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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***RE: Docket No. FDA-2016-N-0436; Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments***

Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to the Food and Drug Administration's (FDA's) Federal Register Notice requesting comment on refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices performed by third-party entities and original equipment manufacturers.

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed's members manufacture and service their own products as original equipment manufacturers (OEMs) and some may also provide preventive maintenance and repair services for products made by other companies.

AdvaMed offers both general comments and specific comments in response to the proposed definitions and questions in the Federal Register Notice below.

## **General Comments**

AdvaMed supports the FDA's effort to obtain information and comments on the issue of refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices by third-party entities and OEMs.



We should note at the outset that many OEMs make replacement parts for their devices available to healthcare facility biomedical technicians, distributors, and other third-parties. Many OEMs similarly publish maintenance or service manuals or make them available for sale. OEMs may also offer training or certification to third-party individuals or third-party service entities to service OEM equipment. Other OEMs may service their own equipment or may not make service manuals public as this could result in disclosure of proprietary, confidential, commercial trade secret information to competitors. And as noted above, many OEMs provide preventive maintenance and repair services for other OEMs. In short, there are a variety of business approaches and models, all of which are appropriate and designed to ensure that products are safe and effective for patients.

AdvaMed has three over-riding concerns:

- Medical device repairs are being performed by untrained, unqualified<sup>1</sup> personnel who may not be using the necessary specialized equipment or who may not be performing appropriate calibration and testing to ensure the product is safe and effective before it is returned to use;
- Medical device replacement parts, components or subassemblies of unknown provenance (e.g., potentially salvaged from non-functional equipment) or manufactured by third-party entities which claim compatibility with OEM devices, are available on the open market and are being used in the service and repair of devices. Repairs by untrained, unqualified personnel potentially lacking access to the necessary calibration or other repair equipment can either be performed by healthcare providers such as hospitals, home healthcare providers and other specialized facilities or by third-party service providers that specialize in device repairs. Health care providers and third-party service organizations are able to purchase aftermarket, non-OEM parts from a variety of sources online, advertised in trade journals, etc.; and
- Medical device repairs are being performed without required compliance with core servicing standards to which OEMs are held under 21 CFR Part 820 and which AdvaMed believes is essential for the safety and efficacy of regulated medical devices. Such practices include but are not limited to: Personnel Controls (including the initial and ongoing training of personnel), Design Changes (and the strict implementation of only those changes authorized by the OEM), Document Control, Calibration of Inspection and Test Equipment, Control of Non-Conforming Product, and Servicing.

All three situations have the potential to significantly impact patient safety and to impact the safety and effectiveness of devices. In fact, failure to appropriately repair devices and the use of

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<sup>1</sup> Throughout this document, AdvaMed uses the term non-OEM-qualified or unqualified third-party to encompass all of the activities referenced in the Federal Register Notice (i.e., refurbish, recondition, rebuild, service, repair).

non-OEM replacement components has been directly linked to serious adverse events requiring medical intervention and are directly linked to numerous adverse events which have been submitted as Medical Device Reports (MDRs) by AdvaMed member companies.

Often, problematic repairs or non-OEM parts are discovered serendipitously by the OEM. One common scenario is that a device has a difficult-to-repair failure and is sent to the OEM for repair. The manufacturer may then discover forensics logs (“black box”) showing unauthorized repairs or mis-matched serial numbers demonstrating use of non-OEM or salvaged parts.

It is not unlikely that adverse events related to repairs by untrained, unqualified personnel or non-OEM replacement parts are going unnoticed or are undercounted. It can be difficult to assess the potential impact to patient safety because if there is a patient event or a near-miss, it may not be obvious to the health care provider or facility how the adulterated product contributed to the event. These patient events may not be reported to the OEM.

For these reasons, AdvaMed believes that refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices whether performed by OEMs or performed by third-party entities should generally be subject to FDA regulation and oversight via key elements of the Quality System Regulation (QSR) (21 CFR 820). Based on a risk-based approach, certain elements of the QSR may or may not be applicable depending upon the nature of the activity being performed. OEMs are subject to *all* the requirements of the QSR. Of note, if an OEM used parts from an unauthorized supplier or relied upon untrained personnel to perform service and repair activities on its own devices, the affected products would be considered adulterated and would potentially be subject to field action. To consistently apply the QSR to third-party entities, language modifications would likely be needed. As FDA considers this topic, we encourage FDA to follow Paperwork Reduction Act requirements which include notice and comment and economic impact analyses.

Some have argued that OEM servicing and repairs increase the costs of health care delivery because OEMs use service and repair contracts as a profit center. OEM service and repair costs are generally higher than those of third-parties because OEMs must follow and adhere to the regulatory requirements of 21 CFR 820. The Agency requires OEMs to follow the Quality System to ensure the safety and effectiveness of devices for patients. It seems that Quality System Requirements and safety and effectiveness of devices should be equally applicable with respect to third-party repair and refurbishment. Attachment A includes the key elements of 21 CFR 820 that we believe should apply to third-party service repair entities.

## **Specific Comments**

### ***AdvaMed Comments on Proposed Definitions***

FDA asked for assistance in defining terms related to third-party refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing of medical devices. AdvaMed provides our comments on FDA’s definitions below. We would also note that third-party service providers may use multiple terms to describe the types of activities they perform, not all of

which may be captured by the below definitions. If FDA decides to take action in this area, it should make clear all like activities are intended to be covered whether specifically referenced and/or defined or not.<sup>2</sup>

**FDA definition of recondition as modified:** ~~Restores and/or refurbishes a medical device to the OEM's original specifications. Under limited circumstances the medical device may be restored and/or refurbished to current specifications.~~

And

**FDA definition of refurbish:** Restore device to a condition of safety and effectiveness that is comparable to when new. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

**AdvaMed comment:**

AdvaMed believes that given the similarities between the FDA proposed definitions of recondition and refurbish and the fact that both definitions are defined by the other term (i.e., the definition of recondition includes refurbish and the definition of refurbish includes reconditioning), only one term and corresponding definition is needed. We recommend retaining the term “refurbish.” We would note, however, that there is ambiguity as to what “comparable to new” means, i.e., is it “new” at the time of manufacture or as updated by the OEM? Similarly, if FDA retains the definition of recondition, there is ambiguity around “under limited circumstances” i.e., when would devices be reconditioned to original specifications versus current specifications?

**FDA definition of repair:** Return the device or component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

**FDA definition of service as modified:** ~~Preventive m~~Maintenance or repair of a finished device after distribution for purposes of maintaining it within or returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

**FDA definition of remanufacture:** Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance, safety specifications, or intended use.

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<sup>2</sup> For example, FDA referenced the term “rebuild” in the title of the Federal Register Notice but it is not proposed to be defined. Third-party service providers could then argue that FDA does not intend to regulate rebuilding.

**AdvaMed comment:** AdvaMed agrees with the FDA definitions of repair and remanufacture. We believe the definition of service should be modified to incorporate the concept of preventive maintenance i.e., preventive maintenance or repair of a finished device after distribution for purposes of maintaining it within or returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

**FDA definition of remarket as modified:** The act of ~~facilitating the~~ transferring of a previously owned medical device from one party to another by sale, donation, gift, or lease.

**AdvaMed comment:** AdvaMed recommends removal of the term “facilitate” because it implies the use of “brokers” or third-parties who refurbish or remanufacture medical devices. Under the FDA definitions of refurbish or remanufacture, these devices must meet certain safety and effectiveness requirements. However, not all remarketed devices meet safety and effectiveness requirements. For example, used medical devices may be sold on e-Bay without any entity ensuring the safety and effectiveness of the device. The essential issue is that remarketing results in the transfer of a used medical device. If FDA decides to take action in this area, it should ensure that minimum safety and effectiveness standards govern all device remarketing. Some third-parties are significantly modifying OEM devices and then reselling them – typically on the internet (e.g., via eBay) – with no guarantee of safety or performance. It is unclear whether these entities are remanufacturers who are failing to follow FDA regulations or remarketers. This is extremely concerning and we believe FDA should address these remanufacturer and remarketer issues.

### ***AdvaMed Responses to Questions Posed in the Federal Register Notice***

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

**AdvaMed response:** There are multiple stakeholders that either play a role or are impacted by refurbishment, reconditioning, servicing, repair, and remanufacture of medical devices. They include the following:

##### ***Patients***

Patients are the ultimate recipients of the intended use and benefit of the devices provided by clinicians.

##### ***End Users (Health Care Providers, Health Care Facilities, Patients and Caregivers)***

Health care providers, patients and caregivers have expectations regarding medical device functionality and performance based on the intended use of the device as described by the manufacturer.

***Original Equipment Manufacturers (OEMs)***

OEMs design and manufacture medical devices, perform device service and repair on their own devices, record data into Device History Files (DHF), and analyze trends in data (including postmarket complaints and adverse events). Under the QSR, they ensure that all devices meet current specifications and that all corrections are properly documented and reported in the DHF and/or Device Master Record. OEMs must consider, evaluate, and recommend anticipated service activities and the repercussions of these activities on device life.

***Qualified Third-Party Service Providers (i.e., Authorized, and Contracted Service Organizations or OEM-Affiliated Partners)***

Qualified or authorized service providers (also known as OEM-affiliated partners or contracted service organizations) service and repair medical devices under a supplier agreement or contract with the OEMs. This includes training in product service, appropriate access to documentation such as technical service manuals and specifications, authorized purchase of OEM components and/or tools or equipment, and regular information updates regarding product and component changes. These service providers may also act as an OEM agent in the field for installation and service activities and assist with complaint investigations.

***Hospital Biomedical Engineers***

Biomedical engineers conduct performance assessments of devices and may perform varying levels of product service or repair.

***Non-OEM Qualified Third-Party Service Providers***

Unauthorized service providers service and repair OEM medical devices without an OEM service agreement.

***Centers for Medicare and Medicaid Services (CMS)***

As the nation's primary health insurer, CMS establishes appropriate requirements governing coverage and reimbursement for health care services under Medicare, Medicaid and the Children's Health Insurance Program (CHIP). For example, a December 20, 2013 CMS Memorandum on Hospital Equipment Maintenance Requirements allows hospitals to establish alternative equipment maintenance (AEM) frequency or activities which are different from those recommended by the manufacturer for medical equipment, including "critical equipment, i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail." However, CMS does not allow AEM programs for imaging and radiologic equipment.

***The Joint Commission***

The Joint Commission accredits and certifies health care organizations to ensure that performance and quality standards are met in the delivery of health care.

**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.**

**AdvaMed response:** The ability to gather data on this question is difficult because third-party entities are not required to mark the device with their name or to mark the device as refurbished, reconditioned, remarketed, or remanufactured. The end clinical user may not know that the device that failed is from a third-party entity and not from the OEM. In addition, reportable events are listed under the OEM, not the third-party entity.

As we noted in our general comments, it is also not unlikely that adverse events related to repairs by untrained, unqualified personnel or non-OEM replacement parts are going unnoticed or are undercounted. It can be difficult to assess the potential impact to patient safety because if there is a patient event or a near-miss, it may not be obvious to the health care provider or facility how the adulterated product contributed to the event. These patient events may not be reported to the OEM.

Many OEMs do not have coded complaint analysis findings with the relevant key terms (e.g., refurbish, remanufacture, non-OEM parts, etc.) to appropriately assign MDRs to third-parties. However, where evidence is clear, numerous adverse events have been submitted as MDRs by AdvaMed member companies related both to use of third-party parts or components and unqualified service on devices.

Over the course of just three years, AdvaMed has become aware of at least 137 MDRs for just three medical device product categories. This, despite the fact that it can be difficult for OEMs to become aware of or to detect third-party repair problems (as discussed in more detail below).

Companies have reported that their records indicate that, for devices refurbished by a third-party, or repaired with unauthorized components, the mean time between device failures is less than for new devices or those devices refurbished by an OEM-qualified partner. They may also have new or more risky failure modes. Additionally, devices refurbished by a third-party require more preventive maintenance attention than those refurbished by an OEM or an authorized partner.

We also understand that unqualified service providers may assemble devices from gray market or cannibalized components resulting in non-standard device configurations.

As a means of highlighting the serious nature of these adverse events, two infusion pump examples and a ventilator example include:

- Use of a non-OEM part to repair an infusion pump. The device was subsequently used on a patient, and use of the non-OEM part led to unregulated flow (over infusion) causing serious patient harm and transfer to a higher level of care.
- An unqualified repair was performed on an infusion pump, and the repair was performed incorrectly. The device was subsequently used on a patient, and the incorrect repair

resulted in an over-delivery such that an 18-hour opioid infusion was completed in less than 3 hours.

- A ventilator worked on by a third-party contributed to two deaths. Internal components were contaminated with a significant amount of dust and dirt particulate and the main inlet filter for the compressor was missing. Multiple components in the device had been replaced with modified parts some which were not OEM designed. Additionally, component modules were poorly assembled and loose connections were detected. Error and alarm logs specific to the incidents had been over-written. Although this example occurred OUS, there is nothing that prevents these same types of issues occurring in the U.S. Additionally, nothing prevents a device that was repaired or refurbished OUS from being sold via the internet for use in the U.S. market.

Additionally, there can be significant performance-based and safety concerns related to the utilization of unqualified service providers. If non-verified parts or configurations are added to a device, the previously validated performance of the device now becomes unknown. While some of these performance issues may be easily recognizable, there will be significant concern surrounding unknown or unexpected performance either immediately after or over time following service by an unqualified third-party. Various examples of safety and performance-related issues follow:

- Non-OEM motor controllers (e.g., large and small bone orthopedic handpieces) have allowed too many amps to be demanded from the battery, which in turn compromised the OEM fuse and resulted in permanent damage to the battery. With a damaged battery, the device may either stop working completely or may have a significantly reduced use time.
- Non-OEM motor controllers leak exhaust, likely from an internal component failure and due to lack of an adequate seal. The failure to seal likely leads to moisture entering the device, contributing to component failure. Use of a device leaking exhaust during a sterile surgical procedure would be a significant concern.
- Due to poor design, non-OEM motor controllers can pinch internal 10v + wires which can result in permanent damage to the OEM battery. Even though the handpiece continues to perform after the event, this creates a difficulty when the damaged battery reaches the charger. Users will continue to replace batteries without understanding that the handpiece is faulty.
- Use of non-OEM insulation to repair a PEEK (polyether ether ketone) Multifunction Handle can lead to additional cracking and potential for patient harm. MDRs are conservatively filed for potential adverse consequences due to arcing caused by a breach in insulation.
- Non-standard greases have been found inside of bearings and assemblies after non-OEM repairs. The grease utilized by OEMs is developed in coordination with the OEM



bearing engineering manufacturers to ensure the correct grease is chosen for delicate device components. Non-standard greases can result in overheating of the device, potentially during use on a patient. Additionally, all greases utilized in OEM attachments are chosen to be biocompatible – the biocompatibility of non-OEM greases is unknown.

- Scopes repaired by non-OEMs fail after certain sterilization methods due to improper repair and lack of sealing and may result in poor image quality. Furthermore, shaft and distal end repair using improper replacement parts and bonding agents obstruct visualization and prevent the scope from producing a diagnostic image. This may extend the procedure, require a repeat procedure or result in misdiagnosis or improper sterilization.
- Issues with refurbished laparoscopic ultrasonic device handpieces include parts shearing off during a surgical procedure, as well as connectivity issues with the generator, and failure of the device to operate.
- A potential performance example includes compression devices to prevent deep vein thrombosis. Third-parties who are unaware of the pressure ranges in the controller could inadvertently allow for reverse gradient if pressure in the calf is higher than in the ankle.
- Radiation exposure to operators and patients.

**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.**

**AdvaMed response:** In general, risks can include: increased safety and performance issues; devices being used in unapproved or uncleared configurations; devices lacking mandatory quality or reliability updates or containing device modifications, all of which may impact the safe use or function of the device. As a result, the product may be altered from what was initially cleared or approved (i.e., the device is in effect remanufactured for which a submission may be required) or it may be adulterated or misbranded. Modifications of device configurations can also nullify certification labeling such as UL or CE mark resulting in a mislabeled product.

Activities by unqualified third-parties could also cause unintended interactions between hardware timing circuits and software/ firmware timing responses within a device that is in an unapproved OEM configuration. Non-approved OEM configurations can result when substituting parts from one OEM-approved and tested configuration into a different OEM-approved and tested configuration. These types of changes may go undetected with a device passing functional testing and operating normally in a nominal mode. However, when the device is operated at its edge conditions, non-approved configurations may stress both component and timing interactions causing unpredictable device behavior or reliability issues. Testing of edge

conditions is conducted by the OEM during the design and approval of configurations; however, this level of stress testing is typically not done as part of routine maintenance or repair testing and would not be included in service documentation.

***Risks to Patients***

Potential risks to patients include longer surgeries with potential for increased infections, more blood loss, delays in treatment, incorrect diagnoses, and other serious injuries or death. The use of unauthorized components or repairs conducted by unqualified service providers can result in failures and reliability issues. These failures are a result of components and mechanisms that do not work as designed and were not verified by the OEM.

Potential failures and risks to patients or users for infusion pumps include:

<b>Failure Modes</b>	<b>Risk to Patient/Users</b>
Infusion delivery mechanism failures	Over or under infusion
Incompatible software with hardware resulting in product malfunctions	Delay or interruption in patient therapy
Incompatibility between pump components and dedicated IV sets	Over or under infusion, failure to alarm
Circuit failure/damaged components resulting in product malfunctions	Delay or interruption in patient therapy Device overheating
Premature wear of components or physical damage to the device resulting in pump malfunctions	Delay or interruption in patient therapy Over or under infusion
Keypad failures resulting in data entry errors	Over or under infusion
Rate accuracy errors due to components out of calibration/tolerance	Over or under infusion
Occlusion detection failures	Delayed clinical response or interruption in patient therapy
Battery or power system failure	Delay or interruption in patient therapy
Remanufacturing/refurbishment sometimes involves disassembly processes such as breaking adhesive bonds or ultrasonic welds which can add major stress to the product and increase the risk of mechanical failures	Delay or interruption in patient therapy

Improper servicing of diagnostic imaging equipment by unqualified third-parties can lead to oil leakage due to incorrect assembly or repair which can cause serious patient harm, electrical safety issues, and the risk of contamination. The risk is even greater during interventional cardiovascular procedures where loss of image can have serious consequences for the patient.

For handpieces and scopes, failure to perform within the intended performance range or other malfunctions can extend the duration of the surgery, or require additional procedures (either during or after the surgery). Failure modes can include mechanical or electrical failures as a result of mixing newer replacement or component parts with worn components. The subsequent effect on the tolerance stack-up may present failure modes that were not anticipated when designing use of all new or un-worn components. These effects can be exacerbated by the use of repair or replacement parts that do not meet the geometric dimensioning and tolerancing (GD&T) of the OEM design. Similarly, the use of un-validated lubricants or other such chemicals can impact electro-mechanical performance. Lastly, sterilization failures can occur due to gaps and crevices created during repair and could result in patient infections.

We are aware of a grey market for reprocessed integrated circuit components (ICs) that are recycled by removal from discarded printed circuit board assemblies (PCBAs). These ICs are available as replacement parts and can be purchased through component distributors or brokers who do not have traceability of the materials. These items may also be counterfeit. Manufacturers typically utilize qualified electronic component suppliers for procurement of electronic components whereas third-party entities may scavenge parts.

We are also aware of situations in which third-parties scavenge PCBAs or modules from other non-functioning units. Third-parties are unable to ensure that these components are not degraded or defective. Degraded or defective components can lead to electrostatic discharge, power spikes or brown-outs and mechanical stresses that can weaken components, solder integrity or electrical connector integrity.

**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?**

**AdvaMed response:** We don't believe it's the "who" performing the repair that is important, rather it's whether the entity has current or up-to-date experience, training and knowledge about the product and its approved configurations, how it was designed to operate, and ongoing design changes and their interactions. Any one of these entities could potentially be qualified as third-party providers if they meet the requirement to stay current.

In contrast to OEMs, third-parties are not required to be trained in all aspects of the device design, manufacture, quality controls, quality assurance, regulatory compliance, clinical efficacy and patient safety for the products they are repairing. Third-parties may not have the training,

specialized equipment necessary or the procedural controls in place to ensure that they meet all of these elements.

We believe risks relate to the thoroughness of the servicing and whether or not the service provider is qualified and uses or has access to manufacturer information and resources, such as instructions, specifications, OEM spare parts and calibrators, etc. OEMs and OEM-qualified servicers are aware of all product changes and compatibilities and test the devices according to current device specifications for the specific product configuration using validated processes. Therefore, OEMs and OEM-qualified partners, by definition, are more equipped to limit the risks associated with service and repair than third-party entities.

There are currently increased risks when unqualified third-parties perform these activities. Importantly, as required by 21 CFR 820, the OEM has the most current Device Master Record which is linked to the original documentation in the Design History File. As a result, the OEM has access to the information needed to make informed decisions regarding risks and benefits to best assure the safety of the device. Reliability information is needed to make decisions for what should be replaced when being serviced. Without reliability information, expected service life is indeterminate. Without access to or an understanding of the OEM's information for delivering the essential requirements and design intent, there is greater potential for risk. When unqualified third-parties perform these activities, they are not subject to the Servicing requirements of 21 CFR 820.200. Therefore, there is no requirement for the unqualified third-parties to analyze service reports with appropriate statistical methodologies and to report events to FDA under 21 CFR 803, as appropriate. This can adversely affect public health as it prevents the OEM and FDA from having important product performance data that could serve as an indicator of a product performance issue that might necessitate a correction or removal.

For comparison, OEM technicians are typically trained by the engineers who designed the product; they conduct repairs referencing documents written by the design engineers and using tools created by the design team. Outside unqualified third-parties may not utilize the latest technical documentation and may have to rely on trial and error or, in effect, experiment with product repair. OEM technicians frequently repair many of the same items a day while third-parties may have limited exposure to multiple types of devices. Some OEM products, such as heavy duty handpieces, require in excess of 90 custom made tools along with a custom programmer. It is not clear how unqualified third-parties are disassembling/reassembling these products and what impact the use of non-custom tools has on product performance and safety.

After repair and reprogramming, retesting is required. Some OEM products use custom retest fixtures or require safety analyzers or high potential electrical safety testing equipment that require significant oversight in order to ensure correct calibration. It is unclear to what degree the correct tools are being used and to what specifications these products are being tested by unqualified third-parties and what impact that may have on product performance and safety.

### ***Third-Party Component Manufacturers and Used Parts***

With respect to components, unqualified third-party component manufacturers do not have the design knowledge or access to the specifications to design, qualify and test replacement components to ensure proper operation under all applicable conditions. Some OEM products utilize custom circuit boards and motors. Cannibalizing or scavenging parts from one product to repair another or reverse engineering the device and building new parts fails to take into consideration that parts work together as a system and are therefore verified and validated as a system. It is not possible to properly dimension one part without understanding the system. OEMs run life testing on the system with the original components and specifications. The impact to performance and safety of replacing a custom component with non-validated components can result in patient safety and performance issues as referenced in our General Comments. In short, per 21 CFR 820, OEMs validate equipment and processes used to manufacture and service products. The use of different equipment/processes and parts constitutes an unknown risk.

**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.**

**AdvaMed response:** In general, we believe the difficulty and risk associated with these activities increases as the devices increase in complexity (for example, a scalpel versus a power tool). Devices obtained from unknown sources (e.g., devices purchased from eBay or scavenged components) with unknown performance history can also increase risk.

As examples, service and repair of high-risk devices such as infusion pumps or ventilators could be considered more risky and difficult than other medical devices. OEMs are continuously making product quality improvements, enhancements and addressing component and material end-of-life issues. The complex mechanical and software nature of critical assemblies within devices, such as an infusion delivery mechanism, requires significant verification and validation when product changes are introduced and this is directly related to the configuration(s) that are qualified. If repairs are performed by unqualified and untrained technicians using insufficient information, or using unapproved components without conducting adequate testing post repair, this can directly result in product malfunctions that may result in death or serious injuries to patients.

Devices which require sterilization or that deliver potentially harmful energy may present significant concerns when serviced by unqualified third-parties. And for certain technologies such as medical optics, the ability to restore full function to parts such as lasers can be impossible or prohibitively expensive. That said, the service of any device presents the potential for its defined safe and effective intended use to be altered if it is not serviced correctly.

**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.**

**AdvaMed response:** in general, third-parties require training, access to proper equipment, approved components, and service manuals related to the level of repairs they are qualified to perform. Importantly, they need to have a quality system in place that includes processes that control purchasing of qualified components, traceability, and device history records for service/repairs, inspections and testing. Third-parties that are qualified by OEMs would have access to appropriate elements depending upon the level of repair they are performing.

More specifically, third-party entities need to know the following in order to perform these activities in a way that results in the safe and effective operation of the device:

- Training related to the level of repair they are performing.
- Access to product specifications.
- Notification and content of product upgrades (e.g., firmware or software updates to remove bugs, hardware updates as a result of correction activities, etc.).
- Release/performance criteria to place the device back into service to ensure its safe and effective operation.
- History of the instrument (cycles, mechanical failures, etc.) to determine if the instrument is beyond its mechanical limits.
- Replacement part history (whether or not known wear parts have been replaced).
- Access to OEM-manufactured or approved spare parts or components.
- Access to specialized repair equipment, custom retest fixtures or calibration equipment.
- Staff certified and trained on the device.

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

**AdvaMed response:** Patients may be unaware that devices – repaired by third-parties – which may not be safe or effective, are being used on them. Moreover, patients (or their insurers) will pay the same price for third-party repaired devices as for new devices or for OEM-maintained or repaired devices.

Health care providers may also be unaware that they are using devices – repaired by third-parties – which may not be safe or effective. Because there are no labeling or marking requirements for third-party serviced devices, patients and health care providers may believe

they are using an OEM-maintained device. Any problems with third-party serviced devices may be inadvertently assigned to OEMs by patients and users via the medical device reporting (MDR) system.

For OEMs and OEM-affiliated partners, device history traceability beyond the manufacturer's records (such as whether updates were implemented, which activity was performed by whom on what date and which device) is a significant challenge. OEMs and OEM-affiliated partners must often correct the inappropriate repairs or damage to the device brought about by third-party entity refurbishment, servicing, and/or repair activities.

OEMs are also required to conduct adequate postmarket surveillance and ensure appropriate complaint processing and trending and MDR reporting in accordance with FDA regulations (as described in our response to Question 4). There are concerns with how an OEM can adequately monitor the postmarket environment and comply with complaint handling, trending and MDR reporting for their devices if others are servicing or repairing product without reporting this information to the OEM and to FDA. OEMs may also not be able to correctly attribute MDRs to the relevant third-party without knowledge of who is servicing the device.

Further, inappropriate servicing by third-parties can result in liability for OEMs and can negatively impact an OEM's reputation, the associated brand equity and the viability of a product in the market.

Sincerely,

/s/

Tara Federici  
Vice President  
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## **Attachment A**

### **Key Elements of 21 CFR 820 Applicable to Third-Party Service Repair Entities\***

#### **820.20 Management Responsibility**

- (a) Quality policy
- (b) Organization
- (c) Management review
- (d) Quality planning
- (e) Quality system procedures

#### **820.22 Quality audit**

#### **820.25 Personnel**

- (a) General
- (b) Training

#### **820.40 Document Controls**

- (a) Document approval and distribution
- (b) Document changes

#### **820.50 Purchasing controls**

- (a) Evaluation of suppliers, contractors and consultants
- (b) Purchasing data

#### **820.60 Identification**

#### **820.70 Production and Process Controls**

- (a) General
- (b) Production and process changes
- (c) Environmental control
- (d) Personnel
- (e) Contamination control
- (f) Buildings
- (g) Equipment
  - 1. Maintenance schedule
  - 2. Inspection
  - 3. Adjustment
- (i) Automated processes

#### **820.72 Inspection, measuring and test equipment**

- (a) Control of inspection, measuring, and test equipment
- (b) Calibration
  - 1. Calibration standards
  - 2. Calibration records



**820.80 Receiving, in-process, and finished device acceptance**

- (a) General
- (b) Receiving acceptance activities
- (c) In-process acceptance activities
- (d) Final acceptance activities
- (e) Acceptance records

**820.86 Acceptance Status**

**820.90 Nonconforming product**

- (a) Control of nonconforming product
- (b) Nonconformity review and disposition

**820.100 Corrective and preventive action**

**820.140 Handling**

**820.150 Storage**

**820.160 Distribution**

**820.180 General Requirements**

- (a) Confidentiality
- (b) Record retention period

**820.186 Quality system record**

**820.198 Complaint files**

**820.200 Servicing**

**820.250 Statistical Techniques**

\*Some of these responsibilities are maintained by the OEM when the third-party is a qualified third-party. Certain elements of the QSR may or may not be applicable depending upon the nature of the activity being performed.