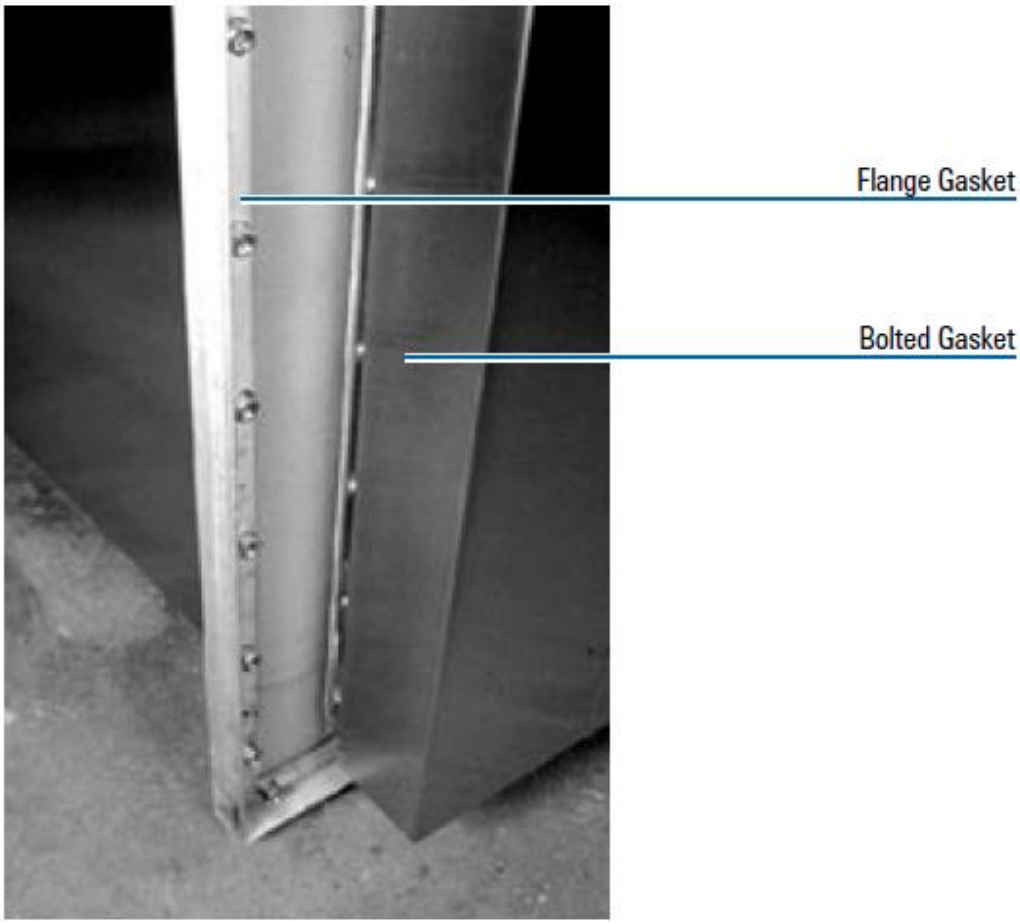
- Air differential pressure seal is designed to maintain clean room pressure.
  压差密封设计成用于维持洁净区压差

Figure A-9 Example of Air Differential Seal 压差密封示例



- Biological safety seal is designed to maintain 3 biologically classified area. The seal maintains room pressure and ensures no microorganisms will pass through the barrier.
  生物安全密封用于维持三个生物分级区。密封要维持洁净室压差并保证无微生物穿过屏障。

Figure A-10 Example of Biological Safety Seal生物安全密封示例


Flange Gasket
Bolted Gasket

Appendix B Sterilizer Verification Activities附件B 灭菌器查证活动

Task/Action/Activity(15)	FAT	SW	SAT	IV/IQ	OV/OQ
Requirements, Specifications and Test Plans ***要求，标准和测试方案***					
Vendor Quality Plan 制造商质量方案	X				
User Requirements Specifications 用户需求规范	X			X	X
Functional Requirements Specifications 功能需求规范	X				X
Detail Design Specifications 详细设计规范	X			X	
Equipment Qualification Plan 设备确认方案				X	X
Factory Acceptance Test Plan 工厂接收测试方案	X				
Site Acceptance Test Plan 现场接收测试方案					
Supplier Documentation to Support Verification / Qualification Activities ***供应商文件支持查证/确认活动***					
Operation and Maintenance manuals 操作维护手册	X		X	X	
Parts/component list with catalog cut sheets 带目录的设备部件清单	X			X	
Equipment arrangement diagrams (skid) 设备布置图	X			X	
Equipment arrangement diagrams (site installation) 设备布置图（现场安装）	X		X	X	
Diagrams for accessories (e.g. loading carts) 附件图（如装载小车）	X			X	
Process and Instrumentation Diagrams 工艺和仪器仪表图	X		X	X	
System performance calculations 系统性能计算	X			X	
Pressure vessel certification report (e.g. ASME U1 form) 压力容器合格证	X			X	
Material certificates for product contact parts/components 直接接触产品的材质证明	X			X	
Weld logs and inspection records for sanitary piping 洁净管道焊接日志和检查记录	X			X	
Slope checks and inspection reports 坡度核对和检查报告	X			X	
Cleaning and passivation records for product contact materials 直接接触产品材料的清洁和钝化记录	X				
Pressure relief device certification 泄压装置证书	X		X	X	
Activities that Support Site Installation Requirements ***支持现场安装要求的活动***					
Inspection *of* system installation details (fit and finish)	X		X	X	

系统安装细节的检查					
Verify that all spare parts are available, have part numbers, assembly numbers (where necessary), and are labeled 确认所有备用件可用，有部件编号安装编号（如需要），并有标签	X			X	
Verify that all safety guarding is in place and functional 确认安全设施在场并正常	X		X		
Verify operator accessibility and ergonomics 确认操作人员可访问性和人体工程学	X		X		
Check chamber and al piping for drainability/slope verification 核对腔室和管路的排水和坡度	X		X	X	
Verify that the P&ID reflects the as-built condition of the equipment 确认P&ID反映了设备竣工情况			X	X	
Verify that all components are tagged consistent with the P&ID. schematics and instrument list 确认所有部件与P&ID，图表和设备清单的标识一致	X		X	X	
Verify that the component part numbers match the information on the instrument list 确认组件编号与设备清单信息一致	X		X	X	
Verify the machine nameplate is installed, and that the information on it is correct 确认设备铭牌安装并且信息正确			X	X	
Verify that all motors are correctly labeled with nameplate and data 确认所有发动机有正确铭牌和数据			X	X	
Verify that all utility connections are made, sized correctly, and labeled with type and limit data 确认公用设施连接，尺寸正确，标志了类型和限制数据			X	X	
Pumps and motors. Verify component label information (voltage, amps, phase, frequency, and horsepower) and control information (fixed or variable speed, direction of rotation and RPM). Capacities must conform to specifications. 泵和发动机。确认部件标签信息（电压，安培，相，频率和马力）和控制信息（规定的或可变的速度旋转方向和RPM）。容量要与标准一致。	X		X	X	
Verify that the equipment has been cleaned in preparation for shipment to the customer 确认装货运输给客户前已经清洁。	X				
Verify that the surface finish of the equipment matches the customer requirements 确认设备的表面抛光符合客户需求	X			X	
Check for mechanical safety according to the mechanical safety checklist line Emergency Stop Verification 确认机械安全，根据安全检查列表和急停确认	X		X		
Check for electrical safety according to the electrical safety checklist	X		X		

根据电路安全检查表检查电路安全					
Verify that all process critical measuring instruments have been calibrated to an NIST reference. This applies to individual components as well as control loops (e.g. sensor and signal input to a transmitter; transmitter output to a controlling device) 确认所有关键计量仪表已经按照NIST标准进行校验。这个适用于单个组件和控制回路（例如探头和信号输入、输出装置）				X	
Activities that Support Functional Requirements ***支持功能要求的行为***					
Test decibel level of operating equipment with equipment 测试仪器操作时噪音	X		X		
Test the ability of the vacuum pump to attain the specified full vacuum levels in the specified time. 测试在规定时间真空泵能达到的最高真空	X		X		X
Verify the operational range of any programmable set-point 确认可编程的设计点的操作范围			X		X
Open all utility services to the autoclave and check for leaks (in both static and dynamic conditions). 打开连接灭菌柜的所有公用设施核查是否泄漏（动态和静态）			X	X	
List all lubricants used for each piece of direct contact equipment. Verification that these lubricants are approved for use must be documented during the execution phase. 列出直接接触产品的部件所用的润滑油。确认这些润滑油被批准使用并且在使用阶段有文件资料。	X			X	
All filters are properly installed and integrity testing the documented. 滤芯安装并有完整性测试				X	
Site Utilities Verification现场公用设施确认: • Electrical电力 • Peak Steam Flow高峰蒸汽流量 • Steam Quality during Peak Times高峰时期蒸汽质量 • Pipe size管道尺寸 • Water Temperature for vacuum pump真空泵水温			X	X	
Verification of jacket temperature and chamber temperature with calibrated surface thermometer during sterilization simulation is recommended 推荐在模拟灭菌时用校验过的表面温度计确认腔室和夹套温度			X		X
Empty Chamber Thermal Mapping 空载温度分布					X
Cycle Tests: (if applicable) 灭菌周期测试（如果可用） • Porous/hard Goods Cycle硬质物体灭菌周期	X		X		X

• Liquid Cycle液体灭菌周期 • Filter Sterilization Cycle滤芯灭菌周期 • Effluent Decontamination Cycle污水净化 • Air Detector空气检测器 • Bowie-Dick Air Removal Cycle去除空气循环 • Pressure Leak Cycle压力泄漏测试 • Vacuum Leak Cycle真空泄漏测试					
Tests that Support Software Qualification and Part 11 Compliance ***支持软件确认和PART 11符合性的测试***					
Software Quality Control Plan 软件质量控制方案	X				
Control system architecture diagrams控制系统结构图	X			X	
Wiring, cabling and communications Diagrams 线路、线缆、通信图	X		X	X	
Control loop diagrams 控制回路图	X		X	X	
User manuals to support PLC/HMI systems 支持PLC/HMI的用户手册					
Confirmation of software versions for PLC PLC软件版本确认	X		X	X	
System graphics 系统图表	X		X	X	
Record part numbers, versions and serial numbers of all computerized hardware 所有计算机化硬件的编号、版本和序列号	X			X	
Record version numbers of all computerized software Software Version Verification 记录所有计算机化软件版本号	X	X		X	
Test parameter entry for format, upper and lower limits 测试用于格式和上下限的参数输入	X	X			X
Test HMI screens for function Operator Interface Verification (Screen Navigation) Control Panel and System Functionality Verification 测试HMI屏幕来确认人员操作界面、控制面板和系统功能	X	X			X
Test HMI screen navigation 测试HMI画面导航	X	X			X
Test HMI screens for SCADA function and display 测试HMI屏幕的SCADA功能和显示	X	X			X
Test for alarm function and terminology Alarms and Warning Messages Verification 测试报警功能和术语报警和警告信息	X	X			X
Test for control and interlock functions Safely Interlock Verification (Door Open/Close. Steam Valve, Door Seal back-up. etc) 测试控制和互锁功能（门开/关。蒸汽阀门，门密封等）	X	X			X
Data Integrity Test (if unit permanently stores data) 数据完整性测试（如果设备能够持久储存数据）	X	X			X
Audit Trail Test (if unit creates a permanent	X	X			X

audit trail record) 审计追踪测试（如果设备能够创造永久的审计追踪记录）					
PID controllers parameters configuration printouts PID控制器的参数配置打印输出	X	X		X	X
Communication Loss 通讯缺失	X	X			X
Test log-in function and security levels Security/Access Level (Password Tests) 测试登录功能和安全等级（密码测试）	X	X			X
Test fail-safe function of critical sensors-all safety devices and functions should be verified in real tests 测试关键探头的失败安全功能，所有安全设备和功能应在真实测试中进行确认。	X		X		
Test input and output loops for wiring Input/Output Verification 确认接线输入/输出功能	X			X	
Test back-up and restore procedure for al programmed devices System Back-Up Disaster and Recovery Verification 测试所有可程式化的设备系统的备份和恢复程序。备份、灾难恢复确认		X	X		X
Test controls for power loss and recovery Loss of Power (Power Break) Controller On/Off Recovery Test 测试电源缺失和恢复（电源中断）。控制器开关恢复测试。	X	X	X		X
Cycle alarms/aborts testing -Determine how the autoclave control system safety aborts the cycle during each phase of the sterilization cycle. For a double door chamber, confirm operation of door interlocks after an aborted cycle, only the load door should open. 灭菌周期报警/中止测试-确定在灭菌周期每个阶段灭菌柜控制系统如何中止程序。对于双开门腔室，在中止灭菌后，确认门的互锁操作，只能打开装载侧的门。	X	X	X		X
Verify password and security levels for different levels *of* program access (operators, supervisors, service personnel). 确认不同登录级别的密码和安全级别(操作人员，监管人员，维修人员）。	X	X			X

Appendix C Documentation 附件C 文件
Figure C-1Documentation 图 C-1 文件