

Docket No. OOD-0053  
Dockets Management Branch (HFA-305)  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5603 Fishers Lane, Room 1061  
Rockville, MD 20852

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Re: Docket No. 99N-4491, FDA's Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

April 3, 2000

Dear Committee members:

I am a Central Service Manager at Botsford General Hospital in Farmington Hills Michigan. I am writing in response to the FDA's two draft guidance documents: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme. The following are my comments and not the comments of my hospital or any organization. My views and comments are based upon my 23 plus years in the hospital field working in many various capacities, the last 14 as a Central Service Manager at various institutions observing many different ways of "reusing and item". I have several comments on these documents.

Overall I am very pleased with the documents. My position has always been that hospitals should not be reprocessing single-use devices in-house and I have always favored some type of regulation for any party that attempts to reprocess single-use items. I am in support of the FDA considering hospitals that reprocess to be manufacturers and therefore subject to the same regulatory requirements as OEM. The combination of infection risk and performance in the Risk Categorization flow chart is excellent showing how to evaluate whether an item presents a specific risk to the patient when it is reprocessed.

The role out time frame seems adequate for these documents.

I do have some concerns, and my first concern is that "opened-but-unused" items are exempt from the regulatory guidance.

My reason is that many single-use items are made from plastic and other material not known to the hospital that wants to resterilize the opened-but-unused item. Plastic and other material contain molecules and compounds that give these substances their unique characteristics. They allow these substances to have characteristics that are different, such as the ability to bend, to have a smooth exterior, and not shatter when

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the product is used in patient care. These compounds can be cooked out or leached out of the plastic even with low temperature sterilization. This can happen to items that are resterilized. Thus the product is altered from its original form. Without some type of guidance from the OEM, or testing of the product, how can anybody insure its safety for the patient who will receive it?

Following this same point is the question of the validation of the sterilization procedure used for each item that will be resterilized. The reprocessor (either hospital or third party or whoever) sets himself or herself up for legal challenges by the patient involved in the use of the item. If the item has not been through a validated sterilization cycle, how does the reprocessor know the item can withstand another sterilization process without altering its function?

Lastly, another issue with opened-but-unused items is how to maintain the original lot number with the reprocessed item. A tracking system of some type is required or the item cannot be identified if there is a recall by the original manufacturer.

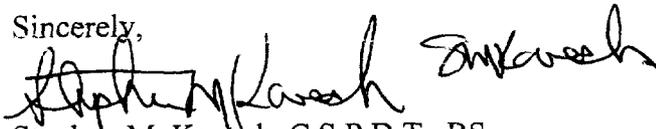
Guidance in this area needs to be given and not left up to the reprocessor, because we have seen what has taken place without guidance and enforcement.

This is why I am in favor of any item being reprocessed, resterilized, or reused having all the proper process followed to insure safety for both the patient and staff who do this function. I feel not regulating "opened-but-unused" products put the patient at risk and should be in the scope of the document.

My next concern is that the documents do not apply to "Health care facilities that are not hospitals". It is my belief that any institution regardless of where they are located or affiliated with should comply with these documents.

I want to thank you for the opportunity to comment on these documents and will offer my help when ever possible on the rolling out of these documents.

Sincerely,



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c.c.       The Honorable Carl Levin, U.S. Senator, Michigan  
            The Honorable Spencer Abraham, U.S. Senator, Michigan  
            The Honorable John D. Dingell, U.S. Congressman, Michigan



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