



Association of periOperative Registered Nurses

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April 10, 2000

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 208852
Reference: Docket No. 00D-0053

Dear Sir/Madam:

These comments are submitted on behalf of the Association of periOperative Registered Nurses (AORN), reference Docket No. 00D – 0053. AORN is a member organization representing over 43,000 perioperative nurses serving the public by providing perioperative nursing care.

1. AORN supports the Food and Drug Administration (FDA) efforts toward regulating reprocessors of single-use medical devices.
2. AORN favors enforcing all regulatory requirements including Quality Systems Requirements for hospitals and third-party reprocessors as is done for original equipment manufacturers.
3. With the large percentage of surgical procedures being done in the ambulatory/outpatient setting, AORN questions the wisdom of excluding healthcare facilities that are not hospitals from the proposed regulations at this time. More shortcuts are taken and standards breached in outpatient surgery settings, physician-office surgery setting, and clinic-type surgery settings than are seen in hospitals.
4. AORN strongly disagrees with excluding unused but opened single-use devices from regulation. There can be no assurance that the second sterilization and/or subsequent sterilization processes do not compromise product integrity. Processing of these opened but unused devices should be subject to the same requirements as used devices.
5. AORN supports a categorization scheme of low risk and high risk, but does not favor a moderate-risk category as this seems to be a "default" category when there is insufficient information about an item.
6. AORN supports the practice of placing all implants and all uncategorized devices into the high-risk category.
7. AORN respectfully disagrees with your assessment of the drill bit in Example 1 of the document. A dull drill bit results in the surgeon exerting excessive force to drill the bone with the bad bit. If the drill slips off the bone as is sometimes the case when excessive force is used, soft tissue damage including nerve damage can and does occur. Further, in question 2b of the example, it is AORN's opinion that dullness cannot be detected by visual inspection of the drill bit.

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8. AORN supports the proposed phase-in of regulatory requirements based on risk categorization and finds the proposed tie lines to be acceptable.
9. Recognizing the resource limitations at FDA , AORN strongly supports FDA's proposal to use external entities for oversight of compliance with the final regulations when published. AORN respectfully requests the FDA seek out those with the appropriate knowledge and expertise to perform this function. This knowledge and expertise exists with the cadre of persons, often independent consultants, who work with healthcare facilities in the area of processing and sterilization. This necessary expertise does not necessarily exist within present accrediting bodies.

Thank you for the opportunity to participate in this process. We look forward to the final regulation.

Sincerely,

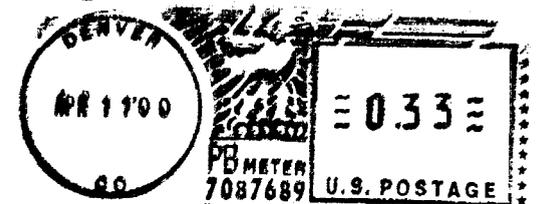
A handwritten signature in black ink, appearing to read "Dorothy Fogg". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

Dorothy M. Fogg, RN, BSN, MA
Senior Perioperative Nursing Specialist
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DMF/ddi



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