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Comment about The CDRH WWW CDRH server:

Docket No. 97N-0477

There is much concern among hospital based Biomedical Equipment Technicians (BMET) as to the inclusion of servicers in this document. I believe that the term is redundant and confusing. The definition of a servicers is essentially a subset of the refurbishers definition. Also the servicers definition makes no reference to the remarketing of a device. As a BMET for 20 years I have serviced many devices yet have never remarketed any.

Ideally, I would like to see all references to the term servicers removed from the document since it appears, to me, that simply servicing a device is outside the scope this proposed rule. In lieu of that, there should be a reference to remarketing of devices within the servicers definition.

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Institutional Review Board

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