Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments
March 4, 2016

Docket Number: FDA-2016-N-0436

Comments from the American College of Clinical Engineering - ACCE
June 01, 2016

The membership and leaders of the American College of Clinical Engineering (ACCE) welcome this opportunity to present the ACCE's viewpoint on the issues raised in this Request for Comments (RFC). Founded in 1990, the ACCE is a voluntary, not-for-profit association representing professionals that support and advance patient care by applying engineering and managerial skills to healthcare technology. The membership of ACCE is comprised of 765 members representing 414 personal members and 351 Corporate and Institutional members. The majority of members are located in the United States; 18% are international members. Further information regarding ACCE may be found on their website at http://accenet.org.

The mission of ACCE is:

- To establish a standard of competence and to promote excellence in clinical engineering practice
- To promote safe and effective application of science and technology in patient care
- To define the body of knowledge on which the profession is based
- To represent the professional interests of clinical engineers

Clinical Engineering is an interdisciplinary profession, based in classical engineering, supplemented with a combination of understanding in medical technology, human factors, systems analysis, communications systems, information systems and computer networking. Clinical Engineers practice in research, design, academia, and most often, in the clinical environment.

While we do not at this point in time fully understand the exact rationale for the FDA's concerns on behalf of the public health relative to medical equipment service, we do consider this to be an important opportunity to help clarify some of the related issues and we hope that you will find the comments and suggestions below to be helpful.

We have organized our comments in the form of responses to the questions posed in **Section II; Issues for Consideration.**

A. **Proposed Definitions of Third-Party and OEM Activities.**

Unfortunately, even within the industry, there is no real consensus on the exact meaning of many of the terms used to describe the entities that you are intending to define. And, somewhat confusingly – even within the industry, some of the key terms are used interchangeably. Except for the terms "remarket" and "remanufacture", we think that the definitions suggested in the RFC are still not sufficiently precise. Below are some alternative definitions that were developed by the AAMI RCM Task Force (see HTM ComDoc 2 "Important definitions" on Page 3 of www.HTMCommunitydB.org). Please note however, that the membership and leaders of the ACCE have not yet formally approved or adopted these particular terms.

There are a number of **basic** maintenance activities, besides repair that we believe should be defined quite precisely and given unambiguous names such as those offered below.

"Repair" – is the restoration of the device to its original level of functional performance and safety after it has malfunctioned or sustained damage. Repairs may or may not include "cosmetic restoration" (which is the restoration, partial restoration, or replacement of any components of the device that do not have a direct effect on the functional performance or safety of the device – see below).

"Cosmetic restoration" – is the restoration, partial restoration, or replacement of those components of the device that do not have a direct effect on the functional performance or safety of the device.

"Device restoration" – is the periodic restoration or replacement of any non-durable (consumable) components of the device that have a direct effect on the functional performance or safety of the device but are not intended to last for the anticipated useful lifetime of the device.

"Safety verification" - is the periodic testing conducted to verify that the device is still functioning properly and meeting the device's original performance and safety specifications.

"Updating" – is the completion of any changes recommended or required by the device manufacturer since the device, or hardware or software components of the device, was originally sold

"Installation" – is the setting of a device, or a hardware or software component of a device, into its proper position and making it ready for use according to the manufacturer's specifications

In addition to these specific maintenance activities, there are several commonly used terms that encompass several combinations of these basic activities. The first two (maintenance and service) are terms that are frequently used interchangeably. The second pair (refurbish and recondition) are terms that are also often used interchangeably within the used equipment marketplace. Currently there are no generally agreed-upon definitions.

"**Maintenance"** – is a broad general term for activities encompassing some or all of the basic maintenance activities listed above that keep a device in good condition, in proper working order and completely safe to use. It is the "maintenance" part of the ubiquitous phrase "maintenance and repair".

"Service" – is a term that is sometimes used in the same way that others use the term "maintenance". The two terms appear to be synonyms.

"Planned maintenance" (also known as PM, preventive maintenance, periodic maintenance, or scheduled maintenance) - is made up of a combination of two of the basic maintenance activities; **"device restoration"** and **"safety verification".**

"Refurbish" – is a term generally used by remarketers to describe maintenance activities performed on devices that are being "remarketed". Ideally, all used devices that are being "remarketed" have also been "updated" with respect to any outstanding recalls. To help protect buyers of used equipment we would like to suggest that the FDA consider requiring disclosure to the purchaser if the device has not been fully updated with respect to any outstanding recalls when it is being remarketed by requiring that the device be described as "not fully refurbished" or "only partially refurbished".

"Recondition" – is a term that is also used by remarketers in the same way that they use the term "refurbish". These two terms also appear to be synonymous.

In addition to the maintenance activities described above, there are the following maintenance-related activities – already defined in the RFC - that are also in fairly common usage. Our recommended definitions are very similar to those in the RFC.

"Remarket" – means facilitating the transfer of a previously owned device from one party to another by lease, sale or donation.

"Remanufacture" – involves making changes to a device that significantly alter its original performance specifications, and/or safety specifications, and/or its intended use. A remanufactured device is essentially a different device from the original, and for regulatory purposes it is treated as such.

B. Evaluation of the Risk Associated With These Third-Party and OEM Activities

1. Who are the different stakeholders involved with the medical device activities listed previously? What are their respective roles?

Device manufacturers. Their primary role consists of the design and fabrication of medical devices. They usually manage the FDA approval process and subsequent marketing of the devices. They provide after-sale support and offer post-warranty maintenance services for the devices. Some manufacturers contract with ISOs for post-warranty maintenance services.

Device owners and users**.** Their role is putting the devices into clinical service. They are responsible for keeping the devices in proper working order during the time that the devices are in clinical use. This usually requires ensuring that the devices conform to the safety requirements of the institution or organization in which they are being used. The owners and users are responsible for ensuring that the devices receive adequate maintenance and repair services.

In-house (IH) servicers. These individuals are usually employed by the institution or organization in which the devices are being used. They play an important role in having responsibility for balancing the cost and effectiveness of the maintenance of the organization's entire inventory of medical devices, as well as ensuring that the safety of the equipment is maintained at the highest possible level. This entity may consist of one or two individuals or it may be a bigger group. Either way, these people are Healthcare Technology Management (HTM) professionals who either perform the required maintenance and repair services or contract for, and oversee, such work when it is provided by others. To comply with the Human Resources standards of The Joint Commission in-house servicers must meet the qualifications established by their institution.

Independent service organizations (ISOs). These stakeholders offer a variety of maintenance services including repair parts and other maintenance supplies. They range from small, local businesses to large, nation-wide or international businesses. They do not manufacture the devices they service. They sometimes specialize by offering services for only a limited range of devices, such as certain brands of anesthesia machines. They usually provide services that are cost competitive with those offered by the equipment manufacturers. Some ISOs offer contracted on-site services replicating the role of in-house servicers. To comply with the Human Resources standards of The Joint Commission, the employees of the ISO must meet the qualifications established by their employer.

Multi-vendor servicers (MVSs). These stakeholders are manufacturers of medical devices who also service devices made by other manufacturers. The devices they offer to service are often in competition with the devices they manufacture. The maintenance services they offer are very similar to the services provided by ISOs.

Independent vendors of repair parts and other maintenance supplies. These stakeholders sell repair parts and other maintenance supplies. They range from small, local businesses to large, nation-wide businesses. They do not manufacture the devices for which they provide parts and supplies and in many cases they acquire the parts they resell from the same sources that the manufacturers use. The items they sell are usually cost competitive with those offered by the equipment manufacturers.

Refurbishers (aka Reconditioners). These stakeholders specialize in restoring used medical devices for resale as an alternative to new devices to clinical users with budgetary constraints.

Remarketers. Facilitate the transfer of a previously owned device from one party to another by lease, sale, or donation. Sometimes these entities are not-for-profit, humanitarian organizations that are motivated by the lack of technology-dependent medical services in impoverished parts of the world. Sometimes remarketers also act as the device refurbishers; sometimes they contract with others for the refurbishment services.

Remanufacturers .. build what are essentially new devices using substantial pieces of existing used devices. For example, some "new" sterilizers are created by combining upgraded electronic controls with pressure chambers cannibalized from existing used sterilizers. The brand name on the "new" device is that of the remanufacturer, not the original manufacturer of the pressure chamber.

2. **What evidence exists regarding actual problems with the safety and/or performance of devices that result from these activities? Specific examples should be submitted.**

We have no knowledge of any statistically significant level of safety problems resulting from the activities of any kind of maintenance/ service provider.

In 1998, staff from ECRI Institute made a very thorough search of the FDA's medical device reporting (MAUDE) database and ECRI's own records of reported incidents. This revealed an extremely low level of reported adverse incidents that could be attributed to medical device maintenance activities. We understand that ECRI has committed to updating this search to investigate the level of incidents during the time since the original study, and we assume that, when completed, they will report on their updated findings.

According to our research, it appears that there have been only four other systematic studies of possible maintenance-related incidents since the time of that first report by ECRI. (See the annotated listing in Attachment 1). All of the studies have reported very similar findings – i.e. that there is virtually no evidence of a substantial safety risk from poor or inadequate maintenance.

Even unsubstantiated or uninvestigated anecdotal reports appear to be very rare. However, even if there have been occasional events in which some patient injury was attributable to the occasional servicing error, we do not believe they represent enough justification for sweeping regulatory changes that would have an adverse impact on the cost of the nation's healthcare.

According to one of our members who until quite recently had been an executive with responsibility for customer service for one of the larger ISOs, when the question of service provider competence is posed to device users during routine evaluations of medical equipment maintenance services, the device users typically express no concerns whatsoever because of the lack of evidence of patient incidents due to maintenance failures or omissions. Based on this report we anticipate that the FDA will receive very little feedback from the device-user community, and we suggest that this lack of response be interpreted as a lack of adverse experiences rather than a lack of interest. We also want to point out that there are two significant restraining forces already present in the healthcare marketplace. First, there are the maintenance mandates issued by CMS and codified by its accreditation organizations (such as The Joint Commission - TJC) into standards that must be complied with by every accredited healthcare organization. The overwhelming majority of hospitals are accredited. Institutions already must ensure they employ or contract for qualified staff and assess the competency of those individuals on an annual basis. This existing standard guards against the use of unqualified equipment servicers.

The second restraining force is the fear of litigation. Healthcare organizations and clinicians are acutely aware of the potentially severe financial repercussions from litigation if they do not maintain their medical devices in a responsible manner. The maintenance and safety standards from CMS, the accrediting agencies, AAMI's standards, and the device manufacturer's published maintenance procedures help provide a very adequate definition of what is expected.

Yet another study, reported in 2009 (Ridgway M, Atles L, and Subhan A; *"Reducing equipment downtime; a new line of attack"*; in the Journal of Clinical Engineering; 34: 200-204; 2009) points out that about 97% of most medical equipment failures are attributable in about equal parts to inherent failure modes, such as mechanical and electronic failures, and process-related failure modes, such as the device being dropped or improperly applied by the user. We applaud the importance that the FDA has placed on improving the application of human factors and usability engineering to medical devices. We believe that this will reduce the number of apparent device failures. We also applaud the changes the FDA is introducing to improve post-market surveillance of medical devices and believe that these improvements will allow everyone to get better data about the number of true device failures and the root causes behind those failures. Until these highly desirable process improvements have been fully assimilated, we believe it would be premature to make any substantive changes to the current arrangements for servicing medical device systems.

3. **What are the potential risks (patients/users) and failure modes (devices) introduced as a result of performing the previously defined activities on medical devices? Please speak to issues common to all devices as well as specific risks with specific devices.**

   Based on the evidence available to us, there are relatively few failure modes related to device maintenance activities compared to the number attributable to the processes surrounding the use of devices in typical clinical environments; and inherent shortcomings of the design and construction of the devices themselves. Both the process-related failure modes and the design/ construction failure modes result in much greater potential risks to patients and users than do maintenance-related activities because of the relatively large variety and number of devices and the much larger number of patients potentially affected.

4. **These activities are performed by OEMs and various third-party entities, including hospitals and humanitarian organizations. Are the risks different depending on who performs the previously mentioned activities?**

   There seems to be very little, if any, evidence of any difference in the risks associated with the various maintenance activities performed by the different stakeholders. From the reports and discussions surrounding and after the 1997 ANPR we are only aware of anecdotal allegations that there were remarketers who do not diligently disclose that some refurbished devices had not been brought up to like-new levels of device performance and safety, even though they had been made to look like-new cosmetically. We know of no tangible evidence of the extent of this practice as a potential safety issue in more recent years.

   Maintenance and service activities do require adequate information, and in some cases access to parts or software, in order to be performed properly. Our concern about lack of access to service information and software is explained more fully in in our response below to item B6.

5. **We are interested in knowing if these activities are more difficult or riskier to perform on certain devices versus others. Please cite specific examples in your response, along with an explanation of the source of this particular complexity**.

   Of course some medical devices are more elaborate and technically more complex than others. And some are highly critical in the sense that the severity of the outcome of a device failure is potentially greater. For example, some devices are characterized as life-support devices because their failures can be life threatening. Examples include critical care ventilators that take over the breathing function of paralyzed patients, and defibrillators that could fail to resuscitate a patient in cardiac arrest if they should fail while in use. It is to be hoped that these more critical devices are scrupulously manufactured to have a high level of inherent reliability and that the manufacturer has provided enough information to allow all who might be servicing the device to sustain its aftermarket reliability.

There are some devices that combine this potential for high-severity failure outcomes with a fairly high level of technical complexity, and they are frequently given priority for being maintained by the manufacturer. This is often considered to be prudent on the part of in-house servicers and ISOs for reasons driven by the perceived higher potential for liability.

There is one other class of medical device that is particularly challenging to maintain, and that is devices that are dependent on an extensive or complex level of embedded or connected software, unless the manufacturer has intentionally designed the device so that it can be supported by third party entities. In some cases these devices are challenging to maintain, not because of their complexity, but because of restrictions on access to training and service manuals imposed by the manufacturers, or because of a contractual restriction imposed when it is sold that only the manufacturer can service the device. Examples of devices that are sold with this contractual restriction are some surgical robots and surgical navigational systems.

6. **What information do third-party entities need in order to perform these activities in a way that results in safe and effective operation of the medical device? Please provide specific examples**.

At a minimum, third-party entities require enough information to verify that devices are functioning safely and meet essential performance specifications after repair activities. Third party entities also need enough information to perform the service/ maintenance activities safely. When the manufacturer believes third party service is not prudent for safety reasons - and therefore recommends that service/ maintenance activities be performed only with certain specialized test instrumentation, and/or only with certain manufacturer-supplied parts; the manufacturer should be required to fully disclose the safety rationale for those recommendations.

Unfortunately, at this time, some manufacturers make strong recommendations that all service and/or all parts should be provided only by the manufacturer without providing any substantial safety-based rationale. This creates a strong impression that the manufacturer's motivation is largely self-serving in terms of service revenues.

7. **What additional challenges do stakeholders encounter with devices that result from these activities?**

In addition to the very important need for consistently formatted, practical safety testing and functional verification procedures, we feel that patient safety would be enhanced if the device manufacturers would make more readily available - and at a reasonable cost - all necessary repair parts, thorough repair documentation, and "factory" training. In addition to these items there is one other issue that is particularly important to current device owners, and that is continued support for earlier versions of devices that the manufacturer

has declared “obsolete” - and no longer supports with parts or repair services. Sometimes this seems to happen quite quickly after a new version of the device appears in the manufacturer’s catalog and appears intended to drive new sales.

With respect to the issue of requiring “manufacturer-certified” parts, except for instances where the manufacturer can supply a reasonable rationale we would like to make a case for legitimizing the use of alternate non-manufacturer made parts that are “certified” after installation by performing appropriately rigorous safety and performance tests. Proprietary manufacturer-certified parts are usually significantly more expensive than comparable parts obtainable from other reputable sources. If an alternate part restores the device to a *demonstrably safe level of performance* it would seem that there is no case for making it be an exclusive, proprietary requirement.

In summary, we do feel that there is much to be gained by redefining many, if not all, of the proposed maintenance terms more precisely. We have offered our suggestions. And because of the lack of credible evidence of problems associated with device maintenance services provided by third party entities we believe that there is simply no rational justification for any action that would increase, by any amount, the overall cost of maintaining the nation’s medical equipment.

We thank you for this opportunity to offer these comments. We believe that the suggestions we have made provide a sound basis for a coherent, effective and cost-efficient approach to ensuring the highest possible level of medical device safety in the nation’s healthcare marketplace.

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Attachment 1

There appears to have been only five systematic studies since 1998. They are listed below in chronological order:

1) ECRI, " Is There Evidence of A Problem", 1998. This is a study of ECRI's Health Devices Alerts and FDA's MAUDE databases performed by ECRI and presented at the AAMI/FDA Conference in September 17-18, 1998.

2) UK-MHRA Report on Devices Adverse Incidents in 2010. Although this study was conducted in the UK, the devices deployed in that country and the quality of MHRA investigation process are similar to those found in the USA. The Medicines and Healthcare Products Regulatory Agency (MHRA) is an executive agency of the Department of Health in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe. After investigating each adverse incident, an MHRA device specialist uses its standard category list to record the outcomes of the investigation (i.e., primary causes of the incident). Figure 8 of that report compares the conclusions of outcomes for the three-year period of 2008-2010 for eleven primary causes. This figure shows that "improved maintenance" is the 10th—i.e., least significant—cause, accounting for a far lower percentage of reports than those traceable to manufacturers (e.g., design, label or packaging change; manufacturer notice; improved QA; field safety action; other manufacturer field action; and production ceased). This report is available at http://www.fdanews.com/ext/resources/files/archives/c/con129234.pdf. (Accessed 4/29/2016).

3) Survey conducted by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of TJC in 2012. This survey with 1,526 responses did not uncover any sentinel events caused by maintenance "omissions". These results have not been published but were presented by TJC Director of Engineering, George Mills, at the AAMI 2012 Conference & Expo, so a copy of his presentation can only be obtained by sending a request to him at GMills@jointcommission.org. A summary of the results is mentioned in the article #4 cited immediately below.

4) Wang B, Rui T & Balar S. "An estimate of patient incidents caused by medical equipment maintenance omissions", Biomed Instrum & Techn., 47:84-91, 2013. This article reports the results of an analysis of The Joint Commission's Sentinel Events database accumulated between 2004 and 2011. It concluded that sentinel events that could be caused by maintenance omissions ranged between 0.140 and 0.74 in 2011, which translates to 0.00011- 0.0006 per million equipment uses or 7.58 - 7.85 sigma. (As the original article is copyrighted by the publisher (available at http://pinnacle.allenpress.com/doi/abs/10.2345/0899-8205-47.1.84), it is not included in this document; however, the article's abstract is available online at http://www.ncbi.nlm.nih.gov/pubmed/23432570

5) Fedele J & Wang B, "How to Comply with the Revised Equipment Management Standards issued by CMS and TJC", presented at MD Expo, Orlando FL, Oct 2, 2014. Among other topics presented, an analysis of a decade of incidents involving equipment managed by Aramark Healthcare Technologies was reported. This analysis showed only 6 incidents in 10 years, out of an inventory that averaged almost 1 million/year, was traced back to maintenance omissions. Those 6 incidents were caused by "active failures" committed by individuals in three different stakeholder categories. The results can be summarized as 0.26-0.35 errors per million equipment items serviced or 6.46-6.52 sigma.