Reprocessing of Single-Use Devices: FAQs (FDA)

Question related to
SELECTION OF A THIRD-PARTY REPROCESSOR

Q: How can I obtain information about third-party reprocessors of single-use devices (SUDs)?

A: At this time, FDA cannot provide a complete list of reprocessors because some companies have registered in our registration and listing database as reprocessors when, in fact, they are not and we believe there could be other reprocessors including hospitals that have not registered or listed.

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 CDRH FOIA Electronic Reading Room[2]. *(posted 6/5/01)*

Question related to
MEDICAL DEVICE REPORTING

Q: What are FDA's requirements for reporting an adverse event with a SUD reprocessed by the hospital?

A: 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 in the Report a Problem section[3] and Guidance on Adverse Event Reporting for Hospitals that Reprocess Devics Intended by the Original Equipment Manufacturer for Single Use[4]. *(posted 6/5/01)*

Questions related to
QUALITY SYSTEM

GENERAL

Q: 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?

A: Yes. Regardless of whether or not the SUDs that your hospital is reprocessing require premarket submissions, your hospital is required to meet 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:*(posted 7/10/01)*

Medical Device Quality Systems Manual: A Small Entity Compliance Guide[5]

Design Control Guidance for Medical Device Manufacturers[6]

Q: Is the CEO of a hospital responsible for quality policy and implementation under the Quality System (QS) Regulation?

A: 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. In many cases, this would be the CEO or equivalent. 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.*(posted 6/5/01)*

STERILIZATION

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

A: 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 processes;
- 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 sterilization 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. *(posted 7/10/01)*

Q: What kinds of documentation should a hospital reprocessor maintain for sterilization reprocessing of SUDs?

A: 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 the specifications for sterilization parameters have been met for each run [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.*(posted 7/10/01)*

Q: What guidance is applicable to hospital reprocessors that are sterilizing SUDs?

A: 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. FDA documents relating to the Quality System (QS) Regulation[7] also are applicable for sterilization processes. General guidance is available from other sources such as the Global Harmonization Task Force document entitled "Process Validation Guidance for Medical Device Manufacturers." *(posted 7/10/01)*

Many national and international consensus standards provide requirements for validation, process controls and routine monitoring of sterilization processes.. We encourage reprocessors 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 the hospital reprocessors sterilization process will meet the same levels of scientific soundness as the standards. The FDA consensus standards program[8] has a list of standards useful in the sterilization of health care products. This list of standards includes information on reusable medical devices in health care facilities and resterilizable devices. 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 to meet either the requirements of the industrial standards or have an equally rigorous scientific rationale for sterilization procedures used in reprocessing SUDs.*(posted 7/10/01)*

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

Q: 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?

A: 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 will inform CMS of any hospital SUD reprocessor not in compliance with FDA's reprocessing requirements.*(posted 6/5/01) (HCFA name change posted 7/10/01)*

Questions related to
ATTACHMENT 1

Q: If a particular device is listed in Attachment 1 (List of SUDs known to be reprocessed) of the September 29, 2005, Federal Register Notice, does that mean FDA believes the device can be safely reprocessed?

A: No. Attachment 1 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.

Q: If a device is identified as "Exempt" on the List of SUDs (Attachment 1), is it exempt from both premarket and non-premarket requirements?

A: 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. For information on all premarket and non-premarket requirements please see our searchable public Classification Database at http://www.accessdata.fda.gov/scripts/[9] cdrh/cfdocs/cfPCD/classification.cfm[10].

Questions related to
SPECIFIC DEVICES

Q: Where can I obtain specific guidance for the SUD that I am interested in reprocessing?

A: You can search for guidance on a specific device in the Guidance Documents (Medical Devices)[11] section.

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?

A: 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[12] on the Internet. Click on the Premarket Notifications Database [510(k)s] or the Premarket Approvals Database (PMA).

Question related to
REGISTRATION AND DEVICE LISTING

Q: How do we register our facility and list the SUDs that we are reprocessing?

A: A medical device establishment that is registering for the first time must use the electronic device registration and listing system (FURLS). You should list all SUD's that your facility reprocesses and check the "single-use device reprocessor" activity box during the listing process. Each registered establishment must also do an annual registration between October 1 and December 31 of each year. Note that SUD reprocessors must pay the annual device establishment registration user fee. Complete information about the registration and listing[13] process can be found on our website. *(posted 8/21/09)*

Q: My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to add the establishment operation type of "Reprocessor of Single-Use Devices" to our existing registration information?

A: Yes, your establishment needs to be registered for all of the operations that are being performed at the same location.*(posted 12/12/02)*

Q: My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to update our existing device listing information?

A: Yes, your establishment needs to have all of the operations that are being performed on a particular device listed with FDA.*(posted 12/12/02)*