Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
Div. of Device User Programs and Systems Analysis

GRZAN

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. 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 at (http://www.fda.gov/cdrh/ohip/guidance/1333.pdf) . You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1333) to identify the guidance you are requesting.

Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Background

On August 14, 2000, the Food and Drug Administration released a document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to provide guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third-party and hospital reprocessors of single-use devices (SUDs) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Section 513 and 515 of the Act; 21 *Code of Federal Regulations* Parts 807 and 814).

Since its release on August 14, 2000, the agency has received numerous questions about the enforcement priorities guidance. The following questions and answers are meant as clarification of the original document. This guidance will be updated as the need arises.

The Least Burdensome Approach

We believe FDA should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

Question related to
SELECTION OF A THIRD-PARTY REPROCESSOR

Question. *How can I obtain information about third-party reprocessors of single-use devices (SUDs)?*

Answer. At this time, FDA cannot provide a list of reprocessors because our registration and listing database was not designed to identify third-party reprocessors. We plan to create a specific code that will identify reprocessors.

To help you select a third-party reprocessor, we suggest you talk with other hospitals to determine their experiences with third-party reprocessors and arrange to visit the reprocessors' facilities. In addition, you may consider asking a potential reprocessor the following questions:

- When did FDA last inspect your facility? What were the results of that inspection?
- Do you have documentation that demonstrates that your company has been cleared/approved by FDA to reprocess SUDs?
- How do you monitor the manufacturing processes and what records do you maintain in order to comply with FDA's Quality System regulation?
- What aspects of your overall process have been validated, for example, cleaning, packaging, sterilization?
- Has your company set limits on the number of times a SUD can be reprocessed? If yes, how did you determine the number of times a SUD can be reprocessed? What procedures do you have in place to ensure that a SUD is not reprocessed beyond the set number of times?

To obtain the 483 inspection report from a reprocessor's most recent FDA inspection, contact FDA's Freedom of Information Staff by fax at 301-443-1719 or 301-443-1726. You also can obtain information about a reprocessor's inspection history at http://www.fda.gov/cdrh/foicdrh.html.

Question related to
MEDICAL DEVICE REPORTING

Question. *What are FDA's requirements for reporting an adverse event with a SUD reprocessed by the hospital?*

Answer. If a hospital reprocesses a device that was previously marketed as a single-use device, FDA considers the hospital to be the manufacturer of that device and subject to the same adverse event reporting requirements (Medical Device Reporting or "MDR") as original equipment manufacturers or commercial reprocessors. A manufacturer is defined in Title 21 of the *Code of Federal Regulations* (CFR) at 803.3(o) as "any person who manufactures, prepares, propa-gates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure." The manufacturer MDR

requirements are in addition to the hospital's current user facility adverse event reporting requirements. Information on MDR requirements is available on the Internet at http://www.fda.gov/cdrh/mdr.html and http://www.fda.gov/cdrh/osb/guidance/1334.pdf.

Questions related to QUALITY SYSTEM

GENERAL

Question. *Should my hospital comply with the Quality System regulation even if the SUDs that we are reprocessing do not require premarket submissions to the FDA?*

Answer. Yes. Regardless of whether or not the SUDs that your hospital is reprocessing require premarket submissions, your hospital should comply with the requirements of the Quality System regulation [which also is referred to as the current Good Manufacturing Practice (cGMP)] as described in 21 CFR Part 820 (see Appendix question #7 below). The following Internet web sites provide information about the requirements of the regulation:

http://www.FDA.gov/CDRH/dsma/gmpman.html - Medical Device Quality Systems Manua l: A Small Entity Compliance Guide

http://www.FDA.gov/CDRH/comp/designgd.html - Design Control Guidance for Medical Device Manufacturers

http://www.FDA.gov/ora/inspect_ref/igs/qsit/qsitguide.pdf - Quality System Inspection Technique (QSIT) Handbook

http://www.FDA.gov/CDRH/ode/425.pdf - Guideline on General Principles of Process Validation

Question. *Is the CEO of a hospital responsible for quality policy and implementation under the Quality System (QS) regulation?*

Answer. Under 21 CFR 820.20 (Management responsibility) management with executive responsibility is the level of management that has the authority to establish and make changes to the facility's quality policy. The implementation of the quality system may be delegated; however, it is up to the highest level of management to establish quality policy and ensure implementation. Management reinforces understanding of policies and objectives by demonstrating a commitment to the quality system visibly and actively on a continuous basis. This can be demonstrated by providing adequate training and resources to support quality system development and implementation.

STERILIZATION

Question. *What sterilization activities does FDA expect in a hospital reprocessor that is reprocessing single-use devices (SUDs)?*

Answer. A hospital reprocessor that reprocesses SUDs is considered a device manufacturer as defined under 21 CFR 820.3(o). As such, FDA expects that its sterilization reprocessing of SUDs will meet the requirements of the Quality System (QS) regulation (21 CFR Part 820). This regulation is applicable to the sterilization activities in many ways. Several key elements affect whether a device is sterile or nonsterile and whether it will function as intended at the conclusion of the process. The success of a sterilization process is dependent to a large degree on how well the hospital reprocessor:

- has validated the sterilizing equipment and process;
- controls the routine processing; and
- reaches decisions to assure that only a sterile product is released for use.

A hospital SUD reprocessor should prove during validation studies that each sterilization process is capable of achieving sterility for each run (21 CFR 820.75). The sterilization process should achieve a sterility assurance level (SAL) of 10^{-6} for devices used in normally sterile areas of the body. A hospital reprocessor cannot just assume that standard sterilizer cycles will effectively and safely reprocess devices; it should demonstrate with microbiological lethality study data that the SAL is achieved by the process utilized. Also, a hospital reprocessor should develop evidence that the sterilization process does not have an adverse impact on the materials or functioning of the SUDs being reprocessed.

Process controls used for routine sterilization should be adequate to assure that the specifications for process parameters established during validation are always met [21 CFR 820.70(2)]. By doing validation studies, a hospital reprocessor can prove that when certain parameters (for example, temperature or humidity) are used, sterility will be achieved. A hospital reprocessor should establish controls over the routine processing to assure that the specifications for these parameters are met during each run.

Finally, a hospital reprocessor should have procedures for releasing the SUDs for use, so that any possibly non-sterile reprocesssed SUD is detectable [21 CFR 820.80(d)]. It should review documentation from each run to be sure that the parameter specifications have been met. Many hospital reprocessors also include biological confirmation of sterility by using biological indicators (BIs) with each run. While FDA strongly encourages the use of biological indicators, there may be circumstances when the validation studies and the process controls are so rigorous that BIs might not be needed. In these cases, the process should meet the parametric releases that are defined in recognized consensus standards.

Question. *What kinds of documentation should a hospital reprocessor maintain for sterilization reprocessing of SUDs?*

Answer. A hospital that reprocesses SUDs should maintain written procedures and data to show that it is meeting requirements of relevant portions of the Quality System (QS) regulation (21 CFR Part 820). In the area of sterilization, a hospital reprocessor should maintain documentation to show that equipment has been installed correctly and operates as intended. Likewise, it should have documentation that shows the sterilization process has been validated as being effective in achieving sterility without adversely affecting the devices [21 CFR 820.75(a)]. Also, a hospital reprocessor should maintain documentation for process control procedures and data to prove that for each run the specifications for sterilization parameters have been met [21CFR 820.70(a) and 820.184]. FDA may also ask to see any test results relating to the validation or routine sterilization of SUDs.

Question. *What guidance is applicable to hospital reprocessors that are sterilizing SUDs?*

Answer. FDA has guidance documents that apply generally to all types of manufacturing processes including sterilization. For example, the "Guideline on General Principles of Process Validation" applies to sterilization activities as well as to other manufacturing processes. This document is located on the Internet at www.fda.gov/cdrh/ode/425.pdf. FDA documents relating to the Quality System (QS) regulation also are applicable for sterilization processes. These documents are located on the Internet at www.fda.gov/cdrh/dsma/cgmphome.html. General guidance is available from other sources such as the Global Harmonization Task Force document entitled "Process Validation Guidance for Medical Device Manufacturers."

Many national and international consensus standards provide specific sterilization processes. We encourage you to become familiar with these standards. FDA has worked closely with other experts from industry, healthcare facilities, and academia in developing these standards for the various types of sterilization processes commonly used for medical devices. FDA recognizes many of these standards as providing acceptable guidance for good sterilization practices. Although acceptable to FDA, these standards are voluntary, and there is no regulatory requirement that they be followed. If these standards are not followed, FDA expects that processing will meet the same levels of scientific soundness as the standards. The FDA consensus standards program is described on the Internet at www.fda.gov/cdrh/stdsprog.html. A list of standards useful in the reprocessing sterilization of SUDs is located at www.fda.gov/cdrh/reuse/reuse-standards.shtml. Although consensus standards for the sterilization of medical devices have been directed either to healthcare facilities or to industrial users, many are being rewritten to include both types of facilities. For example, in the area of sterilization methods commonly used in hospitals (moist heat or ethylene oxide), there are standards for both industrial users and for healthcare facilities, as follows:

STERILIZATION METHOD	INDUSTRIAL FACILITY USE	HEALTHCARE FACILITY USE
ETHYLENE OXIDE	ISO 11135	ANSI/AAMI ST 41
MOIST HEAT	ISO 11134	ANSI/AAMI ST 46

Note that ANSI/AAMI ST 41 states that it does not cover the reprocessing of items labeled for single-use only. Revisions of ANSI/AAMI ST 46 have been written and indicate a similar exclusion for reprocessing of SUDs.

When deciding which standards to use for sterilization of SUDs, remember that FDA considers hospitals to be manufacturers if they reprocess SUDs. FDA, therefore, expects hospitals will meet either the requirements of the industrial standards or have an equally rigorous scientific rationale for sterilization procedures used in reprocessing SUDs.

Question related to
Center for Medicare and Medicaid Services
(formerly the Health Care Financing Administration)

Question. *Will FDA work with the Center for Medicare and Medicaid Services (formerly the Health Care Financing Administration) to link compliance to reimbursement or participation in Medicare and Medicaid programs?*

Answer. Yes. FDA and the Center for Medicare and Medicaid Services (CMS) have agreed to work together to ensure that hospitals reprocessing SUDs are doing so safely. FDA plans to inform CMS of any hospital SUD reprocessor not in compliance with FDA's reprocessing requirements.

Questions related to
APPENDIX A

Question. *If a particular device is listed in Appendix A (List of SUDs known to be reprocessed) of the August 14 guidance document, does that mean FDA believes the device can be safely reprocessed?*

Answer. No. Appendix A is simply a list of those types of devices that FDA believes have been reprocessed. It does not mean that a particular type of device can or cannot be reprocessed safely. In fact, such a list would be impossible to develop. Whether or not a device can be reprocessed safely depends not only on the device but on the reprocessor and the methods used for cleaning and sterilizing. Because of materials used or design of the device, some models within a particular type of device may be able to be reprocessed safely while others may not.

Question. *If a device is identified as "Exempt" on the List of SUDs (Appendix A), is it exempt from both premarket and non-premarket requirements?*

Answer. No. A "Y" (yes) in the column identified as "Exempt (Y/N)?" means that the device is exempt from the premarket requirements only. It does not provide any information on whether or not the device is exempt from any of the non- premarket regulatory requirements. A revised list that includes a column titled "Premarket Exempt" and another column titled "GMP Exempt" has been provided to clarify the types of exemptions that apply to a particular type of device. That list can be found on the Internet at www.fda.gov/cdrh/reuse/1168a.html .

Questions related to SPECIFIC DEVICES

Question. *Where can I obtain specific guidance for the SUD that I am interested in reprocessing?*

Answer. You can search for guidance on a specific device on our Internet web site at http://www.fda.gov/cdrh/guidance.html and http://www.fda.gov/cdrh/devadvice/11.html.

Question. *How can I obtain information on the status of a premarket notification [510(k)] submission or a premarket approval (PMA) application for a reprocessed SUD?*

Answer. The status of an application under FDA review is confidential. Once an application has been cleared or approved, it is included in FDA's releasable database on the Internet at http://www.fda.gov/cdrh/databases.html. Click on the Premarket Notifications Database [510(k)s] or the Premarket Approvals Database (PMA).

Question related to REGISTRATION AND DEVICE LISTING

Question. *How do we register our facility and list the SUDs that we are reprocessing?*

Answer. A medical device establishment that is registering for the first time should complete form FDA 2891 (Initial Registration of Device Establishment). Enter the establishment type code "MB" for a reprocessor if the form you receive does not have the code preprinted on it. You should list all SUDs that your facility reprocesses. Submit a form FDA 2892 (Device Listing) for each type of device being reprocessed. Information on how to obtain blank registration and listing forms and how to complete them is located on the Internet at http://www.fda.gov/cdrh/reglistpage.html.

Note: Additional Questions are available at:

http://www.fda.gov/cdrh/ohip/guidance/1408.html

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