On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

FDA notes that in particular, the QMSR does not utilize certain terms, such as "Design History File (DHF)," "Device Master Record (DMR)," "Design Controls," "Design Validation," and "Process Validation." The elements that comprise these terms are described in ISO 13485:2016, including Clause 4.2 and Clause 7 and its subclauses. The definition of "establish" from 820.3(k) is not retained in the QMSR, and ISO 13485:2016, Clause 0.2 clarifies that "document" encompasses the activities of establishing, implementing, and maintaining.

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

Appendix E of this guidance was updated on June 9, 2017.

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (INCB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2011-D-0293. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1748 to identify the guidance you are requesting.

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable[1] medical devices. This guidance document also provides recommendations for the content and review of premarket notification submissions [510(k)], premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, *de novo* requests and investigational device exemption (IDE) applications, concerning the labeling instructions for reprocessing reusable medical devices. Please note that exemption from 510(k) does not mean a device is exempt from compliance with labeling or Quality System (QS) requirements. Manufacturers of 510(k)-exempt devices should follow the recommendations of this guidance pertaining to such requirements, unless, for example, the device is specifically exempted by regulation from specific QS requirements.

Manufacturers of reusable medical devices are responsible for having labeling that bears adequate directions for use, including instructions on preparing a device for use. While FDA recognizes the critical role and responsibility of the device user community to follow the validated reprocessing instructions in the device labeling, the focus of this document is to provide guidance to medical device manufacturers in the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

[1] While the scope of this guidance also includes single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use, the majority of the devices addressed by this guidance are reusable devices. Accordingly, this document uses the term "reusable devices" for editorial convenience.

be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Pursuant to section 502(f) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 USC 352(f)), a device must have labeling that bears adequate directions for use. Adequate directions for non-prescription use include instructions on preparing a device for use. 21 CFR 801.5(g). Prescription devices are exempt from the adequate directions for use requirement as long as certain conditions are met, including that the labeling bear "information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended..." 21 CFR 801.109(c). Because instructions on how to adequately reprocess a reusable device are critical to ensuring that a reusable device is appropriately prepared for its next lay use and that licensed practitioners can use the device safely, we interpret adequate reprocessing instructions to be part of providing adequate directions for use under 21 CFR 801.5 and a condition for exemption from adequate directions for use under 21 CFR 801.109. For editorial convenience, we use the phrase "adequate directions for use" throughout this document to refer to the requirements for both prescription and non-prescription devices.

Labeling must comply with 21 CFR Part 801 and any applicable device-specific requirements given in Part 801; labeling for in vitro diagnostic (IVD) devices must comply with 21 CFR 809.10. General labeling requirements for medical devices are also discussed in the guidance entitled "Labeling Regulatory Requirements for Medical Devices" available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf.

In recent years, there has been an evolution towards more complex, reusable medical device designs that are more difficult to reprocess. In addition, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. This guidance reflects the scientific advances in these areas. Appendix A provides additional information on the definitions of common terms used in this guidance document.
As additional scientific information becomes available in the field of device reprocessing, further revisions to this guidance may be provided.

III. Scope

The scope of this guidance is limited to devices that fall into any of the four reprocessing situations below.

1. Reusable medical devices initially supplied as sterile to the user and requiring the user to reprocess (i.e., clean and disinfect or sterilize) the device after initial use prior to the subsequent patient use.

2. Reusable medical devices initially supplied as non-sterile to the user and requiring the user to process (i.e., clean, clean and disinfect, or clean and sterilize) the device for initial use, as well as to reprocess the device after each use.
3. Reusable medical devices intended to be reused only by a single patient and intended to be reprocessed between each use.
4. Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use.

Please note that the following sections of this guidance are not applicable to single-use devices initially supplied as non-sterile:

- Section VI., Criteria 5.b – Point-of-use Processing
- Section VI., Criteria 5.l – Reuse Life

Exclusions

The five situations listed below are not within the scope of this guidance, because they are not relevant to reusable medical devices or because they focus on the reprocessing of single-use devices.

1. Processes that are used in industrial settings for the manufacture of single-use medical devices that are intended to be sold sterile (For more information on this topic, see FDA's draft guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109884.htm). FDA's draft guidance represents FDA's proposed approach on this topic.)
2. Processes intended to be used by reprocessors of single-use devices (See "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm).)
3. Any process used for a sterile device provided without any reprocessing instructions from the original equipment manufacturer to permit use after the package has been opened. (Single-use sterile devices that do not have reprocessing instructions should not be reprocessed and should not be used if the sterile packaging has been compromised. The device should be appropriately discarded or returned to the manufacturer.)
4. Processes regarding the removal or inactivation of transmissible spongiform encephalopathy (TSE) agents (i.e., prions) from contaminated medical devices. Please note that as of the date of this guidance, FDA has not approved or cleared medical devices, including sterilizers, for the intended use of reducing the infectivity of TSE agents.
5. Reusable medical devices that include a component that is not initially supplied as sterile and between uses cannot be adequately (1) cleaned and disinfected or (2) cleaned and sterilized (e.g., the hand-held wireless receiver of a multi-patient use continuous glucose monitor (CGM)).

This document is not intended to provide device-specific recommendations on design, testing, or reprocessing validation. You should also follow the recommendations in device-specific guidance, when available.

IV. General Considerations for Reusable Medical Devices

A. Design of Reusable Medical Devices

Manufacturers of reusable devices should consider device designs that facilitate easy and effective cleaning, as well as any necessary disinfection or sterilization by the users. Some complex device designs present particular challenges to cleaning and cleaning validation (e.g., shaft-within-lumen configurations, elevator channels, fine channels, seals and mated articulating surfaces). From the earliest stages of device design and engineering, manufacturers should consider alternative designs to facilitate effective reprocessing (e.g., replace features that are challenging to reprocess with single-use parts; include flush ports; specify and/or provide dedicated cleaning accessories).

B. Ensuring the Safety of Reusable Medical Devices

Manufacturers of reusable devices and accessories, as well as their users, have important roles to play in ensuring the safe and effective reprocessing of medical devices. Manufacturers of reusable devices should provide adequate labeling that includes instructions for reprocessing devices and device accessories safely and preparing them for reuse. In the labeling, manufacturers should identify for users the materials and equipment, including reprocessing supplies with part numbers, if applicable, that will be needed to reprocess the devices. The labeling should also clearly specify the appropriate material and equipment parameters to adequately reprocess the devices, as well as materials and equipment that are readily available to users. FDA encourages users to ensure that they have the facilities, equipment, and easy access to manufacturer-specified cleaning, sterilization/disinfection agents to implement the instructions, and that the instructions are followed.

Manufacturers should maintain in the Device Master Record and/or Design History File, as appropriate, documentation of tests that were performed to demonstrate that the reprocessing instructions have been validated, are complete and understandable, and can reasonably be implemented by the user. The Device Master Record must comply with the requirements of 21 CFR 820.181; the Design History File must comply with requirements of 21 CFR 820.30(j).

V. General Considerations for Reprocessing Instructions in Device Labeling

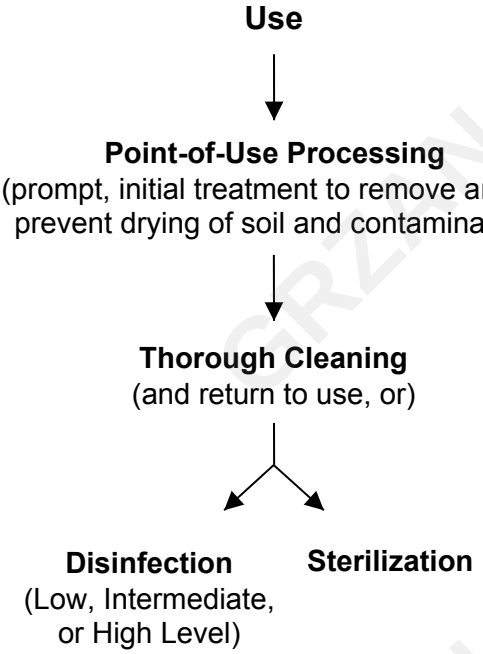
A. Overview of Reprocessing

Reprocessing is defined as validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization. Reprocessing of reusable devices encompasses appropriate steps that begin in close proximity to the point of use of the device and, in general, involves the following three steps in sequence:

1. Point-of-Use Processing: Reprocessing begins with processing at the point of use (i.e., close proximity to the point of use of the device), to facilitate subsequent cleaning steps. We define this as point-of-use processing, which includes prompt, initial cleaning steps and/or measures to prevent drying of soil and contaminants in and on the device.
2. Thorough Cleaning: The device should be thoroughly cleaned after the point-of-use processing. Generally, thorough cleaning is done in a dedicated cleaning area. Devices that will likely not become contaminated with pathogens during use (e.g., room vital signs monitor) may not require disinfection, and therefore may be suitable for use after cleaning only.
3. Disinfection or Sterilization: Depending on the intended use of the device, the device should be disinfected or sterilized, and routed back into use.

A simple overview of reprocessing is presented in Figure 1. A more detailed overview of each reprocessing step is provided in Appendix B.

FIGURE 1. PROCESS OVERVIEW



It is important to note that cleaning, disinfection, and sterilization are distinctly different processes.

Cleaning is the physical removal of soil and contaminants; the methods and agents used for cleaning should be designed to remove such soil and contamination effectively. Effective cleaning should:

- minimize the soil transfer from one patient to another or between uses in a single patient;
- prevent accumulation of residual soil throughout the product's use life; and
- allow for successful, subsequent disinfection/sterilization steps.

In comparison, disinfection and sterilization processes are intended to kill microorganisms; the methods and agents employed for disinfection and sterilization should be designed to achieve appropriate microbicidal effects. Please see Appendix A for the definitions of disinfection and sterilization, and Section VI. Criterion 3 for specific information on appropriate microbicidal processes.

Accordingly, cleaning steps should be validated separately and independently from disinfection or sterilization steps.

An overview of reusable medical device processing is found in Appendix B of this document.

B. Resources for Developing Reprocessing Instructions

The following are resources to consider when developing reprocessing instructions for reusable medical devices.

1. You should follow the labeling recommendations in device-specific guidance, when available. Device guidance may be found by searching FDA's Guidance Document Database available at http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
2. The following Technical Information Reports (TIRs) developed by the Association for the Advancement of Medical Instrumentation (AAMI) provide technical information for manufacturers and users and may be helpful when developing labeling instructions for reusable medical device:
    a. AAMI TIR12, Designing, testing and labeling reusable medical devices for reprocessing in health care settings: A guide for medical device manufacturers.
    2. AAMI TIR30, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
3. We recommend you refer to the current FDA-recognized version of AAMI/ANSI ST81, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.
4. We recommend you use current FDA-recognized test methods available from standards developing organizations (SDO). A searchable database of FDA-

recognized consensus standards is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

5. You should also consult any relevant clinical practice guidelines and recommendations for infection control published by professional societies and associations, standards developing organizations, and government agencies (for example, the "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008" from the Centers for Disease Control (CDC), available at http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf). Clinical practice guidelines, however, do not always consider or correctly address all FDA regulatory requirements. As an example, some professional organizations may recommend using disinfectants in ways that may not necessarily comply with FDA regulations. Compliance with FDA regulations is required.

C. Human Factors in Developing Reprocessing Instructions

You should consider the following recommendations regarding human factors in developing your reprocessing instructions:

1. We recommend that you develop consistent reprocessing instructions across each of your product lines. Labeling that provides consistent methods and terminology, and utilizes the same document layout for all devices of a type, may help improve the user's comprehension and adherence to the instructions.
2. You should address any known post-market human factors issues known to exist for reprocessing your device or similar devices. Examples of human factors issues include, but are not limited to, actions requiring substantial dexterity or strength, good visual acuity, or familiarity with uncommon practices. Information on post-market issues may be found by reviewing your internal user complaint files, the published literature, the FDA's Medical Device Reporting (MDR) system, and FDA Safety Alerts and Public Health Notifications. We recommend that you refer to the following sources for additional information on human factors:
   a. FDA's guidance "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094461.pdf).
   b. FDA's guidance, "Human Factors Principles For Medical Device Labeling" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095300.pdf).
   c. The current FDA-recognized version of IEC Standard 62366, "Medical Devices – Application of usability engineering to medical devices."
   d. The current FDA-recognized version of ANSI/AAMI HE75, "Human Factors Engineering – Design of Medical Devices."
3. For devices that are subject to design controls under 21 CFR 820.30, you should validate your reprocessing instructions to ensure that users will be able to successfully understand and follow them. FDA recommends considering the following:

a. Your validation study participants should be representative of the professional staff that would perform these actual reprocessing procedures. If users would be wearing personal protective equipment (PPE), such as goggles, full-length face shields, heavy-duty utility gloves or liquid-resistant covering with sleeves, then the validation study participants should wear them as well.
b. Participants may use the instructions to perform an actual or simulated reprocessing procedure or verbally describe what they would do as they read the instructions.
c. If attributes of the use environment might affect use of the instructions and reprocessing of the device, they should be represented in the study.
d. Observing and documenting participant behavior during testing will allow you to assess the participants' adherence to the instructions and to identify and understand the nature of any errors or problems that occur.
e. After using the instructions independently, you should ask the participants if they had difficulty in performing the reprocessing, and allow them to describe their experience. You should ask specifically about any errors, problems or hesitations that were observed. The participants should provide subjective feedback regarding any wording in the instructions that they found confusing, misleading, or incomplete. The participants' responses and comments should be documented. If you make significant changes to the instructions after testing them, you should validate the success of the changes at eliminating or reducing the problems previously identified.

VI. FDA's Six Criteria for Reprocessing Instructions

Your labeling should address the six criteria below for clear reprocessing instructions, which will ensure users understand and correctly follow the reprocessing instructions.

Criterion 1. Labeling should reflect the intended use of the device.

Your labeling should include instructions for a reprocessing method that reflects the physical design of the device, its intended use, and the soiling and contamination to which the device will be subject during clinical use. Appropriate reprocessing instructions depend on whether the device will:

- contact only intact skin;
- contact intact mucosal surface;
- contact normally sterile tissues, blood, or bodily fluids such as cerebrospinal fluid, peritoneal fluid, aqueous humor, etc.;
- be subject to splatter or splash of body fluids or blood because of proximity to the patient, although it is not in direct contact with the patient;
- be subject to contamination during use from contact with soiled hands of patient caregivers or patients; (note that both unwashed and gloved hands can carry organic soil as well as microorganisms to the surfaces they touch);
- be subject to contamination by unexpected or accidental events (e.g., patient bleeding, incontinence, vomiting, wounds leaking through dressings);

- be subject to reprocessing with disinfectants or other chemicals that might leave harmful residues, or adversely affect device materials or performance, if inadequately rinsed; or
- present specific or unique risks to the patient or user.

Criterion 2. Reprocessing instructions for reusable devices should advise users to thoroughly clean the device.

Cleaning is the first step in reprocessing and should be described in the labeling as part of the overall reprocessing instructions. Adequate sterilization or disinfection depends on the thoroughness of cleaning. Instructions to the user should clearly communicate how to achieve thorough cleaning. Details of the cleaning procedure will vary depending on the complexity of the device.

Devices with features that may result in soil retention or have features that make them difficult to clean, may need to be disassembled in order to be completely cleaned, unless the manufacturer can validate effective cleaning without disassembly (i.e., data should be obtained from testing soiled devices cleaned with and without disassembly for comparison). For such devices, instructions/diagrams for adequate disassembly should be included in the cleaning instructions (see Criterion 5.C. for details).

Directions for use of the device may include the use of protective covers and sheaths to try to reduce the extent of cleaning needed before the device can be reused (e.g., bronchoscopes). If you recommend the use of protective covers, your labeling should include the recommendation to use only legally marketed protective covers. However, the cleaning instructions for your device should assume the worst-case where the device is used uncovered, because of the potential for loss of cover integrity during use. Unnoticed loss of cover integrity may result in degrees of soiling that are difficult to see but will present a risk to the health of the next patient unless the device is properly reprocessed.

Flushable devices (e.g., endoscopes, laparoscopic instruments and other devices with flush ports) are prone to debris accumulation and should have instructions/diagrams to ensure proper flushing during cleaning procedures. Proper flushing of the device is important to remove retained soil from inside of the devices during these procedures. Flushing instructions/diagrams should include information on how to properly flush the device, the specific accessories to be used including proper size connectors for the flush ports, and the type and volume of flushing agent to be used to ensure thorough and effective cleaning of the device.

Criterion 3. Reprocessing instructions should indicate the appropriate microbicidal process for the device.

Your instructions should be consistent with current infection control principles. The microbicidal process recommended should be sterilization or disinfection (high, intermediate, or low level), depending on the intended use of the device.

Note that whichever reprocessing method(s) is/are recommended, the compatibility of the device with the method(s) and the ability of the method(s) to successfully reprocess the device features should be validated and then stated in the instructions for use. The validation should demonstrate that soil and contaminants have been effectively removed and that the device is free of viable microorganisms.

FDA uses the Spaulding Classification[2] scheme described below for critical, semi-critical and non-critical devices to describe the potential risk of infection caused by the device and the appropriate microbicidal processes. Because the Spaulding classification does not address all clinical device uses and reprocessing needs in detail, we have modified it accordingly as described below.

A. Critical Devices

Critical devices are devices that are introduced directly into the bloodstream or which contact a normally sterile tissue or body-space during use. There is a likelihood of microbial transmission and risk of infection (subclinical or clinical) if the device is not sterile. Users should be instructed to disassemble (if applicable), thoroughly clean, and sterilize critical devices after each use.

Examples of critical devices include surgical instruments, irrigation systems for sterile instruments in sterile tissues, endoscopes used in sterile body cavities (such as laparoscopes, arthroscopes, intravascular endoscopes) and all endoscope biopsy accessories.

B. Semi-Critical Devices

Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body. Intact mucosal surfaces are relatively resistant to small numbers of spores. However, these devices should be reprocessed to be free from all microorganisms. Users should be instructed to thoroughly clean these devices and then reprocess them by sterilization. If the device design does not permit sterilization (e.g., device materials cannot withstand sterilization), then high level disinfection should be used.

Examples of semi-critical devices include duodenoscopes, endotracheal tubes, bronchoscopes, laryngoscope blades and other respiratory equipment, esophageal manometry probes, diaphragm fitting rings, and gastrointestinal endoscopes.

Heat-stable devices (e.g., rigid endoscopes) should be processed by steam sterilization. For heat-labile devices, available "low temperature" reprocessing

[2] Spaulding, EH The role of chemical disinfection in the prevention of nosocomial infections. In: Brachman PS, Eickoff TC, eds Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago: American Hospital Association, 1971:254-274

technologies include hydrogen peroxide (H_2O_2) sterilization, ozone (O_3) sterilization, ethylene oxide (EO) sterilization[3] (including device aeration) and liquid chemical sterilant/high level disinfectant chemical systems used to provide either liquid chemical sterilization or high level disinfection. High-level disinfection methods used in health care settings include liquid chemical sterilants used at high level disinfection conditions and hot water pasteurization (often used for respiratory and anesthesia equipment reprocessing).

C. Non-Critical Devices

Non-critical devices are instruments and other devices whose surfaces contact only intact skin and do not penetrate it. Non-critical devices also include devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care (e.g., blood, body fluids); such devices may not be visibly contaminated. FDA recommends thorough cleaning, then intermediate or low level disinfection for non-critical devices depending on the nature and extent of contamination.

Examples of devices that contact only intact skin include blood pressure cuffs, stethoscopes, and skin electrodes. Examples of devices that have no direct patient contact, yet may become contaminated during patient care, include infusion pumps and ventilators.

Note that some disinfectants are fairly effective cleaning agents while others are not. Always consider the worst-case microbes to which the device may be exposed during clinical use, the likelihood of significant organic soiling of the device during use, and the ability of the device material to repeatedly withstand disinfectant contact when selecting a disinfectant to validate and then recommend for use with your device. Also consider the products that are frequently used in health care settings when selecting a disinfectant to study and validate. If a product or class of products can damage the materials in your device, your device label should include a warning not to use that product or class of products to reprocess your device.

Items contaminated with blood or body fluids, which may contain blood-borne pathogens, should be cleaned and then receive intermediate level disinfection with a product having an EPA-registered claim for activity against hepatitis B.[4] Blood glucose meters used in healthcare settings are an example of a blood-contaminated device which has been a source of hepatitis B transmission during patient-to-patient use when not properly cleaned and disinfected after each patient and not used in strict compliance with glove use and hand washing after glove removal.

Be aware that in some clinical situations (e.g., patients with Norovirus or *Clostridium difficile* infections, drug-resistant organisms, etc.), isolation precautions

[3] EO sterilization may not be ideal for certain device types, such as duodenoscopes.
[4] Center for Disease Control and Prevention (CDC), "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

recommended for use by CDC may include the use of specific disinfectants and should be followed. You should instruct the user to follow the specific EPA label disinfectant contact times when using the disinfectant as well as the instructions specified in the medical device labeling.

Devices that will likely not become contaminated with pathogens during use (e.g., room vital signs monitor) may not require disinfection, and therefore may be suitable for use after cleaning only.

Criterion 4. Reprocessing instructions should be technically feasible and include only devices and accessories that are legally marketed.

Reprocessing instructions should be technically feasible in the intended location (e.g., health care setting or home use). The equipment and accessories needed to implement the instructions should be clearly defined (including detailed descriptions and part numbers, if applicable) and readily available for the users to obtain.

The type of sterilizer, and the manufacturer-validated sterilization cycle parameters and accessories should be available to the users. For example, radiation sterilization is generally only used in manufacturing facilities. Steam sterilization is the most common method of sterilization used in health care settings. EO, H_2O_2, O_3 and liquid chemical sterilization processes are also available in some health care settings. Dry heat and chemical vapor sterilization are less common.

FDA recommends that the instructions specify sterilization methods and parameters that are technically feasible for the user. That is, sterilization cycle parameters specified in the labeling for reprocessing a device should be consistent with validated sterilization cycle parameters for commonly available, legally marketed sterilizers. Examples of cycle parameters commonly found on health care steam and EO sterilizers at the time of this guidance are provided in Appendix C. Designing your reprocessing instructions in accordance with the conventional parameters represented in Appendix C provides assurance that your reprocessing instructions are compatible with existing essential FDA-cleared reprocessing equipment. Information on other methods may be found in AAMI TIR12.

FDA's recommendation that sterilization methods and parameters be technically feasible for the user has direct application to sterilization accessories. Many sterilization accessories used in reprocessing reusable devices in health care settings are class II medical devices subject to FDA premarket notification requirements. These accessories include sterilization wraps, pouches, cassettes, and containers; biological indicators and chemical indicators; and liquid chemical sterilants and disinfectants. These products typically receive FDA-clearance for specific process parameters or sets of parameters, which appear in the "Intended Use" sections of FDA-cleared sterilization accessories. Your reprocessing instructions should match these specific process parameters.
FDA maintains a list of FDA-cleared liquid chemical sterilants and high level disinfectants, which is available at

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm. Designing validation protocols in accordance with the conventional parameters represented in this document provides assurance that your device is compatible with existing FDA-cleared liquid chemical sterilants and high level disinfectants.

Extended Cycles

The expression "extended cycle" has gained common usage to describe any sterilization cycle that includes specifications that deviate from those found on commonly used, FDA-cleared sterilizers, and for which there are limited or no FDA-cleared sterilization accessories. Extended cycles typically include longer exposure times and/or higher or intermediate temperatures, which may also deviate from more conventional sterilization cycles. Implementation of extended cycles poses serious technical challenges in health care settings.

Extended cycles are typically developed to achieve sterilization of complex devices or larger loads. Recommending the use of extended cycles for larger loads or more complex devices in reprocessing instructions may be appropriate provided the appropriate accessory devices have been cleared for use with such extended cycles. While many sterilizers are designed with manual over-ride controls for time and temperature, FDA generally evaluates physical and microbiological performance validation data and product labeling claims for discrete cycle parameter specifications as part of the premarket review process for sterilizers and their accessories, including biological indicators, chemical indicators, and sterilization packaging.

FDA recommends that "ranges" not be used for defining sterilization cycles (for example, 121°C-132°C temperature and greater or lesser than 4 minutes exposure time), as this implies that all intermediate values have been validated, and that there are FDA-cleared accessories for all the intermediate cycles.

The Agency has accepted validated drying time specifications in the labeling that exceed those found on FDA-cleared sterilizers and that require manually setting the drying time controls.

Criterion 5. Reprocessing instructions should be comprehensive.

Comprehensive instructions enable the user to understand precisely how to implement the entire reprocessing procedure safely and effectively. There may be several acceptable formats for instructions.

To ensure the reprocessing instructions are comprehensive, they should include all of the elements below. If any element is not applicable to your device, then you should state this in your premarket submission and provide a justification.

A. Special Accessories

The instructions should describe any accessories that are needed for safe reprocessing. If the device requires any special protection during reprocessing (e.g., valves, plugs or stoppers to prevent ingress of harsh chemicals), they should be described in detail. The instructions should also identify any special tools, sizes and types of brushes (including custom brushes), flush port connectors and connector size specifications, trays, test kits, specific types of sterilization wraps or containers, and part numbers, if appropriate. The instructions should also provide sufficient detail so that the user can purchase the correct items, including any custom cleaning accessories, or identify a source for the purchase of such items.

B. Point-of-Use Processing

As needed, labeling should include applicable instructions for point-of-use processing. For example, instructions for prompt, initial cleaning steps and/or measures to prevent the drying of soil on the device surface prior to cleaning may be appropriate, as this will facilitate subsequent cleaning steps.

In general, reprocessing procedures should minimize or eliminate delays between steps. Delays may create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection/sterilization. Organic contamination may inactivate or prevent full penetration of a disinfectant or sterilant.

C. Disassembly and Reassembly

If the device has removable parts, then reprocessing instructions should include step-by-step instructions for disassembly and reassembly of the device to facilitate cleaning by the user. The equipment needed to perform these activities should be identified. Diagrams, photographs, illustrations and/or videos are recommended. In addition, the instructions should indicate the location where the user should perform the step (e.g., at the point of use, at the designated cleaning area).

Disassembly and reassembly instructions should be explicit, device-specific, and reflect the validation activities. Expressions such as "disassembly, if applicable" leave the determination of "applicability" to the discretion of the user; such ambiguous language should not be used. If a device must be disassembled for cleaning, the instructions should be validated to assure that proper reassembly can be performed at the appropriate point in reprocessing. The labeling should provide the user with a validated method to verify that reassembly has been properly performed; this is to assure that the device is in operable condition for the next use. Instructions should also specify whether to reassemble before or after sterilization. Additionally, disassembly and reassembly instructions should include information to visually inspect the device and components for wear and tear of components that cannot be assessed in the fully assembled configuration.

If reassembly is to be performed by the surgeon and is described in the surgeon's manual, then reference to this should also be made in the reprocessing instructions.

D. Method of Cleaning

The labeling should provide a detailed, validated method of cleaning. The method may be manual or mechanical (e.g., washer, washer/disinfector, ultrasonic washer) or may combine the two. However, manufacturers should be aware that some small health care settings may not have automated cleaning equipment; therefore, validated manual cleaning instructions may be needed.

Cleaning instructions should include a list of the appropriate parameters for each recommended method.

For manual cleaning, the labeling should specify the duration of each processing step, as well as temperatures, water quality, and other necessary conditions. Repeated actuations, flexures, and manipulations should be specified, where appropriate, based on device design and validation activities.

Similarly, for automated cleaning, the labeling should specify all processing conditions. The instructions should recommend equipment settings such as time, temperature, and maximum device load size.

Whether the cleaning method is manual, automated, or a combination of the two, the labeling should contain comprehensive directions, including photographs and/or diagrams, if appropriate, for each cleaning, rinsing, and drying step so that users can accurately follow the steps or program them into the device washer or washer/disinfector. Recommendations for the use of detergents, enzymatic cleaners, and automated cleaning cycles should be consistent with the manufacturer's directions for use for those products.

Labeling should include surface cleaning instructions for medical devices that are at risk of becoming contaminated with patient materials through routine handling by health care workers. Even when only simple surface cleaning is recommended, the label should identify the suggested method, any cautions for specific locations or materials, any disassembly needed, and any subsequent steps.

For a device whose internal components are not contaminated during clinical use but could be damaged by contact with liquids (e.g., cleaning agents, disinfectants), surface cleaning instructions should describe how to adequately clean the device and prevent contact with internal device components that are not designed for contact with liquids.

E. Cleaning Agents

The instructions should recommend only cleaning agents or classes of agents (e.g., detergents such as quaternary ammonium compounds and enzymatic detergents) that were used during the cleaning validation studies, that have been demonstrated to be compatible with the device, and are effective in cleaning the device. Labeling should include instructions for the preparation and use of those agents (e.g., mix one ounce of detergent per gallon of water), or refer to the cleaning agent labeling for preparation and use instructions (e.g., according to the detergent manufacturer's instructions). Labeling for use on specific medical devices should be consistent with the cleaning agent manufacturer's instructions for use of the product.

Certain products (e.g., some quaternary ammonium compounds and alcohols) may be used for both cleaning (removal of soil) and disinfection (inactivation of microbes). Other products are capable of only performing one of these two functions. The instructions for use should address both cleaning and disinfection if both are intended, and should be clear regarding the difference between cleaning and disinfection, and the products used for each step.

F. Rinsing

The labeling should recommend specific directions for rinsing to remove chemical residues used during reprocessing; rinsing steps should be included after cleaning and after use of liquid chemical sterilants/high level disinfectants. Rinsing may be manual or mechanical. The rinsing instructions should include the type and quality of rinse water, duration of rinse (or, for flushes, the volume and number of repetitions), and temperature. You may refer to the detergent manufacturer's labeling to assist in developing your validated rinsing instructions.

Rinsing instructions should be validated to show that residual cleaning agents and liquid chemical germicides are reduced to levels that will not interfere with subsequent reprocessing steps and to levels that are non-toxic. Additionally, for some devices, the final rinse water specifications should be sufficient to remove bacterial endotoxins. (Note that tap water may contain endotoxins.)

We recommend that you refer to the current version of AAMI TIR34 "Water for the reprocessing of medical devices" for more information on final rinse water quality and to establish the optimal water quality for final rinses, based on the intended use of the device. We also recommend that you refer to FDA's guidance "Pyrogen and Endotoxins Testing: Questions and Answers" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM310098.pdf).

FDA generally does not recommend saline solutions as the final rinse because saline solutions may interfere with subsequent disinfection or sterilization steps. Saline rinses may also lead to corrosion on certain devices and build-up of inorganic residues.

G. Lubricating Agents

Use of lubricating agents is an effective way of extending the use life of some medical devices. Lubricants may reduce the friction commonly associated with metal-on-metal movements and thereby reduce device wear and corrosion.

If applicable, the reprocessing instructions should recommend lubricating agents, or a class of lubricating agents (e.g., water soluble lubricants) that are compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization. Also, labeling for the reusable device should refer to the lubricating agent labeling for preparation and use instructions of those agents.

If your reprocessing instructions specify the use of lubricating agents, you should validate the device reprocessing methods using the lubricating agents under the conditions of use of the device.

Caution should be exercised when using oil-based and silicone-based lubricants, as they may coat and protect surface microorganisms and reduce the effectiveness of certain sterilization methods, including steam and EO. They may even provide nutrients for microbial growth.

H. Visual Inspection

All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device.

Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.

I. Method of Disinfection or Sterilization

For reusable devices intended to be disinfected or sterilized, reprocessing instructions should specify at least one validated microbicidal method for disinfection or sterilization.

The type of microbicidal method would depend on the type of device to be reprocessed. Please refer to Criterion 3 for general considerations when selecting the type of microbicidal method.

Specifications for sterilization equipment and sterilization cycle parameters vary with manufacturers and models. Labeling for reprocessing should identify the particular sterilization method and type, and list the validated cycle parameters.

Traditional sterilization processes such as steam and EO are sufficiently well-standardized among sterilizer manufacturers such that sterilization cycles may be identified by the critical cycle parameters. Accessories for these sterilization processes also may be identified using only the critical cycle parameters. Refer to Appendix C for typical parameters of sterilization cycles currently used in health care settings.

The proprietary characteristics of sterilization processes using newer low-temperature chemical sterilization methods (e.g., H_2O_2 and O_3) vary from one device manufacturer to another. Therefore, for these sterilization processes, the manufacturer of the device, the sterilizer model, and the specific cycle identification (name or cycle parameters) should be explicitly identified in the reprocessing instructions. Accessories for these sterilization processes should be labeled by the accessory manufacturer to specify sterilizer manufacturer, sterilizer model, and sterilizer cycle name and/or cycle parameters.

For all methods, complete cycle specifications should include all critical cycle parameters and other pertinent information that identifies the cycle. For example:

- Moist Heat/Steam – Type of cycle (dynamic air removal vs. gravity), exposure time, temperature, drying time
- EO – EO concentration (and gas composition), exposure time, relative humidity, temperature, aeration time
- H_2O_2 and O_3 – Manufacturer, model, specific cycle identification per model either by name or specific cycle parameters
- Dry heat – Exposure time, temperature

Additionally, specification of device design, packaging, and load characteristics should be addressed to the greatest degree possible in the labeling for the load for sterilization. For example:

- Weight – Labeling should specify a maximum weight of loaded trays. You should follow the recommendations in the current FDA-recognized version of AAMI ST77 "Containment devices for reusable medical device sterilization" and the health care sterilizer specifications.
- Materials – Labeling should warn against including incompatible materials within the sterilization load (e.g., cellulose incompatibility with H_2O_2 sterilization).
- Device Design – Labeling should recommend sterilizing only devices with dimensions or characteristics (e.g., lumen specifications, powered hand-pieces) that are compatible with the labeling of the specified sterilizer and sterilization cycles.

- Chamber load – Labeling should describe the chamber load; for example, if the validation was conducted in an empty load or in a full worst case load.
- Drying – Labeling should indicate that devices should be dry before they are packaged for sterilization.
- Sterility Maintenance – Labeling should identify packaging that is FDA-cleared and designed to allow adequate sterilant penetration as well as maintenance of sterility. Sterilization packaging should be cleared and labeled for the same sterilization parameters as those recommended for the devices it is to contain.

J. Reduction of Sterilant Residuals

Labeling should include instructions for reducing sterilant residuals (e.g., by aeration), after processes such as sterilization by EO, hydrogen peroxide, or other sterilization processes that may leave sterilant residuals on the device.

For example, for devices intended to be sterilized by EO, the labeling should recommend an aeration time that results in reduction of EO residuals to acceptable levels. For more information on EO aeration recommendations, and to establish the optimal aeration process specification based on the intended use of the device, we recommend that you refer to the current FDA-recognized version of AAMI ST41 "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness." For more information on acceptable levels of EO residuals, we recommend that you refer to the current FDA-recognized version of ANSI/AAMI/ISO 10993-7 "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals."

K. Drying

Active device drying may reduce or eliminate recontamination of unwrapped devices after high level disinfection/liquid chemical sterilant reprocessing, because the devices will be wet at the end of reprocessing. Labeling should recommend the procedures that should be used to thoroughly dry the device, after processing and before storage, to eliminate moisture that can support the survival of contaminating microorganisms.

Labeling should also recommend a validated minimum drying time specification for terminal sterilization methods for wrapped/contained devices. Moisture remaining on wrapped/contained products after sterilization could compromise the package integrity and performance by impairing the sterile barrier properties of the packaging materials and the effectiveness of the seals.

Mid-process drying (i.e., drying after cleaning) is another important consideration, as moisture remaining on devices may interfere with subsequent microbicidal processes. If complete processing is delayed, labeling should recommend an intermediate and effective drying step before any delayed sterilization.

L. Reuse Life

The labeling should either 1) inform the user how many times the device can be reused, based on testing; or 2) provide the user with a mechanism or method to ascertain whether the device has exceeded its use life. In the latter case, the labeling should identify a method to establish that the device is still within performance specifications, as well as instructions for appropriate disposal of devices that fail. For example:

- labeling that refers to a device design feature, such as a built-in, automatic pre-check function;
- labeling that identifies a performance test that should be passed prior to reuse;
- labeling that recommends visual inspection along with acceptance or failure criteria (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals).

Whichever method is chosen, labeling should recommend how to evaluate deterioration in difficult to see areas of complex devices, especially those with lumens (e.g., leak testing).

Reuse life may also be addressed by validating the number of times the product can be reprocessed and reused, and providing this specification in the labeling. If the reuse life of a device is limited to a specific number of use/reprocessing cycles, the labeling should also describe a specific tracking method for the number of reuse cycles. It may be appropriate for labeling to remind the user that the specific number of reuse cycles is dependent on full compliance with the directions for use of the device.

M. Additional Labeling Recommendations

Devices that are initially supplied non-sterile to the user and require the user to sterilize the device before use should be prominently labeled "Non-sterile" directly on the individual device label (e.g., as opposed to only on the shipper carton) to ensure the non-sterile product is sterilized before use.

Labeling should include any special warnings or precautions about the reprocessing procedure, when warranted. These may be related to user safety or emphasize conditions that could significantly alter the safety or effectiveness of reprocessing or the performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. It may also be appropriate to note situations where damage to the device may affect the reprocessing procedure.

N. Patient or Lay Use

Devices that are intended to be maintained by a patient or lay care provider (e.g., family member or other) should have reprocessing instructions that are understandable to a lay person and can be performed at home. The equipment and accessories needed to implement the instructions should also be readily available in the intended location of use. Please also refer to FDA's guidance document "Guidance on Medical Device Patient Labeling" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm).

O. Reference to Guidelines or Accessory Labeling

In addition to all of the recommendations set forth in this guidance, the reusable device labeling should also refer the user to the following for the purpose of additional education but not in lieu of validated reprocessing instructions: professional organizations' clinical practice guidelines or clinical guidelines of the CDC. Please note that clinical practice guidelines, however, do not always consider or correctly address all FDA regulatory requirements and compliance with FDA regulations is required.

Referencing the labeling of devices used in reprocessing, such as an endoscope washer-disinfector, may be acceptable as long as the referenced labeling is relevant and consistent with the reusable device's labeling. For example, labeling for an endoscope may refer, in part, to endoscope washer-disinfector labeling for certain details on scope reprocessing (e.g., placement in chamber).

P. Manufacturer's Contact Information

The manufacturer of the reusable device is the appropriate contact for user questions about the reprocessing procedures. The instructions for reusable devices should include a telephone number, email address, and web page address to obtain additional information about reprocessing the device, including questions on infection control procedures for the device.

Customer service representatives of device manufacturers are often the initial point of contact when a device user has a question about device reprocessing. The training of these persons should include information on the reprocessing of devices for which they are responsible and the provision of information resources that they can access rapidly in order to provide assistance to device users.

Criterion 6. Reprocessing instructions should be understandable.

Reprocessing instructions should be clear, legible (i.e., reasonable font size), and provided in sequential order from the initial processing step through the terminal processing step (e.g., point-of-use processing, disassembly, cleaning, rinsing, reassembly,

disinfection or sterilization, final rinsing after disinfection or liquid chemical sterilization, and post-process handling). The instructions should be written in simple language to the greatest extent possible. They should also be sufficiently detailed to explain the correct procedures for all steps. Charts, diagrams and/or device reprocessing instructions with pictures that can be posted in work stations, are helpful in ensuring adherence to reprocessing instructions. Web-posted pictures/diagrams of devices can also be helpful in answering user questions directly or through customer service representatives.

Where applicable, instructions may include technique diagrams or other graphic representations designed to communicate recommended practices. However, any graphics should be accompanied by explanatory text. The instructions should be validated to ensure that users will be able to understand and to follow them.

VII. Validation of Reprocessing Methods in Accordance with the Quality System Regulation

For class II and class III devices and select class I devices, manufacturers must establish and maintain procedures for validating the design of their device, which shall ensure that the device conforms to defined user needs and intended uses. 21 CFR 820.30(g). Manufacturers must also establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, 21 CFR 820.75(b). Establishing procedures includes implementation. 21 CFR 820.3(k). FDA interprets these regulations to require manufacturers to validate the design, including reprocessing instructions, of reusable devices to ensure that the device can be effectively reprocessed and safely reused over its use life, as intended. Please note that exemption from 510(k) does not mean a device is exempt from compliance with labeling or Quality System (QS) requirements. Some devices are specifically exempted by regulation from most QS requirements. Manufacturers should refer to applicable regulations for their specific device type to determine what QS requirements apply.

It is possible that similarities in design, materials, and other factors may allow for establishing product families (e.g., devices with a range of available sizes) for the purpose of minimizing reprocessing validation efforts. That is, it may be possible to establish that validation data for the most difficult to reprocess devices in a family (i.e., the worst case device or "master device") covers devices that present an equivalent or lesser reprocessing challenge. If this method is utilized, all design features of the less difficult to reprocess devices in a family, such as lumen length and diameter, materials, configuration, and texture relevant to reprocessing challenges of the subject device should be evaluated and assured to be less challenging to reprocessing than the master device. Any changes in design or materials that could affect sterilant penetration or potency may result in a need to revalidate. If a master device is used, supporting information for the justification should be well documented.

For devices that are subject to design controls under 21 CFR 820.30, the device design, including its labeling (e.g., reprocessing instructions) is to be validated to ensure that the device conforms to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. The human factors methods used should ensure that the

characteristics of the user population and operating environment are considered, in accordance with 21 CFR 820.30(g). See Section V.C. of this guidance for more information about human factors in developing reprocessing instructions.

Cleaning, disinfection and sterilization processes should be validated to provide a high degree of assurance that a device will consistently meet predetermined specifications, in accordance with 21 CFR 820.75.

VIII. Validation of Cleaning Process

This section describes FDA's recommendations on how to comply with the QS requirements discussed in the previous section regarding the validation of processes designed to clean reusable medical devices. Although many FDA-recognized consensus standards related to medical device sterilization are available, limited standards or guidances are currently available regarding cleaning of medical devices.

You should conduct validation activities to demonstrate: 1) that your methods (manual or mechanical) are adequate to allow the device to undergo further processing and to eventually be reused safely; and 2) that your reprocessing instructions are effective in conveying the proper reprocessing methods to the user.

A. Validation of the Cleaning Process Using Worst-Case Testing

You should validate the cleaning process you provide in your labeling. Your validation activities should be based on comprehensive validation protocols that use soils that are relevant to the clinical use conditions of the device. These should include the worst-case (least rigorous) implementation of the cleaning process, medical devices that represent the worst-case (most challenging to reprocess and most contaminated), and at least two quantitative test methods that are related to the clinically relevant soil. The cleaning process validation protocols should specify predetermined cleaning test endpoints. These protocols should be designed to establish that the most inaccessible locations on your devices can be adequately cleaned during routine processing.

For all testing, you should choose a justifiable number of replicate samples to support the validity of any instructions based on the tests being performed.

1. Artificial Soil, Inoculation Sites, and Simulated Use

Implementation of a well-established, simulated use test protocol should be an integral part of reprocessing validation.

a. Artificial Soil

The manufacturer should select an artificial test soil, the composition of which accurately represents materials that the device would likely be exposed to during

an actual clinical use, and would create the greatest (worst-case) challenge to the cleaning process. For example, a laryngoscope is intended to provide visualization of the larynx as part of a medical procedure, including facilitation of tracheal intubation, cardiopulmonary resuscitation, and surgery in this anatomical location. A laryngoscope would likely be exposed to both blood and mucus. Therefore, to simulate a worst case cleaning challenge, the artificial test soil should be a multi-component soil that includes substances that simulate both blood and mucus. Note that conducting separate cleaning validations for blood and mucus individually would not be representative of a worst case challenge, because the mixture of blood and mucus is more difficult to clean.

The artificial test soil chosen should allow at least two clinically relevant soil components to be quantified for validation testing (e.g., total organic carbon, protein).

FDA does not recommend the use of spore (or any other microbial marker) log reduction testing as a method to determine the effectiveness of the cleaning method. Currently, there is lack of adequate scientific evidence regarding whether or not the removal of bacterial spores directly correlates to the removal of clinical organic soil from the devices. Such testing only indicates how well a process reduces spore count and provides no information on any other component of organic soil.

b. Inoculation Sites

Soil inoculations should mimic worst-case clinical use conditions. We recommend you use the artificial soil to inoculate the device in all locations likely to contact patient materials, including all locations that are difficult to clean.

c. Simulated Use Conditions

Simulated use conditions for the validation studies should be considered, especially for devices with features at risk for the accumulation of soil with repeated use. In such cases, your validation studies should use devices that have undergone some simulated use. Your validation studies should incorporate multiple full use cycles and should be designed to assess the accumulation of soil over time. The number of simulated use cycles that you use should be scientifically justified.

If the device is powered or becomes hot during clinical use, these situations should be replicated during simulated use testing. Examples of such devices include powered hand-pieces and electrosurgical instruments.

Simulated use conditions should account for real-world use conditions to mimic worst-case clinical use (e.g., the worst-case duration of clinical exposure). You should also conduct all functional procedures (repeated articulations, flexures,

manipulations) for which the device is intended in order to soil the device sufficiently to represent worst-case conditions.

If the device is likely to be repeatedly subjected to "pushing" soil into a hard to reach area during use, validation soiling should include repeated soiling to adequately reproduce such a "worst-case" use situation. If after clinical use of the device, drying of soil might occur and cleaning might not be performed immediately after use (such as with loaner devices that will be shipped without adequate reprocessing), the validation methods should allow soils to dry for a length of time that simulates worst-case (longest duration). The control devices should be prepared and processed in exactly the same manner as the test devices; positive control devices should be soiled and negative control devices should not be soiled.

2. Validation Protocols: Documentation of Methods Designed to Test the Cleaning Process

Validation protocols should support the cleaning instructions provided in your device labeling; they should be detailed and specific with respect to the parameters such as time, temperature and concentrations.

The cleaning validation protocols should use the shortest times, lowest temperatures, weakest dilutions, etc., for each step of the cleaning instructions. You should perform a detailed, side-by-side comparison of the text of the cleaning instructions and the text of the validation protocols, to identify and account for all worst-case processing conditions.

Examples of worst-case processing conditions:

- If the cleaning instructions recommend a 10 to 20 minute pre-soak, the validation protocols should specify 10 minutes.
- If the cleaning instructions advise the user to manually clean at 45ºC ± 5ºC, the validation protocols should specify cleaning at 40ºC.
- Enzymatic Detergents: In general, "worst-case" implies shortest times, lowest temperatures, etc. An exception to validation at lowest temperature would be enzymatic detergents, which typically have "optimally effective" temperature ranges. Validation protocols should adequately address the temperature range specified in the cleaning instructions for enzymatic detergents.
- Medical Washers/Disinfectors: If your process validation uses automated medical washers/washer disinfectors or ultrasonic cleaners, your worst-case should include the extremes of the intended cycle parameters for the available washer/washer disinfector cycles or ultrasonic cleaners.
- If a device consists of lumens, ports, or channels that must be flushed during cleaning, the validation protocol should include minimal flushing specifications, such as time, flush volume or flow rate, and number of repetitions (e.g., 10 mL flush, performed 3 times).

3. Testing: Test Types and Protocols

a. Choice of Test Types

FDA recommends that you use at least two quantitative test methods capable of directly measuring clinically meaningful levels of clinically relevant soil to meet a relevant, predetermined cleaning endpoint. Many potential test methods exist for the evaluation of soil and contamination, and the effectiveness of cleaning processes. The AAMI TIR 30 "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices" provides a summary of test methods available in the published literature.

When choosing a test method, consideration should be given to a number of factors. These should include, but may not be limited to, the contaminants that the device is expected to come in contact with during actual clinical use (which should be adequately represented in the artificial soil), the test specificity for direct measurement of those constituents, and the sensitivity of the test methods in relation to the proposed cleaning endpoints.

Regardless of the test type you choose, visual inspection of both external and internal surfaces should be performed during validation.

You should provide a justification for the test types chosen, including any relevant documentation (e.g., FDA-recognized standard, published literature, instructions for use for a commercially-available assay). If your chosen test method deviates in any way from what is described in the provided documentation, then you should identify and justify each deviation.

b. Methods Validation

You should validate the test methods you choose to measure residual soil. Your documentation of the method should include analytical sensitivity and specificity information, as well as predetermined cleaning endpoints, and should describe appropriate controls.

The Agency recommends that your test method include the following controls:

- Negative device control – The device should be unsoiled and undergo the same cleaning and extraction as test devices. The amount of residual soil should be at or slightly above the negative sample control.
- Positive device control – The device should be soiled with a known amount of soil, but not cleaned, and residual soil extracted. The amount of residual soil should be equivalent to or slightly lower than the amount of soil placed. Soil recovery efficiencies should be calculated and used during the calculations.

- Negative sample control – "Extraction" is conducted with no device. This sample is used as a blank.
- Positive sample control – A known amount of soil (at or slightly above the limit of quantitation) is added to an "extraction" with no device. This control addresses interference of the extraction fluid and extraction method with soil detection.

c. Extraction Method

Devices should be subjected to a validated method of extraction for recovery of residual soil. The extraction method should be completely described for each device and its recovery efficiency should be determined as part of its validation.

Exhaustive extraction and extraction using a known quantity of soil are commonly used methods for determining recovery efficiency. Extraction should sample all surfaces, including internal surfaces (such as lumens) and mated surfaces. The worst case challenge (most difficult to remove) components of the soil should be addressed in the determination of recovery efficiency testing. You should ensure that the extraction volume used to remove test soil from the device is not so large that the test marker is diluted below the level of detection for the assay.

Some device designs include more complex internal structures (e.g., lumens, internal moving parts) that may become soiled during use, but are difficult to access during cleaning and extraction. Hence, cleaning methods, including disassembly, should be designed to access these surfaces. For such geometrically complex devices, all relevant internal surface areas should be sampled during both the extraction method validation and device cleaning validation. Thus, for validation studies, additional disassembly processes may be required in order to adequately extract residual soil from these difficult to access areas. This additional disassembly should rarely require disassembly beyond the basic elemental component units, or require their actual physical destruction.

For devices with internal compartments that are not intended to come in contact with clinical soil and fluids, you should demonstrate that cleaning solutions, rinse water and/or patient materials will not penetrate into the internal aspects of the devices via incomplete seals, seams, or other internal-external contiguous air spaces.

If you determine that there is a risk of clinical soil or cleaning fluid ingress, you should demonstrate that the cleaning methods meet the cleaning endpoints for all internal surfaces that become contaminated at any time during the device's use life.

B. Resources for Establishing Simulated Use Protocols

FDA recommends the use of worst-case simulated use protocols throughout the validation of the cleaning process. Where applicable, clinicians should be consulted to determine the extent and nature of real-world, worst-case device contamination. Also, practicality and human factors issues should be considered when establishing your reprocessing protocols.

In addition, it may be helpful to refer to the AAMI TIR 30 "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices," for additional information specifically regarding soils and soil recipes described in the published literature.

IX. Validation of the Final Microbicidal Process to Prepare the Device for the Next Patient

A. Disinfection

FDA recommends that you validate your disinfection processes and instructions. FDA also recommends that you follow the recommendations in device-specific FDA guidance documents or any relevant FDA-recognized standards.

B. Sterilization

FDA recommends that you validate as well as provide in your labeling, sterilization cycle specifications that are consistent with the conventional parameters presented in Appendix C. This is to ensure that your device is compatible with the necessary FDA-cleared reprocessing equipment, and the reprocessing instructions are technically feasible for implementation by users. For reusable devices that are intended to be used sterile, labeling should include a sterilization process that you have validated to attain a sterility assurance level (SAL) of 10^{-6} (or 10^{-3}, as appropriate).

Validation data should be generated in FDA-cleared sterilizers and with FDA-cleared sterilization accessories (e.g., biological indicators, physical/chemical sterilization process indicators, sterilization wraps). Alternatively, validation data may be generated in sterilizers that can show equivalent or better control of key sterilization parameters than FDA-cleared sterilizers. If you choose this approach, you should address differences that may exist between the test sterilizer and the FDA-cleared sterilizer.

X. FDA Review of Reprocessing Instructions and Documentation of Reprocessing Method Validation in Submissions

All cleaning, disinfection, and sterilization methods should be validated, and validations should be completed prior to submission of your pre-market submission. Your reprocessing instructions should reflect the validated methods. FDA will review the reprocessing instructions included in

the labeling when we review premarket submissions for reusable medical devices. If the proposed labeling includes reprocessing instructions that do not provide adequate directions for use, FDA will communicate this to the submitter of the premarket submission. In response, the submitter may provide revised labeling or provide a rationale (and any supporting documentation) to explain why the labeling is adequate.

The documentation to be submitted to FDA for the validation of your reprocessing process and instructions will depend upon the type of premarket submission and device type, as described below.

A. Documentation in 510(k)s

Review of Reprocessing Instructions

All 510(k)s must include proposed labels and labeling sufficient to describe the device, its intended use, and the directions for its use. 21 CFR 807.87(e). For a reusable medical device as defined in the scope of this guidance, FDA interprets this to include reprocessing instructions. Validation of the reprocessing instructions should be completed prior to submission of a 510(k).

When evaluating a 510(k), FDA generally compares the labeling for the legally marketed predicate device to the proposed labeling for the new device. A description of FDA's 510(k) decision-making process is described in FDA's guidance The 510(k) Program: Evaluation Substantial Equivalence in Premarket Notifications [510(k)] (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf#page=30). As part of this evaluation, differences in proposed labeling, among other product differences, can impact the assessment of whether two devices are substantially equivalent. However, reprocessing instructions for some older, legally-marketed, reusable devices may not be consistent with state-of-the-art science and therefore may not ensure that device is clean, disinfected, or sterile. This may cause those devices to be adulterated under section 501(c) of the FDCA because its purity or quality fall below that which it purports or is represented to possess, or to be misbranded under section 502(f) of the FDCA because its labeling does not bear adequate directions for use or under section 502(j) of the FDCA because it is dangerous to health, among other possible violations. This should be taken into account when preparing reprocessing instructions as part of a 510(k) submission.

Consistent with standard operating procedures for review of premarket submissions, if post-market experience indicates potentially unsafe reprocessing for a particular reprocessing method, FDA may suggest that proposed instructions utilizing such method for a device under review be changed to address the need for improved reprocessing methods to avoid adverse events of the type reported and violations of the type discussed in the preceding paragraph.[5]

[5] SOP: Decision Authority for Additional or Changed Data Needs for Premarket Submissions (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm279288.htm).

Review of Validation of Reprocessing Instructions

FDA has identified a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed. This identification is based on knowledge gleaned through MDRs; recalls; periodic outbreaks of microbial transmission or patient infection reported in the literature or media; reports provided by the Centers for Disease Control (CDC), the Veterans Administration (VA), and other health care settings; and manufacturer-initiated surveillance studies. These device types are listed in Appendix E. The 510(k)s for these devices should include protocols and complete test reports of the validation of the reprocessing instructions for FDA review, so that FDA has the information it needs to evaluate substantial equivalence.[6] This includes validation of the cleaning instructions as well as the disinfection or sterilization instructions. The reprocessing validation data should demonstrate that the proposed reprocessing instructions will reprocess the subject device at least as well as the reprocessing instructions for the predicate device..

For reusable medical devices not identified in Appendix E, FDA does not expect a complete report of the validation of the reprocessing instructions to be included in a 510(k) submission. FDA staff may request these data, which the manufacturer should have on file in accordance with 21 CFR Part 820, if submission of validation data is recommended in a device-specific guidance or as needed to evaluate substantial equivalence.

B. Documentation in PMAs, HDEs and De Novo Requests

A PMA, HDE or *de novo* request should include the protocols and complete test reports of the validation of the reprocessing instructions in the manufacturing and design section. FDA intends to review the reprocessing validation data in the same manner as the other manufacturing and design data.

C. Documentation in IDEs

An IDE application must include a report of all prior clinical, animal, and laboratory testing of the device as part of the report of prior investigations.[7] We interpret this to include a summary of the validation testing of the reprocessing instructions. Because an approved IDE is not exempt from design controls under 21 CFR 820.30, we recommend that validation of the reprocessing instructions be complete at the time of submission of an IDE.

[6] FDA's submission recommendations and review practices for 510(k)s are described in FDA's guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." That guidance explains the decision-making process FDA uses to evaluate substantial equivalence, including when submission of data may be necessary.

[7] 21 CFR 812.27 states that the report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

FDA intends to appropriately consider the extent of the data needed prior to the initiation of clinical studies to document the safety of the recommended reprocessing instructions for the device.

APPENDIX A. Definition of Terms

The following are common terms that may be used in reprocessing instructions in device labeling, some of which are derived from referenced literature.[8, 9, 10, 11, 12, 13] The list is not exhaustive. Some of the terms defined here are derived from other relevant FDA guidances and some terms have been defined here for the purpose of this guidance. Additional definitions of terms can be found in the referenced literature.

Biological Indicator (BI): A test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

Cleaning: Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.

Design History File (DHF): A compilation of records which describes the design history of a finished device. (21 CFR 820.3(e))

Device Master Record (DMR): A compilation of records containing the procedures and specifications for a finished device. (21 CFR 820.3(j))

Disinfectant: An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores.

Disinfection: A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant (See Appendix D), which leads to the following subcategories:

a. High Level Disinfection: A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

b. Intermediate Level Disinfection: A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.

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[8] Pflug, I.J., Microbiology and Engineering of sterilization Processes, 7th ed. Minneapolis, Environmental sterilization Laboratory. 1990, Chapters 1-3.
[9] Sehulster LM, Chinn RYW, Arduino MJ et al Guidelines for environmental infection control in health care facilities, 2003.
[10] Occupational Safety & Health Administration, available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051.
[11] Association for the Advancement of Medical Instrumentation (AAMI). Sterilization of health care products-Vocabulary. ANSI/AAMI/ISO TIR11139:2006.
[12] Block SS, Definition of Terms In: Block SS, ed. Disinfection, Sterilization and Preservation, 5th ed. Phila: Lippincott Williams & Wilkins 2001:19-28.
[13] Association for the Advancement of Medical Instrumentation (AAMI). Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010 & A1:2010.

c. Low Level Disinfection: A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.

Germicide/Microbicide: An agent that destroys microorganisms, especially pathogenic organisms. Other terms with the suffix -*cide* (e.g., virucide, fungicide, bactericide, sporicide, tuberculocide) indicate an agent that destroys the microorganism identified by the prefix.

Physical/Chemical Sterilization Process Indicator: A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device. (21 CFR 880.2800(b))

Process Validation: Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Reprocessing: Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.

Reusable Medical Device: A device intended for repeated use either on the same or different patients, with appropriate cleaning and other reprocessing between uses.

Single-use Device (SUD): A SUD is a device that is intended for one use or on a single patient during a single procedure.[14]

Spore (or Endospore): The dormant state of a microorganism, typically a bacterium or fungus, which exhibits a lack of biosynthetic activity, reduced respiratory activity, and has resistance to heat, radiation, desiccation and various chemical agents.

Sterilant: An agent that destroys all viable forms of microbial life.

Sterile: State of being free from viable microorganisms.

Sterility Assurance Level (SAL): A SAL is the probability of a single viable microorganism occurring on an item after sterilization.

Sterilization: A validated process used to render product free from viable microorganisms.

> NOTE: In a sterilization process, the nature of microbial inactivation is described as exponential and, thus, the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[14] Food and Drug Administration (FDA), Reprocessing of Single Use Devices, Definitions, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121090.htm (June 18, 2009).

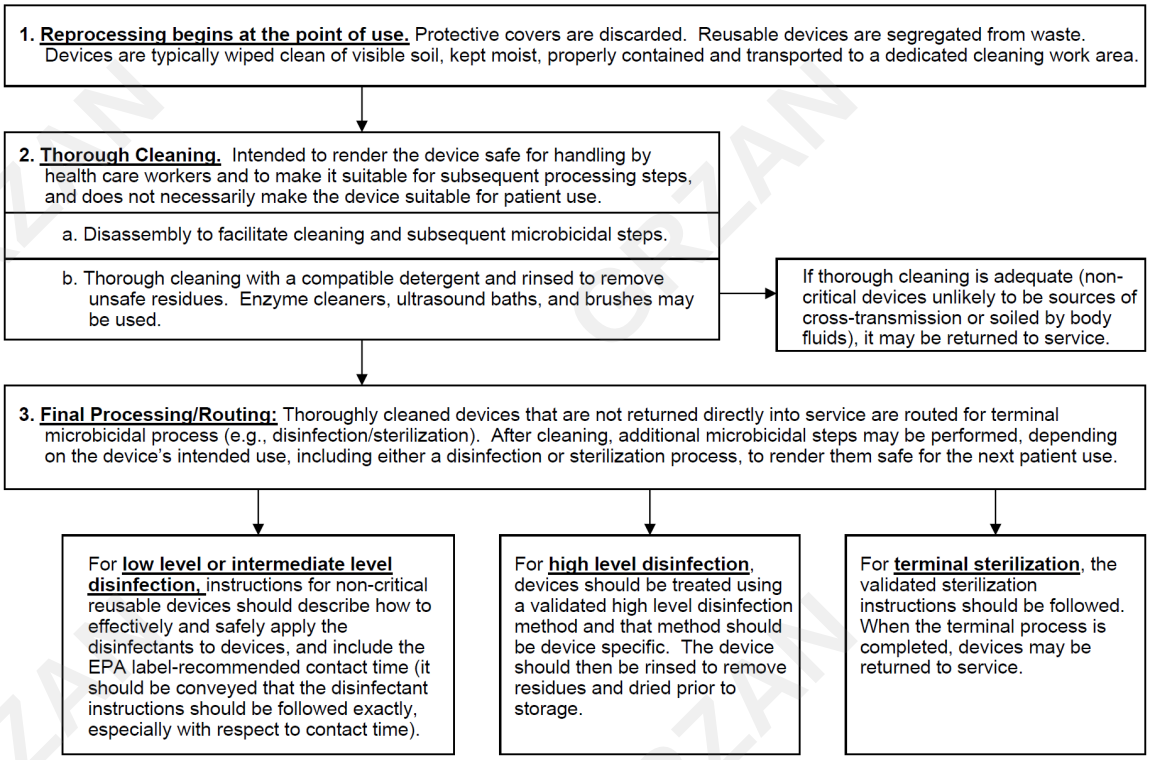
Sterilization Wrap: A sterilization wrap (pack, sterilization wrapper, bag, or accessories) is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. (21 CFR 880.6850)

APPENDIX B. Overview of Reusable Medical Device Reprocessing

As it is difficult for the health care workers responsible for reprocessing reusable devices to assess the amount and resistance of microbial contamination on the devices to be reprocessed, product labeling, professional practices, and institutional infection control procedures help guide the persons who are responsible for reprocessing devices.

Proper handling and reprocessing of reusable medical devices for the next patient is done by carefully adhering to general reprocessing steps described in the following detailed overview, presented as Figure 2.

FIGURE 2. PROCESS OVERVIEW



We recommend that all reusable medical devices be designed and constructed to allow adequate cleaning, because if a device cannot be adequately cleaned, any subsequent disinfection or sterilization process may not be effective.

Additional information on reprocessing for some specific device types, such as endoscopes and ultrasound transducers, is available from FDA in our database of guidance documents[15] and by consulting specific review divisions.

[15] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.

APPENDIX C. Examples of Sterilization Cycles Used in Health Care Settings

STEAM STERILIZATION CYCLES

Table 1. Cycle Times for Gravity-Displacement Steam Sterilization Cycles

Item	Exposure Time at 121ºC (250ºF)	Exposure Time at 132ºC (270ºF)	Exposure Time at 135ºC (275ºF)	Minimum Drying Times
Wrapped Instruments	30 minutes	15 minutes		15 - 30 minutes
			10 minutes	30 minutes
Textile Packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped Utensils	30 minutes	15 minutes		15 - 30 minutes
			10 minutes	30 minutes
Nonporous items (e.g., instruments)		3 minutes	3 minutes	0 - 1 minutes
Nonporous and porous items in mixed load		10 minutes	10 minutes	0 - 1 minute

Table 2. Cycle Times for Dynamic-Air-Removal Steam Sterilization Cycles

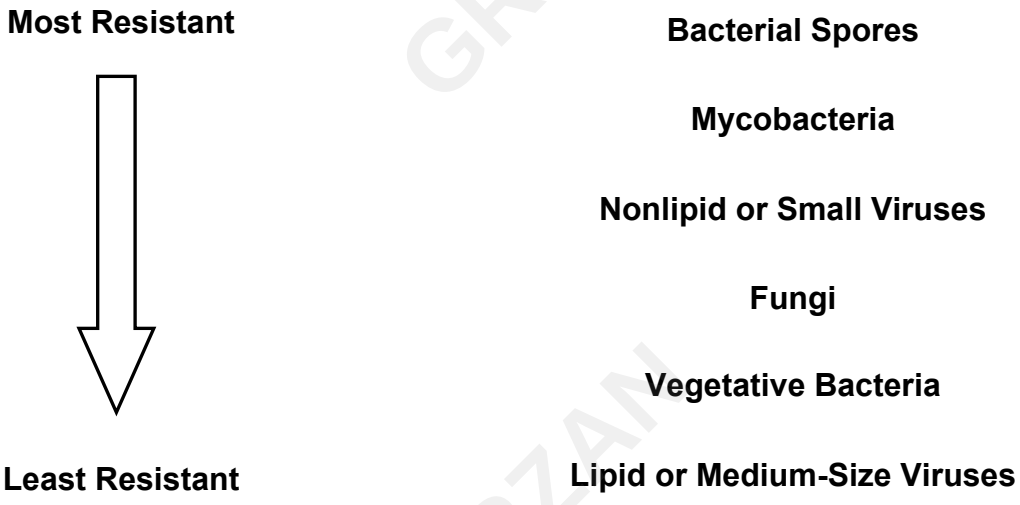
Item	Exposure Time at 132ºC (270ºF)	Exposure Time at 135ºC (275ºF)	Minimum Drying Times
Wrapped Instruments	4 minutes		20 - 30 minutes
		3 minutes	16 minutes
Textile Packs	4 minutes		5 - 20 minutes
		3 minutes	3 minutes
Wrapped Utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Nonporous items (e.g., instruments)	3 minutes	3 minutes	N/A
Nonporous and porous items in mixed load	4 minutes	3 minutes	N/A

Tables 1 and 2 modified and reprinted with permission from ANSI/AAMI ST79:2010 & A1:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Published by the Association for the Advancement of Medical Instrumentation (AAMI). (C) 2012 AAMI www.aami.org.

EO STERILIZATION CYCLES

In general, the most common parameters are EO concentrations from 450 to 1200 milligrams per liter (mg/L), temperatures from 37°C to 63°C (99°F to 145°F), exposure times from 60 to 360 minutes, and chamber humidity from 40% to 80% (ANSI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness). Other cycle parameters may be used if available on an FDA-cleared sterilizer.

APPENDIX D. Descending Order of Resistance of Microorganisms to Germicidal Chemicals



Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

APPENDIX E. Devices for which a 510(k) Should Contain Data to Validate Reprocessing Instructions

The FDA has identified a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed. This identification was based on knowledge gleaned through MDRs; recalls; periodic outbreaks of microbial transmission or patient infections reported in the literature or media; reports provided by the Centers for Disease Control (CDC), the Veterans Administration (VA), and other health care settings; and manufacturer-initiated surveillance studies.

Section 3059 of the 21st Century Cures Act (Pub. L. 114-255) required FDA to publish a list of reusable medical devices for which validated reprocessing instructions and the validation data for reprocessing of the reusable device must be included in a 510(k) submission. This section also gives FDA the authority to determine that a 510(k) submission for these reusable devices are not substantially equivalent to a predicate device if the validated instructions for use and reprocessing validation data submitted as part of the 510(k) are inadequate. As required under Section 3059 of the 21st Century Cures Act, a list of these reusable devices, categorized specifically by regulation and product code (Table 1 below) or by design features for certain device types (Table 2 below), which will require validated instructions for use and validation data in their premarket notifications, was published in the Federal Register (82 FR 26807) on June 9, 2017. The tables below are consistent with this Federal Register Notice.

Reprocessing instructions for medical devices should be validated. However, because of the greater risks to the public health posed by the devices listed below, 510(k) submissions for these devices should include protocols and complete test reports of the validation of the reprocessing instructions so that FDA has the information it needs to evaluate substantial equivalence. This includes validation of the cleaning instructions as well as the disinfection or sterilization instructions. The reprocessing validation data should demonstrate that the proposed reprocessing instructions will reprocess the subject device at least as well as the reprocessing instructions for the predicate device.

Table 1- Reusable Devices that Require Validation Data and Validated Reprocessing Instructions be Included in 510(k) Notification and upon which FDA will Determine Substantial Equivalence

Device Type	Product Code	Device Name	21 CFR Section
Bronchoscopes (flexible or rigid) and accessories	EOQ	Bronchoscope (flexible or rigid)	21 CFR 874.4680
	PSV	Ultrasound bronchoscope	21 CFR 892.1550
	KTI	Bronchoscope accessory	21 CFR 874.4680
	BTG	Brush, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	JEI	Claw, foreign body, bronchoscope (non-rigid)	21 CFR 874.4680
	JEL	Curette, biopsy, bronchoscope (rigid)	21 CFR 874.4680
	BST	Curette, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	BWH	Forceps, biopsy, bronchoscope (non-rigid)	21 CFR 874.4680
	JEK	Forceps, biopsy, bronchoscope (rigid)	21 CFR 874.4680
	ENZ	Telescope, laryngeal-bronchial	21 CFR 874.4680

	KTR	Tube, aspirating, bronchoscope (rigid)	21 CFR 874.4680
	JEJ	Tubing, Instrumentation, bronchoscope (brush sheath A/O aspirating)	21 CFR 874.4680
Ear, Nose, and Throat (ENT) endoscopes and accessories	EOX	Esophagoscope (flexible or rigid)	21 CFR 874.4710
	GCL	Esophagoscope, general & plastic surgery	21 CFR 876.1500
	FDW	Esophagoscope, rigid, gastro-urology	21 CFR 876.1500
	EOB	Nasopharyngoscope (flexible or rigid)	21 CFR 874.4760
	EQN	Laryngoscope, nasopharyngoscope	21 CFR 874.4760
	EWY	Mediastinoscope, surgical, and accessories	21 CFR 874.4720
Gastroenterology and Urology Endoscopes that have elevator channels (not including accessories) [e.g., duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP)]	FDT	Duodenoscope and accessories, flexible/rigid	21 CFR 876.1500
	FAK	Panendoscope (gastroduodenoscope)	21 CFR 876.1500
	ODF	Mini endoscope, gastroenterology-urology	21 CFR 876.1500
Automated Reprocessors for Reusable Devices	FEB	Accessories, cleaning, for endoscopes	21 CFR 876.1500
	NZA	Accessories, germicide, cleaning, for endoscopes	21 CFR 876.1500
	OUJ	High level disinfection reprocessing instrument for ultrasonic transducers, mist	21 CFR 892.1570
	NVE	Washer, cleaner, automated, endoscope	21 CFR 876.1500
	PSW	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	21 CFR 892.1570
Other Flexible Gastroenterology and Urology Endoscopes[1] (not including accessories)	FDF	Colonoscope and accessories, flexible/rigid	21 CFR 876.1500
	FBN	Choledochoscope and accessories, flexible/rigid	21 CFR 876.1500
	FDA	Enteroscope and accessories	21 CFR 876.1500
	FDS	Gastroscope and accessories, flexible/rigid	21 CFR 876.1500
	FAJ	Cystoscope and accessories, flexible/rigid	21 CFR 876.1500
	FGB	Ureteroscope and accessories, flexible/rigid	21 CFR 876.1500
	ODG	Endoscopic ultrasound system, gastroenterology-urology	21 CFR 876.1500
Neurological endoscopes (not including accessories)	GWG	Endoscope, neurological	21 CFR 882.1480
Water-based heater-cooler systems for use in operating rooms	DWC	Controller, Temperature, Cardiopulmonary Bypass	21 CFR 870.4250
	DWJ	System, Thermal Regulating	21 CFR 870.5900
System, Surgical, Computer Controlled Instrument	NAY	System, Surgical, Computer Controlled Instrument	21 CFR 876.1500
Arthroscopes and accessories[2]	HRX	Arthroscope	21 CFR 888.1100
Laparoscopic instruments and accessories[2]	GCJ	Laparoscope, general & plastic surgery	21 CFR 876.1500
Electrosurgical instruments and accessories[2]	GEI	Electrosurgical, cutting & coagulation & accessories	21 CFR 878.4400

[1] For endoscopes that fall under these product codes, 510(k) submissions must include reprocessing validation data for those endoscopes which are flexible.
[2] For devices that fall under these product codes, 510(k) submissions must include reprocessing validation data if the device possesses any of the design features listed in Table 2 below.

Table 2 **Design Features Which May Pose a Challenge to Adequate Reprocessing for Arthroscopes, Laparoscopic Instruments, and Electrosurgical Instruments, and their Respective Accessories**
Lumens (especially lumens of flexible design, multiple internal lumens, lumens that are not freely accessible, bifurcated lumens, lumens with internal surfaces that are not smooth, have internal ridges or sharp angles, or are too small to permit a brush to pass through)
Hinges, depressions, joints with gaps, overlapping or butted joints that result in acute angles, or ribbed or otherwise "roughened" surfaces (e.g., jaws)
Interior device channels
Sleeves surrounding rods, blades, activators, inserters, etc.
Shafts within lumens
Adjacent device surfaces between which debris can be forced or caught during use
O-rings
Stopcocks/Valves
Crevices
Fittings with very close tolerances
Clamps that cannot be fully opened for cleaning
Small internal parts (e.g., springs, magnets, etc.) that may become soiled
Ridges, articulations or grooves
Rough, irregular, discontinuous surfaces that can entrap or retain soil
Capillary gaps
Luer locks
Porous materials (smooth surfaces are desirable, where possible)
Junctions between insulating sheaths and activating mechanisms (as in certain laparoscopic instruments)
Dead-ended chambers
Internal movable device components such as multiple cables
Device features that may entrap debris that can later become aerosolized (e.g., through application of power, etc.)
Devices with these or other design features that cannot be disassembled for reprocessing

In the future this list may be updated as additional information regarding reprocessing medical devices becomes available.