



Setting Standards for Excellence

March 23, 1998

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Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
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Rockville, MD 20857

Reference: Docket No. 97N-0477, Medical Devices; Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information

The National Electrical Manufacturers Association (NEMA) appreciates the opportunity to comment on the request for comments and information regarding refurbishers, rebuilders, reconditioners, servicers, and "as is" remarketers of medical devices. NEMA is the nation's largest trade association representing the electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents over ninety-five percent of the nation's manufacturers of x-ray imaging, computed tomography, magnetic resonance imaging, radiation therapy, diagnostic ultrasound, nuclear imaging, and medical imaging informatics equipment.

NEMA members are pleased that FDA is reviewing and considering revising its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and the persons who refurbish, recondition, rebuild, service, or remarket these devices. NEMA believes strongly that any person performing any of these activities which may result in a change to a finished device's performance or safety specifications, or intended use should be regulated in a consistent manner.

As specifically solicited in the request for comments, we have provided the following responses and recommendations to the four questions posed.

- (1) Has FDA appropriately defined the terms, "refurbisher," "as is" remarketers, and "servicers"? If not, what changes to these definitions should be made?

**Response** - No. Each definition contains the phrase "... do not (significantly) change a finished device's performance or safety specifications, or intended use." This presupposes that regulation

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of such entities is unnecessary. It may be that there is no intent to significantly change a finished device's performance or safety specifications, or intended use, but it is precisely the fact that these entities' activities may produce the opposite effect that they should be regulated. Compliance with quality system requirements and other applicable controls will help accomplish the intent.

**Recommendation** - Change each definition to read "... do not intend to (significantly) change a finished device's performance or safety specifications, or intended use."

(2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing? Specific examples should be submitted.

**Response** - It is difficult to give many specific examples of problems that have occurred when there has been no prior scrutiny of remarketing or any regulatory requirement for remarketers to report problems. It is often difficult for manufacturers to determine the source of observed problems because remarketers generally do not place any labeling on the device to indicate it has passed through their hands, and the type of device problems are probably no different than what is normally seen. The frequency of device problems will increase as equipment becomes less traceable due to turnovers in ownership.

In the case of refurbishers, incomplete or inappropriate testing or lack of knowledge of original equipment specifications can lead to potential safety or effectiveness concerns. For example, replacement of components with non-OEM parts requires a level of verification that may not be done adequately or may require the submission of a new marketing application. Promotion of refurbished devices as "meets original manufacturers' specifications" may be inaccurate or misleading to the purchaser.

"As Is" Remarketers may be placing adulterated devices on the market if the devices' performance is substandard due to improper maintenance, misuse or abuse. For example, it is not unusual for device labeling in the form of user or service manuals to become separated from the device when it passes through multiple ownership. Critical safety instructions or proper maintenance may not be applied if the proper labeling is not supplied with the device.

Servicers can cause multiple problems if they are not properly trained. For example, device problems can result from mis-adjustment of safety mechanisms, failure to perform preventive maintenance at the proper intervals, use of improper replacement parts, makeshift modifications to "get it going again", connection of incompatible accessories, and improper assembly.

**Recommendation** - Each type of remarketer should be regulated to the extent necessary to insure their activities do not increase the frequency of serious injury or medical device malfunctions that may result in serious injury.

- (3) What is the appropriate level of regulatory controls that should be applied to persons who remarket devices?

**Response** - Anyone engaged in placing medical devices into use, or restoring them for use, on patients should comply with those medical device requirements promulgated to protect the public health.

**Recommendation** - Those engaged in selling medical devices or services on medical devices should be known to FDA. The devices they handle should bear their identification. They should operate within a quality system to insure their activities are performed in accordance with established procedures to protect the public health. They should take responsibility in investigating and reporting device problems and remedying these problems when attributed to their activities.

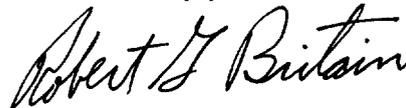
- (4) Should refurbishers, "as is" remarketers, and servicers be subject to the same or different regulatory requirements?

**Response** - It is unclear why FDA should expend resources to develop new or different regulatory controls for remarketers. It seems the most efficient method would be to promulgate a guidance document to advise how existing controls should be applied in accordance with the activities to be regulated.

**Recommendation** - Controls should not be voluntary. Remarketers should register their activities with FDA. They should comply with all applicable parts of the 21 CFR Part 820 quality system regulation and the 21 CFR Part 801 labeling requirements. They should maintain complaint files. They should investigate and report incidents caused by or related to their activities to FDA if they meet 21 CFR Part 803 MDR reporting criteria. They should be required to file marketing applications when their activities meet the criteria for submitting a 510(k) or PMA. They should be subject to controls on corrective actions when caused by their activities.

Again, on behalf the NEMA members, thank you for the opportunity to provide comments for your consideration in the possible regulation of refurbishers, rebuilders, reconditioners, servicers, and "as is" remarketers of medical devices. If you have any questions, please contact me at 703-841-3241 or bob\_britain@nema.org.

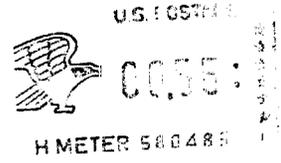
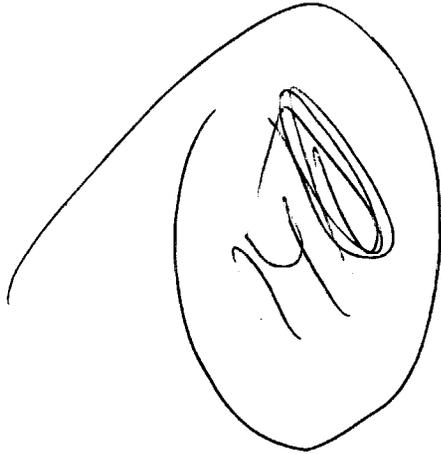
Sincerely yours,



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