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 5.1 – 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

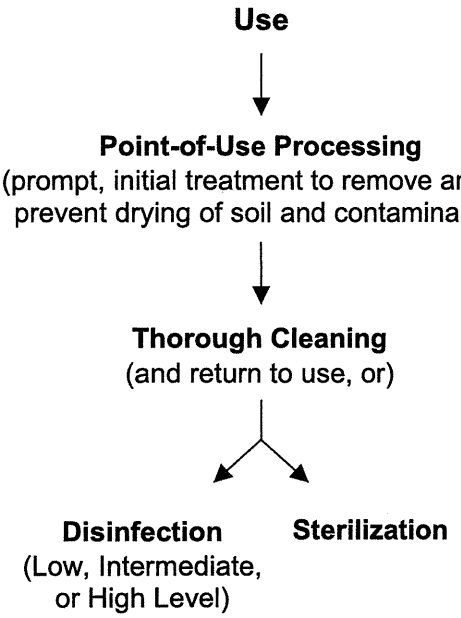
A. Overview of Reprocessing

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,