Draft Guidance for Industry and FDA Staff

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

DRAFT GUIDANCE

evolution towards more complex reusable medical device designs that are more difficult to clean and disinfect or sterilize. The revision of this guidance reflects scientific

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."[2])

Manufacturers of reusable medical devices should provide adequate labeling that inclu001instructions for reprocessing and reusing devices safely. The labeling should provide sufficient1instructions on how to prepare the device for the next patient1use. The user should be able to follow these1instructions because they should refer to materials and equipment1available to deviceusers. The manufacturer should maintain in the Device Master Record and/or 00ign history file as appropriate, documentation of tests that were performed to demonstrate that the instructions are complete and understandable and can reasonably be executed by the user. (The device master record must comply with the requirements of 21 CFR 820.181; the 00ign history file must comply with requirements of 21 CFR 820.30(j).) The users should ensure that they have the facilities, equipment, and

We recommend that you also refer to the following Technical Information Reports (TIR) developed by the Association for the Advancement of Medical Instrumentation (AAMI) when developing labeling instructions for reusable medical devices:

- AAMI TIR 12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.[3]

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D. Human Factors in Developing Reprocessing Instructions

1. We recommend that you develop consistent reprocessing instructions across each of your product lines. Labeling that provides consistent instructions and terminology, and utilizes the same layout for all devices of a type, may help

b. Semi-Critical Device

Semi-critical devices are c

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 and used with strict compliance with glove use and hand washing after glove removal.

Devices in contact with intact patient skin, or devices used in patient care which

Users reprocessing re
reprocessing steps. T
cycle parameters and
radiation sterilization

health care facilities.

b. Special Pre-Processing Handling

As needed, labeling should include any instructions for special pre-processing handling. For example, for devices contaminated with protein material, a special pre-processing handling instruction that helps prevent drying of the device surface prior to cleaning may be appropriate as this will facilitate cleaning.

c. Disassembly and Reassembly

The instructions should recommend lubricating agents, or a class of lubricating agents (e.g., water soluble lubricants) th

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

Manufacturers of reusable devices should ensure that sterilization processes listed in labeling are compatible with the reusable device. Different microbicidal processes may be effective for different types of devices. Each type of process has its advantages and limitations. For example, heat-labile devices should be sterilized by a non-thermal process (e.g., chemical vapor, gas/plasma, or liquid chemical sterilant).

addition, simulated use conditions should account for real world use conditions, to mimic worst case clinical use, for example, the worst case duration of clinical exposure. You should also conduct all functional procedures (articulations, flexures, manipulations) for which the device is intended 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 the "worst case" use situation. If after use of the device, drying of soil might occur an

spaces. Such openings may result in the ingress of patient materials and cleaning fluids, and these contaminants may compromise subsequent disinfection or sterilizf pon processes, as well as exit these device openings in

nt materials and cleaning fluids can
vices, you should demonstrate that the
cleaning meeet the cleaning endpoi nt for all internfl surfaces th
become contaminated at any time during use or reprocessing. Direct evaluation for residufl soil should incl ude complete surface area extraction for hard to clean internfl surfaces. Soil assessment and surface area calculations for these areas should be an integrfl component of the soil reduction calculations.

C. Resources for Establishing Simulated Use Protocols

FDA recommends the use of worst case simulated use protocols throughout [(W)99(lh).15(er arpplicab6.81let,slen)5TJ-902 0 TD.-0002 Tc-0002 Tw5tician should be

APPENDIX B. Examples of Sterilization Cycles Used in Health Care Facilities

STEAM STERILIZATION CYCLES

tuberculocide) indicate an agent that destroys the microorganism identified by the prefix.

- 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 sterilitFbe a4 0 r, baril8allow st2 faf

APPENDIX D. Descending Order of Resistance of Microorganisms to Germicidal Chn254lsn

APPENDIX E. Additional Resources

The following additional references