



Division of Dockets Management (HFA-305)

Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

January 21, 2019

Ref: Medical Device Servicing and Remanufacturing Activities  
(Docket No. FDA-2018-N-3741)

Dear Sir/Madam:

This is to submit comments on the medical device servicing and remanufacturing activities, as requested by the Food and Drug Administration (FDA) through the Request for Comments issued on 10/22/2018. This document is divided into 9 sections for ease of reading and reference.

## **I. Introduction of ACCE**

Before providing information and comments, please allow me to introduce the American College of Clinical Engineering (ACCE) so you can understand our perspective on this subject. ACCE was founded in 1990 with the mission of: (i) to establish a standard of competence and to promote excellence in clinical engineering practice, (ii) to promote safe and effective application of science and technology in patient care, (iii) to define the body of knowledge on which the profession is based, and (iv) to represent the professional interests of clinical engineers.

Currently, ACCE has about 1,000 members who work in almost all segments of the medical device universe, ranging from research and development, manufacturing, servicing, regulatory affairs, marketing, consulting, and education. While most of our members are at the manager or higher levels, many of them are still performing hands-on service on medical devices. Some of our members oversee >1,000 frontline service professionals, while others lead smaller teams. Finally, our membership is very diverse in terms of age, sex, race and educational background.

Since its foundation, ACCE has participated in every discussion with FDA on the issue of servicing, particularly the 1997 ANPR (Docket No. 97N-0477) and the 2016 PR (Docket No. FDA-2016-N-0436). ACCE was also invited to present at the Workshop held on December 10-11, 2018.

## **II. General Comments**

ACCE applauds FDA's initiative in clarifying the distinction between servicing and remanufacturing, and support its plan to issue a guidance document to reduce risks of confusion for all stakeholders involved.

As FDA concluded in its Report on Device Servicing<sup>1</sup>, there is no objective evidence that servicing of medical devices has created any significant risk to the public that would justify imposing additional/different, burdensome regulatory requirements. On the other hand, the same report concluded that most of the alleged inadequate “servicing” caused or contributed to clinical adverse events and deaths actually pertain to remanufacturing.

ACCE believes it is useful to have simple and clear instructions for all stakeholders to understand the difference between servicing and remanufacturing. This is because it is possible that some servicers may have inadvertently strayed into remanufacturing in their earnest desire to restore devices to operating conditions in order to enable prompt care delivery to patients. Obviously, ignorance does not justify regulatory violation but the lack of simple and clear instructions can make such unintentional transgressions more common than desired.

### III. Guiding Principles and Flowchart for Distinguishing Servicing from Remanufacturing

ACCE agrees with the FDA proposal that changes to sterilization methods, reprocessing instructions, control mechanism, operating principle, or energy type, and intended use in significant manner should be excluded from servicing.

On the other hand, the Guiding Principles and the Flowchart proposed by FDA in its White Paper<sup>2</sup> are excessively detailed, time consuming and, at times, difficult to implement due to many pieces of information required that is often not available at the time of service. These challenges were almost universally shared by all the participants during the first day of the Workshop when the participants tried to use these tools in examples provided by FDA<sup>3,4</sup> and, thus, will not be repeated here.

ACCE is particularly concerned about overwhelming the staff of both FDA and servicing entities with good but complex tools if they are included in the future Guidance Document. We are apprehensive that if the frontline service staff—regardless of whether employed by OEM, healthcare organization or third party—were required to apply the 5 principles and the flowchart after each and every repair or scheduled maintenance, they are likely to either make serious mistakes or skip several steps. While unnecessary and not recommended for frontline service staff, the proposed Flowchart—with appropriate adaptations—can be a useful tool to guide organizational leaders in developing their policies and qualifying alternative sources of replacement parts.

As an alternative to the proposed Guiding Principles and Flowchart, ACCE would like to suggest a single, simple rule (“**cardinal principle**”) for distinguishing servicing from remanufacturing. This rule asks the following question “**Has the device’s performance or safety specifications, or intended use been significantly changed?**”

If the answer is “**no**” then it is servicing; otherwise, it is remanufacturing. This rule is based on the first Guiding Principle proposed by FDA, as well as on the definitions of servicing and remanufacturing provided in the White Paper. Actually, it is basically the application of the

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<sup>1</sup> Available at <https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCA/FDARA/UCM607469.pdf>

<sup>2</sup> FDA White Paper: Evaluating Whether Activities are Servicing or Remanufacturing. Available at: <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM623972.pdf>

<sup>3</sup> BM Zegarelli & AL Josephson. Observations from FDA’s Public Workshop on Medical Device Servicing and Remanufacturing, 12/27/2018. Available at <https://www.mintz.com/insights-center/viewpoints/2018-12-observations-fdas-public-workshop-medical-device-servicing-and>

<sup>4</sup> JR Fischer. FDA workshop: is it servicing or remanufacturing? HealthCareBusiness Daily News, 12/12/2018. Available at <https://www.dotmed.com/news/story/45626>

widely-accepted evidence-based medicine concept to device servicing because it is focused on the outcome instead of process.

If the answer is “**yes**,” the service staff need to stop and consult with his/her supervisor. In this case, the supervisor—presumably a more qualified person who also has more time available—would review the situation and perhaps apply the other 3 Guiding Principles (parts assessment, risk assessment, need for 510(k) submission) to determine whether they are indeed exceeding the domain of servicing and venturing into remanufacturing.

The suggested “cardinal principle” is analogous to the regulation that has been in existence for several decades which has successfully ensured the safety of diagnostic X-ray systems. That regulation (21 CFR 1020.30) requires assemblers to test the systems after installing certified components per instructions provided by the manufacturer for assembly, installation, adjustment and test (AIAT). Another “precedent” for this simple and clear rule is the power-on self-test (POST) built into many devices by OEMs to help clinical users determine whether the device is safe and ready to be used on a patient. If the device passes the POST, it is safe and ready (effective) to be used.

During the Workshop, several participants questioned the use of the adjective “significant” in the FDA White Paper because it is subjective and, thus, subject to different interpretations. While ACCE acknowledges this challenge, it believes that this adjective should not be removed and, thus, the word “significant” was included in the suggested “cardinal principle.” Without this adjective, device servicing would become almost impossible. Manufacturers of component/part/material—particularly those shared with the Information Technology industry—continually and rapidly improve their products and these innovations should be allowed to be used in medical devices to advance patient care. Case in point, a wireless network adapter in an EKG machine failed but the currently available one is a dual band (2.4 and 5 GHz) adapter instead of the single band (2.4 or 5 GHz) adapter originally installed by the OEM several years ago. Since the single-band adapter is no longer available (except perhaps scavenged from another broken EKG machine), the healthcare establishment would be forced to replace the entire EKG machine for several thousands of dollars if it is forced to use exactly the same component/part/material without the tolerance offered by “significantly changed,” whereas a new dual-band adapter costing less than thirty dollars would restore the machine to safe and effective use. Similar challenge exists for devices declared to be “out of support” by respective manufacturer or when the original manufacturer is no longer in business.

Furthermore, if FDA were to remove the adjective “significant” in the future Guidance Document on servicing versus remanufacturing, it will be forced to revise numerous other regulations and guidance documents, such as “Deciding When to Submit a 510(k) for a Change to an Existing Device<sup>5</sup>,” where this word is used repeatedly.

#### **IV. Replacements Parts**

Collective experience accumulated by ACCE members show that unwillingness of some manufacturers to sell replacement parts or to provide parts specifications have hindered the proper service of medical devices and, thus, delayed returning vital medical devices to working order and also increased cost of healthcare. While ACCE appreciates the fact that some manufacturers may want to protect their intellectual property (IP) and trade secrets, we believe a reasonable compromise can be achieved in the following manner:

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<sup>5</sup> Available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514771.pdf>.

- (a) FDA requires each manufacturer to clearly identify which component(s), material(s) or part(s) within the device is(are) critical to the device's safety and performance in its Instructions for Use ("labeling");
- (b) Each manufacturer then has two options:
  - (1) disclose sufficiently detailed specification for such critical component/part/material to enable servicers to find appropriate alternative(s); or
  - (2) sell such critical component/part/material to current device owner whenever requested at a reasonable price and delivery time.

On the other hand, ACCE does not believe comparative testing of OEM-supplied versus alternative source component/part/material is a reasonable method. First, the servicer would have to purchase a working component/part/material from the manufacturer in order to conduct the comparative test or scavenge from another device. Second, unless the tests are specified in detail by the respective OEM, it is almost impossible to determine *a priori* which tests are necessary. To conduct all possible tests would be cost prohibitive and excessively time consuming. Finally, elaborate laboratory instrumentation beyond the reach of most servicers may be required for some tests.

## V. Risk-Based Approach

While it is desirable to employ a risk-based approach during servicing and remanufacturing activities, ACCE believes its implementation is time consuming, requires qualified personnel and, most importantly, has serious challenges. As recognized in the White Paper, risk—as defined in ISO 14971—is the combination of the probability of occurrence of harm and the severity of that harm. While the severity of harm can be estimated reasonably well, there is little data for estimating the probability of harm. This fact is recognized by FDA itself in its guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." It is even more challenging for servicers and remanufacturers to perform this assessment rigorously, especially when they are not privy to post-market surveillance (PMS) data. The data available to servicers and remanufacturers are likely to be derived from a small number of devices, making it impossible to apply statistically-valid analysis.

Another challenge is the use of ISO 14971 approach. While it could be adequate for manufacturers to evaluate the risk of individual devices, it is not appropriate for health delivery organizations because it does not consider the "scope" of harm, i.e., the number of patients potentially affected<sup>6</sup>. While a single incorrect part or improper service could pose harm to one or a few patients, a batch of incorrect parts or improper service process could affect dozens if not hundreds of patients.

Therefore, ACCE believes that the risk-based approach should only be used by the organizational leaders when qualifying a new supplier or evaluating a repair process. While the frontline service professionals should be instructed to strictly follow the "cardinal principle" suggested above.

## VI. Software

Due to the contractual terms in software licensing agreements, it is seldom possible for users and servicers to make changes to software. Furthermore, there is almost no tests and measurements available to verify that the device's performance or safety specifications, or intended use have not been significantly changed. Therefore, ACCE agrees with FDA that changes to "integral software" should be excluded from servicing.

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<sup>6</sup> Wang B, A Medical Device Collective Risk Management Model for Health Care Organizations and Postmarket Oversight, J. Clin. Eng., 42:28-35, 2017.

In addition, ACCE agrees that the common activities performed on software listed by FDA in the White Paper should be considered within the realm of servicing and, thus, not in violation of FDA regulations. However, ACCE would like to suggest including some additional permissible activities to that list to reduce risks of misunderstandings in the future:

- (1) Accessing (using the “software keys”) diagnostic and repair information that manufacturers currently provide to its own and distributors’ service staff;
- (2) Collecting data generated by the device operating and self-diagnostic software for analyses that can potentially improve its safety and maintenance (“on-condition” or predictive maintenance);
- (3) Running network-based diagnostic and cybersecurity scanning software;
- (4) Performing back-up of data and/or software to the organization’s storage systems.

## VII. Labeling

ACCE’s answers to the three questions in Section 7 of the FDA White Paper are provided below numbered in the same order as the questions:

1. The device’s performance and safety specifications, and intended use must be included in the device labeling. In addition, the labeling must include the device’s tests and/or measurements instructions—along with the tools—needed to verify that the device’s performance and safety specifications, and intended use have not been changed after service.
2. As explained above, manufacturers must be required to identify in labeling which component(s), material(s) or part(s) within the device is(are) critical to the device’s safety and performance. In addition, the manufacturer must provide sufficiently detailed specification for such critical component/part/material to enable servicers to find appropriate alternative(s). If the OEM believes it has an IP or other significant reason for not providing sufficiently detailed specification for such critical component/part/material, then it must sell the component/part/material to the device owner at a reasonable price and delivery time.
3. “Software keys” (aka passwords) to access the diagnostic and repair information that manufacturers currently provide to its own and distributors’ service staff must be included in labeling. In addition, the labeling should include instructions on accessing and interpreting data generated by the device operating and self-diagnostic software for analyses that can potentially improve its safety and maintenance (“on-condition” or predictive maintenance).

In essence, FDA should require manufacturers to provide as part of required labeling, the respective device’s performance and safety specifications, and intended use, including instructions and tools needed to verify those specifications. This will allow the servicers to answer the “cardinal principle” question suggested in section III above.

ACCE also recommends FDA to include in the labeling requirement for all medical devices that need servicing the “details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times” (aka, service instructions or manuals). Currently, as FDA stated in the White Paper, such requirement exists only for lasers, ultrasound therapy products, and in-vitro diagnostic instruments, whereas manufacturers of X-ray emitting devices are only required to provide “[a] schedule of the maintenance necessary to keep the equipment in compliance ...” (21 CFR 1020.10(h)(1)(ii)). ACCE believes such requirement should be universally

applied to all types of devices for the benefit of public safety, as the European Union has stipulated in its regulation since 1993<sup>7</sup> and quoted in the follow textbox:

*13. Information supplied by the manufacturer*

*13.6 Where appropriate, the instructions for use must contain the following particulars:*

*...*

*(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;*

## VIII. Definitions

ACCE agrees with the definitions of service and remanufacture provided by FDA in Appendix A of the White Paper. However, ACCE is very concerned about the definition of Third Party Servicers and Independent Service Organizations (ISOs) because it excludes manufacturers and healthcare establishments and gives the impression that different rules will be applied to those excluded from this definition.

This segregation of servicers based on the nature of their organization is totally unjustified. First, several major manufacturers have been actively engaged for many years in servicing equipment that they did not manufacture. These “multi-vendor service” activities are not mandated by Quality System regulations (21 CFR 820) to be managed within these manufacturers’ Quality Management Systems (QMS) when the devices services are not manufactured by these manufacturers. These manufacturers don’t necessarily have access to service documentation, training, and design information from their competitors. Therefore, these “multi-vendor service” organizations should be classified as “third-party entities” in these circumstances. Second, many ISOs have staff permanently stationed in healthcare establishments and are required by contract to follow the accreditation standards adopted by those healthcare establishment. So these ISO-employed service professionals should be under the same set of rules as those employed by healthcare establishments. Third, some third-party servicers (including ISOs) work for manufacturers who do not have or don’t want to have service representatives everywhere in the country. These third-party servicers may be obligated by contract to follow the QMS of the manufacturers for whom they provide service. So it is unreasonable for them to follow yet another set of rules. Finally, due to the frequent mergers and acquisitions, many servicing professionals—including ACCE members—have received at different times paychecks from healthcare establishments, ISOs, third-parties and manufacturers during their careers without ever changing jobs or job locations. It would be extremely confusing for all the servicing professionals to change how they perform their servicing activities simply because the name on their paychecks have changed.

In essence, ACCE believes that the same set of rules should be applied to all those who service medical devices, regardless of their employer classification as manufacturers, ISOs, third-parties or healthcare establishment. Afterall, the safety and care of patients cannot depend simply on the name of the issuer of the paycheck. American patients deserve the same level of quality and safety of the medical devices used in their care regardless who is servicing these devices.

Nevertheless, ACCE wants to make it clear that it is not advocating to subject all servicers to FDA regulations as some manufacturers have advocated. Afterall, FDA itself has concluded that there is no

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<sup>7</sup> Medical Device Directive 93/42/EEC 13.6(d) available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042&from=EN>.

objective evidence to justify imposing additional/different, burdensome regulatory requirements. All ACCE is recommending is for FDA to ask all servicers—regardless of the nature of their organization—to adopt the suggested “cardinal principle” to avoid straying into remanufacturing unintentionally.

## IX. Conclusions

Again, ACCE would like to commend the FDA for its efforts in improving the safety of device servicing and, in particular, distinguishing remanufacturing from servicing, as most of the hazards reported to the FDA are due to remanufacturing instead of servicing.

ACCE firmly supports the FDA in issuing a Guidance Document with simple and clear instructions for all stakeholders to understand the difference between servicing and remanufacturing. This will likely reduce significantly the amount of unintentional remanufacturing activities performed by servicers who are unaware of the distinction and potential negative consequences to public health.

In addition, ACCE believes FDA needs to enforce energetically its rules against those who knowingly perform remanufacturing activities without proper registration and regulatory compliance after the publication of the Guidance Document. FDA should also encourage all stakeholders to report violations to the FDA’s Allegations of Regulatory Misconduct Branch so appropriate investigation and enforcement can be made.

Finally, as stated before in my letter of 12/26/2018, ACCE is committed to participate in future activities in this area and we offer participation and assistance as one of the members of the Steering Committee for the coordination of these collaborative communities. Please feel free to contact me if you have any questions.

Sincerely yours,



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