



Allegiance Healthcare
1500 Waukegan Road
McGaw Park, IL 60085

June 3, 2002

Dockets Management Branch [Docket # 02D-0039]
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

Re: Industry Comment - Docket # 02D-0039

Dear Sir/Madam:

Allegiance Healthcare Corporation (Allegiance) appreciates the opportunity to comment on the Draft Guidance for Industry and FDA on Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities currently being considered.

The following comments are respectfully submitted for consideration by the Division of Dental, Infection Control, and General Hospital Devices.

Page 2, Para. 1:

“This guidance includes sterilization trays and cassettes used for sterilization in health care facilities, because they are intended to enclose medical devices for terminal sterilization and they are considered a medical sterilization packaging system.”

Comment:

Allegiance agrees that trays and cassettes that are surrounded, i.e., wrapped with a sterilization wrap for which FDA has granted a 510(k) should be considered medical sterilization packaging systems. The reason for this is that subsequent to the successful completion of the sterilization cycle the cassette(tray)/wrap maintain the enclosed device in a sterile condition until the packaging system is opened or damaged. The packaging system provides a sterilization barrier for the enclosed, sterilized, device. When used in conjunction with a wrap the cassette/tray should be considered as a Class II device under 21 CFR 880.6850.

A clear distinction, however, must be drawn with regard to cassettes and trays that are simply, for lack of a better word, used to organize medical devices for placement into a sterilizer and not intended to maintain the sterility of the sterilized devices after the cycle is completed. Cassettes and Trays with this intended use should be considered as Class I devices under 21 CFR 878.4800. The basic difference being that the higher classified device maintains the sterility of the enclosed device until use while the lower classified device does not serve as a sterility barrier to maintain the sterility of the enclosed device. In our opinion, the intent of the last phrase in 21 CFR 880.6850 is not emphasized sufficiently in the draft guidance as it is now written.

02D-0039

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Page 2, Under Introduction, A. Scope

Comment:

Bullet point three should be expanded to include “when the identified containers and cassettes, including trays, mats, holders, or any other component that is used for sterilization of medical devices is intended to maintain the sterility of the enclosed device until the sterilization system is opened or damaged.”

Page 3, B. Exclusions

Comment:

Add to exclusions the concept of devices that do not provide the maintenance of sterilization, e.g., cassettes and trays that are intended only to organize medical devices in a sterilizer and transport sterilized devices under sterile technique to the surgical field for immediate use.

Page 5, Definitions

Comment:

Add the concept of sterilization maintenance to the definition of Sterilization Medical Packaging Systems, e.g., change last sentence to “They are intended to allow sterilization of the enclosed device and maintain the sterility of the enclosed device until opened or damaged.

Add the concept of sterilization maintenance to the definition of Trays, e.g., add the following sentence to the definition. “Trays that are used to organize medical devices and transport sterilized devices under sterile technique to the surgical field for immediate use are not subject to this guidance.

Add “for its intended use” to the end of the second sentence of the definition of Surgical kraft paper.

Page 7, G. Premarket Notification Procedures

Comment:

It is recommended that brief comments concerning the availability of the two “new” vehicles for 510(k) submission, i.e., abbreviated and special be specifically identified at this location in the guidance.

Page 8, #7

Comment:

Add, if available, to 510(k) number of the predicate device. (This number may not always be available to the submission sponsor.)

Page 8, C. Information Required – last sentence on page

Comment:

Recommend that the cycle parameters of a sterilization cycle not be included in an Indication for Use Statement.

The rationale for this is that including cycle parameters may be providing too many options and confusion between identical devices. E.G., A 45 lb. Paper/Polyester-poly pouch may be qualified by one company under one set of parameters and by another company under a completely different set of parameters – leading to confusion on the part of the user. A better approach might be to state the maximum recommended cycle parameters.

Page 10, Microbial Barrier Properties

Comment:

Recommend that the statement reads, “You should submit performance data comparing the whole package integrity properties of your device or packaging integrity properties of the characteristics of your devices’ packaging system (material and closure) with the predicate. To maintain sterility, your packaging should provide an effective barrier to microorganisms.

Page 10, Material Compatibility

Comment:

Recommend that the last sentence reads, “The functionality of your device should not be degraded by any sterilant used to sterilize it.

Page 10, Toxicological Properties

Comment:

Please clarify if information regarding toxic by-product residues is being requested in terms of the packaging system or in terms of the device contained in the packaging system?

Page 10, E. 1 Material Composition

Comment:

Recommend the inclusion of “Pressure sensitive adhesive description” for self adhesive pouches.

Additionally, “tyvek” is a registered trademark of E.I. Dupont and should be noted as such.

Page 12, III, Performance Information and Testing

Comment:

Recommend that the second sentence of the second paragraph read, “You should also provide information on the closure properties of the seals, gaskets, and filters used in the packaging system.

Page 13, A. 1. Penetration and Contact

Comment:

Please provide clarification, including examples, of how direct sterilant contact with medical instruments is to be demonstrated.

Page 14, Biological Indicators

Comment:

Recommend that the second sentence of the paragraph be modified to read, “In addition, we recommend performing half cycle determinations to demonstrate the minimum exposure time, i.e., the exposure time resulting in a Spore Log Reduction (SRL) value of not less than 6.0 at the half cycle.

Additionally, the last sentence of the section states “The established sterilization cycle time should be within the standardized cycle time of the sterilizers routinely used in the health care setting.” FDA is respectfully asked to reconsider this requirement. If a manufacturer provides a device that has been validated as being safe and effective for its intended use after being sterilized in a validated sterilization cycle and provides information on the validated sterilization cycle in its Labeling to the user, it is not relevant that the sterilization cycle has a processing time longer or shorter than a “standard” cycle time. It is only relevant that the proper information concerning the safe and effective use of the device in question be conveyed to the user.

Page 14, Steam Sterilant

Comment:

Delete steam penetration requirement since BI studies verify effective steam penetration was delivered by the cycle.

Page 14, Physical Properties

Comment:

Companies should be given the choice of validating filter material through either physical tests or microbiological tests. This would be consistent with previous FDA guidance to Industry (Container Enclosure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products.).

Page 15, Microbial Barrier Properties

Comment:

Recommend that the first sentence of the second paragraph read, “The microbial challenge test is a whole package test that consists of placing the packaging system inside a chamber and exposing it to a defined challenge of microorganisms which provide a reasonable simulation of typical user contamination levels. Sterility testing is conducted on the contents”.

Page 17, Maintenance of Package Integrity

Comment:

Recommend that the first paragraph read, “An important characteristic of a medical sterilization packaging system is its ability to maintain the sterility of the enclosed medical device. Per ANSI/AAMI/ISO 11607-97 section 6.4.3.1 Note: The loss of final packaging integrity is usually regarded as event-related rather than time-related. Microbial barrier properties of sterilization packaging should be evaluated after exposure to storage conditions and environmental stresses expected for finished packaging systems. Data should demonstrate that the enclosed devices are sterile and the integrity of the packaging system is maintained.

The rationale for this modification is to maintain consistency with the requirements of this harmonized and FDA recognized standard.

Recommend that the first sentence of the second paragraph be modified to read, “Performance testing should be conducted to evaluate the integrity of the packaging system after stressing by simulating transport, and storage conditions.”

Page 18, Aeration Time and EO Residuals

Comment:

Please provide the basis for these health care aeration times -- 1978 FDA proposed Guidance, ISO 10993-7, etc.

Page 19, Additional Information for Reusable Containers and Cassettes

Comment:

The ability of a device manufacturer to identify a method for a user to track a device once the device is in the user's possession, the manufacturer not knowing the user's operating procedures, is questioned. This obligation should be allocated to the user.

Page 20, Biocompatibility

Comment:

Recommend that the last sentence of the first paragraph be modified to read, "FDA recommends that, the tenets identified in ANSI/AAMI/ISO 10993 Part 1 be followed on polymeric materials." Since FDA has already recognized this Standard; it is not necessary to state any more than for the manufacturer to comply with the accepted document.

Additionally, we recommend that the last sentence of the section read, "In addition, woven materials should be sufficiently free of particulates and lose fiber to be safe and effective for their intended use.

Page 21, Section IV Labeling - Sterilization Method

Comment:

Recommend the sentence read, " The sterilization method and types of cycles, e.g., gravity moist heat, prevacuum moist heat, EO, and Hydrogen Peroxide/Plasma."

Page 21, Section IV Labeling - Shelf-life

Comment:

Should read "Shelf-life (if applicable)"

Page 22, Sterilization Containers

Comment:

It is recommended that a precaution be added identifying that only FDA cleared, legally marketed filter paper be used in sterilization container systems.

Additionally, we recommend that the identification of a tracking system for users be deleted from labeling requirements, for reasons previously stated.

Recommend that the next to the last bullet point under "Sterilization Containers" read, "Instructions for maximum mass and distribution of contents, stacking patterns, etc.

Page 24., Checklist

Same comment as to Shelf-life on page 21, i.e., add "if applicable".

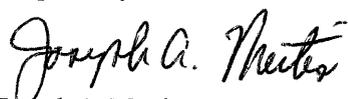
Page 25, VI References

Comment:

ASTM 1670 and ASTM 1671 continue to be used as references with respect to packaging while their intended purpose is for use with protective clothing. FDA is requested to make comment as to the relevance of these standards with respect to packaging.

Please feel free to contact me at 847-785-3310, if there are any questions concerning our comments or if further clarification is required.

Respectfully,

A handwritten signature in black ink that reads "Joseph A. Mertis". The signature is written in a cursive style with a horizontal line underlining the name.

Joseph A. Mertis
Director, Regulatory Affairs
Allegiance Healthcare Corporation

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