



Society of Gastroenterology Nurses and Associates, Inc.

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March 9, 2000

Docket No. 00D-0053
Dockets Management Branch,
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

To Whom it May Concern:

The Society for Gastroenterology Nurses and Associates, SGNA, favors the adoption of the draft guidelines Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme. There are, however, a few areas with which we are concerned. These include the following:

1. The exclusion of non-hospital health care facilities:

Many endoscopic procedures and surgeries are being performed in the outpatient setting in ambulatory facilities that are not hospital owned or operated. These facilities should be held to the same standard as a hospital. In addition, many endoscopic, plastic surgery, ophthalmologic and urologic procedures are occurring in the private office setting. These too should be held to the same standard as the hospital. Devices are being reprocessed in table-top autoclaves as well as by high-level disinfection in these settings. Single-use items should be regulated for these locations as well.

2. The exclusion of hot biopsy forceps and snares in Appendix B:

Device failure during procedures where cautery is used can result in excessive bleeding and/or thermal injury. Therefore, these items should be included as examples of those accessories requiring regulation as high risk devices.

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3. The omission of balloon dilators in Appendix B:

Gastrointestinal balloon dilators, like PTCA and PTA catheters, are frequently contaminated with blood and pose significant risk to patients should they under- or over-inflate. These are also items which should be included as examples of single use accessories requiring regulation as high risk devices.

Thank you for your attention to our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karen I. Laing', written in a cursive style.

Karen I. Laing, RN CGRN
SGNA President

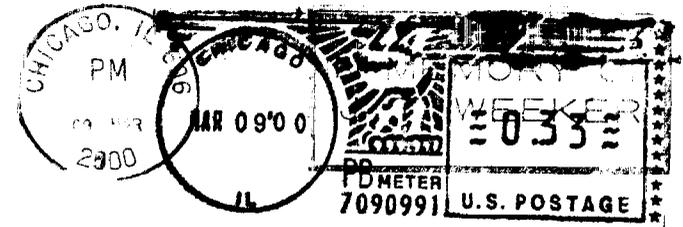
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