



Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

September 22, 2021

Ref: Remanufacturing of Medical Devices
(Docket No. FDA-2018-N-3741)

Dear Sir/Madam:

This is to submit comments on the remanufacturing of medical devices, as requested by the Food and Drug Administration (FDA) through the Request for Comments issued in June 2021. This document is divided into four 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 over 2,000 members in the United States who work in various segments of the medical device ecosystem, 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, professional experience, and educational background.

Since its foundation, ACCE has participated in every discussion with the FDA on the issue of servicing, particularly the 1997 ANPR (Docket No. 97N-0477), the 2016 PR (Docket No. FDA-2016-N-0436), and the 2019 PR (Docket No. FDA-2018-N-3741). ACCE was also invited to present at the Workshop held on December 10-11, 2018 and discuss at the Workshop help on October 27-28, 2016.

II. General Comments

ACCE applauds FDA's initiative in clarifying the distinction between servicing and remanufacturing. ACCE supports its plan to issue a guidance document to reduce risks of confusion for all stakeholders involved and reduce the negative impact of remanufacturing on FDA regulation and ability to deliver care reliably.

As FDA concluded in its 2018 FDARA 710¹ report, there is very little to negligible 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. The FDA further recognized that the continued availability of third-party entities for service and repair of medical devices is critical to the functioning of the U.S. healthcare system.

ACCE presents its concerns about the practical implementation of this guidance:

- First, healthcare technology management/clinical engineering (HTM/CE) teams in healthcare delivery organizations (HDOs) perform significant portion of medical device services, so it is unclear why they are exempted entities that perform services on medical devices.
- Second, servicing versus remanufacturing assessment process is burdensome, time-consuming, and lacking clarity. More so when subjective judgement is required to evaluate if "significant changes" were introduced in the absence of instructions from original equipment manufacturers (OEMs). HDOs and other non-OEM servicing entities still find it a challenge to obtain full-access to service-related information and instructions from OEMs despite huge spend on service contracts and training. If this assessment is required for every corrective maintenance activity, this will significantly impact a HDO's ability to deliver patient care in a timely and effective manner, including increase in downtimes and spend, as was evident during the pandemic.

ACCE strongly believes in FDA's efforts in providing clarity with the remanufacturing guidance and avoiding unintentional remanufacturing that may potentially cause an adverse effect on patient care delivery. Our recommendations will be presented in this written comment.

¹ FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices. Available at: <https://www.fda.gov/media/113431/download>

III. Specific Comments from ACCE

All comments below are organized following the sections of the draft guidance.

1. Scope

The draft guidance discusses whether the activities performed by OEMs and third parties are likely remanufacturing. However, in section VI.B lines 295-297, it exempts all OEMs from complying with the guidance.

ACCE believes that OEMs should not be exempted from complying with this guidance. While OEMs are regulated through the Quality System Regulation (21 CFR 820), there is no specific requirement to identify any service activity as an intentional or unintentional remanufacturing activity. Furthermore, OEMs do not follow a consistent practice of providing detailed service reports to HDOs or third parties when a servicing activity is completed. Finally, there is no requirement or assessment of the servicing activity for HDOs to review and approve that the activity performed did not venture into remanufacturing.

As the FDA is aware, some OEMs also provide their own “Third Party Service” for medical devices manufactured by other OEMs (aka multivendor services – MVSS²), and there is no justifiable reason for them to be exempt from complying with this guidance.

If the final guidance continues to keep this exemption, the FDA should require OEM service personnel and representatives to provide detailed service reports to HDOs/user facilities and state that the service activity did not stray into remanufacturing. This practice can then be adopted by other service entities such as third parties and HDOs, assuming the OEMs will provide service instructions and training, and there is stringent mechanism in place to enforce it.

2. Definition

ACCE agrees with most of the definitions in this draft guidance, except for the definition of “Third-party servicers and Independent Service Organizations (ISOs)” because it does not include HDOs.

This was a concern presented by ACCE in its 2019 written comment, that the definition of Third-Party Servicers and Independent Service Organizations (ISOs) excludes manufacturers and HDOs, giving the impression of lack of consistency around rules for all service entities. Lack of inclusion of HDOs (HTM/CE personnel) demonstrates inconsistent review of current data as numerous studies conducted around the medical device servicing market illustrated that one-half belonged to OEMs and rest was managed by ISOs and HDOs.³ Ignoring HDOs among service entities will result in the development and practicing of inaccurate and inconsistent guidance.

² Multi-vendor services. Available at: <https://www.usa.philips.com/healthcare/services/maintenance-services/healthcare-multi-vendor-services>

³ Market intelligence report. Available at: <https://www.grandviewresearch.com/industry-analysis/medical-equipment-maintenance-market>

ACCE recommends that FDA ask all servicers - regardless of the nature of their organization - to adopt the suggested “cardinal principle” to avoid straying into remanufacturing unintentionally as it impacts patient care and delivery of health care services.

3. Guiding Principles

ACCE believes that the six guiding principles provided in the draft guidance are good suggestions in principle. However, the additional burden imposed in #6 (Adequately document decision-making) and illustrated in Appendix B impose unnecessary burden with documentation and imply that they are not being carefully considered, as required by the Paperwork Reduction Act of 1995.⁴ ACCE firmly believes that the adequate document decision-making imposes time-consuming activity that is inefficient, ineffective, and not economical for service entities thereby increasing downtimes and unavailability of devices for patient care.

Majority of ACCE’s members are HDO personnel and estimates a current dire shortage of service personnel due to accelerated retirement, increasing service demands, technology growth of equipment, lack of availability of service instructions, and lack of timely service by OEMs. With the additional documentation requirements, HDOs would struggle with completion of service events, maintain equipment uptime, afford capital spend, thus resulting in delay or diversion of care services to the population.

The pandemic has imposed several billion dollars of unexpected expenses, including increasing capital spend to bring more devices for surge efforts due to device shortage, service unavailability, and service parts shortage. Imposing this documentation for remanufacturing versus servicing evaluation for each service event would require HDOs to spend significant time, which would result in additional paperwork time, increased labor hours and, above all, less and perhaps unsafe patient care.

4. Relevant considerations to determine if activities are remanufacturing

A. What is a significant change to device performance or safety specifications?

ACCE believes that distinguishing remanufacturing from servicing is challenging, there are some obvious cases such as, changing the sterilization methods, reprocessing instructions, and device’s control mechanisms, operating principle, or energy type.

As stated in the draft guidance, the proper procedure would be to perform verification and validation or a risk-based assessment. Such testing is impossible unless OEMs make operating specifications, design details, and performance instructions available. Performing a risk-based assessment is also practically challenging as existing risk analysis documents is not provided by OEMs to service entities (ISOs and HDOs) and assessing severity and probability of risks require lengthy and detailed analysis by subject matter experts, which are

⁴ Paperwork Reduction Act (PRA). Available at: <https://www.gpo.gov/fdsys/pkg/BILLS-104s244enr/pdf/BILLS-104s244enr.pdf>

constrained among service personnel. Another constraint imposed on this activity is the lack of risks and post-market surveillance data released by OEMs.

B. Determining whether activities are “remanufacturing”

As stated above in section 3 (Guiding Principles), ACCE is concerned that this determination/assessment will result in additional staffing, device downtime, service unavailability, and lengthier service. Particular concerns about determining whether activities are “remanufacturing” are:

- Unavailability of device specifications (e.g., chemical composition of components, dimensional specifications, existing risk analysis).
- Increased equipment downtime because of the time-consuming paperwork and obtaining relevant information from OEMs, including the determination of “no significant change” to device’s performance or safety specifications after each service activity as described in Figure 1.

Currently, this determination and results of this determination are not available from OEMs. Imposing this on service entities other than OEMs would result in inconsistent delivery of regulatory practices.

5. Changes involving software

ACCE agrees that software changes should never be attempted by servicers as it may result in unintentional remanufacturing. ACCE also agrees with the list of activities listed as “likely not remanufacturing.” A rising concern to effectively perform activities in this list is the lack of availability of relevant information and limited access to software keys (privileged access), software licenses, and instructions to apply updates, upgrades, and running diagnostics to reinstate a device to full clinical-function condition.

All of these activities are essential for cybersecurity management of medical devices and current constraints from OEMs do not allow other service entities to ensure that cybersecurity risks are managed adequately.

6. Considerations for labeling

A continuing and key concern for service entities outside of OEMs is the unavailability of service information and instructions, despite increased spend on service trainings and service libraries. Unintentional remanufacturing can be avoided by service entities if OEMs provided information required to return a device to its original performance and safety specifications, as recognized in the draft guidance. ACCE strongly recommends the FDA to “encourage” OEMs to provide service instructions, proprietary parts and tools, and software licenses and keys that facilitate routine scheduled and corrective (unscheduled) maintenance of their devices, including reusable devices.

If OEMs do not provide the above information based on the current regulation (21 CFR 801.109(c)) for prescription devices (which includes most devices used in the HDOs), then FDA should emulate the European Union, which has required the inclusion of service

information in the “information for use” (IFU) through its Medical Device Directive (MDD)⁵ that replaced its Medical Device Regulation (MDR)⁶ earlier this year.

IV. Conclusions and Recommendations

ACCE applauds FDA for its efforts in clarifying the difference between servicing and remanufacturing. It continues to be a challenging space due to multiple reasons as stated by all service entities, OEMs, ISOs, and HDOs.

Considering the details provided in the previous sections of this written comment, ACCE would like to recommend the following:

- Include all service entities in the draft guidance regardless of the device ownership. This includes OEMs, MVSSs, ISOs, HDOs, and HDO-affiliated service entities.
- Each service entity should establish clear policies, procedures, and processes to comply with applicable FDA regulations and avoiding unintentional remanufacturing.
- Each service entity that does not allow remanufacturing should establish education and training materials for their service personnel so they can avoid unintentional remanufacturing.
 - The six guiding principles can be used for this purpose or further simplified by asking the service personnel the basic question if changes to device’s performance or safety specifications or intended use has been made.
- FDA should follow EU’s practice of “mandating” the inclusion of service information in the information for use (or instructions for use). This allows all service entities to perform the testing required to ensure there is no change to safety and performance specifications of the device.
 - This will also ensure all service entities to comply with CMS’s requirement.⁷
- FDA should encourage all service entities (OEMs, MVSSs, ISOs, HDOs, and HDO-affiliated), including users of devices to report violation of the remanufacturing regulation.
 - This will ensure consistent adoption and monitoring of the remanufacturing regulation, which is essential for safe and high-quality patient care.

Finally, ACCE is grateful for the opportunity provided by the FDA to comment on this draft guidance and more importantly on this issue, which continues to be a challenge for its members. ACCE and its task force is committed to participating in future workshops, further discussions, and any assistance in this effort. Please feel free to contact me if you have any questions.

⁵ See <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF>

⁶ See <https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng>

⁷ See <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-07.pdf>

Very Sincerely,

A handwritten signature in black ink that reads "Priyanka Upendra". The signature is written in a cursive style with a horizontal line underneath the name.

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