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September 22, 2021

Dr. Jeffrey Shuren, MD, JD
Director
Center for Devices and Radiological Health
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Draft Guidance: Remanufacturing of Medical Devices

Dear Dr. Shuren:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing to offer comments on the draft guidance document on remanufacturing of medical devices.

Although the development of this guidance is a step in the right direction, we are concerned that it will not achieve the outcome intended by the Food and Drug Administration (FDA) given that the Agency is relying on third party servicers and independent service organizations (ISOs)—who are not regulated by the FDA; who do not seek out nor follow FDA policy, regulations or guidance; whose activities regarding medical devices are unregistered and therefore unknown to the FDA; who have not established quality management processes and documented procedures; and who do not report device malfunctions resulting from their servicing activities—to comply with this regulatory guidance. Until FDA removes its enforcement discretion, requires all third-party servicers and ISOs to comply with registration, regulatory, quality and safety requirements, and proactively exercises appropriate oversight (i.e, inspections) and enforcement policies, the current servicing activities actually constituting unregulated remanufacturing of medical devices will continue.

Remanufacturing of medical devices is included within the regulatory scope of FDA good manufacturing practices regulation. 21 C.F.R. 820.1 et seq. Under 21 CFR §820.3(w), a remanufacturer is defined as, "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." Remanufacturers of medical devices, like device original equipment manufacturers (OEMs) must adopt good manufacturing practices as defined in regulation.

The draft guidance references the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices published in May 2018.[1] In this report, FDA concluded, "A majority of comments, complaints, and adverse event reports alleging that inadequate 'servicing' caused or contributed to clinical adverse events and deaths actually pertain to 'remanufacturing' and not 'servicing'."

[1] https://www.fda.gov/media/113431/download

This conclusion demonstrates that entities performing servicing activities often cross into remanufacturing, resulting in changes to devices that impact device performance and patient safety. These servicing entities should be known to FDA and have proper oversight prior to interaction with a regulated medical device. Without FDA removal of enforcement discretion and enforcement of quality, safety, and regulatory requirements, a significant number of remanufacturing activities will continue to be unknown to and unregulated by the FDA.

Uncontrolled remanufacturing activities not subject to appropriate oversight present a significant risk of:

a. Performance or safety events, leading to misdiagnosis, mistreatment, or even death,
b. Creating uncleared, unapproved, adulterated, or otherwise non-conforming devices,
c. Allowing non-conforming devices to remain in use, or
d. Reintroducing non-conforming devices into interstate commerce.

For this reason, MITA supports expedient finalization and enforcement of this guidance and offers the following comments.

* * * *

Regulatory Requirements for Remanufacturing

This guidance must make clear the regulatory requirements associated with remanufacturing activities. FDA rightly asserts that remanufacturing is a regulated activity whether or not the entity in question considers itself a "remanufacturer" or some other kind of entity. The activity itself determines the applicable regulatory requirements.

In this guidance document, FDA should make explicit that remanufacturing is a regulated activity, requiring compliance with the CFR, including, but not limited to, registration with FDA, adoption of a quality management system, and reporting of adverse events.

Relevant regulation and guidance documents include:

- 21 CFR Part 807 Registration and Listing
- United States Code of Federal Regulations Title 21 Part 820, Quality System Regulation
    - Establishes the quality management system requirements for the manufacture and remanufacture of medical devices
- Food Drug & Cosmetic Act Section 510(k) (premarket notification) and Section 515 (premarket approval/PMA)
- 21CFR Part 803 Medical Device Reporting
- 21 CFR Part 806 Reports of Corrections & Removals
- Product-specific 510(k) guidance documents
    - Provides information about the expected contents of a 510(k) submission, and in many cases outline what kinds of modifications to specific device types require submission of a new 510(k), a good analog for remanufacturing
- Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and Food and Drug Administration Staff
    - Provides guidance on when modifications to a device require submission of a new 510(k), a good analog for remanufacturing

Risk Assessment

In this draft guidance, FDA establishes as one of its "guiding principles" that entities should employ a risk-based approach when assessing whether an activity they are planning to perform or are currently performing is remanufacturing.

MITA supports employing a risk-based approach when entities perform activities on medical devices. We also believe that medical device servicers should be required to adopt relevant portions of a quality management system conformant with 21 CFR 820.

Quality management systems ensure that the entity is proactively engaged in ensuring patient safety and device performance. Adoption of a quality management system enables an organization to understand the nature and scope of the activities it is undertaking. In this case, a sufficiently robust and adequately scaled QMS would help ensure that servicing and remanufacturing activities are properly identified, performed, documented, and controlled.

A quality management system is necessary to ensure that finished medical devices consistently meet applicable requirements and specifications. Performance of servicing and remanufacturing activities within an appropriate quality management system by properly trained technicians using qualified, properly sourced parts greatly reduces the risk of harm to the patient or operator and objectively maintains the performance of the device.

A quality management system also provides a framework—including verification and validation processes—for ensuring that servicing activities do not bridge into remanufacturing and that remanufacturing activities are appropriately controlled and have appropriate oversight. In some cases, this may require a new 510(k) submission to the FDA.

Activities that Likely Constitute Remanufacturing

In the draft guidance, FDA identifies certain types of activities that, in general, the Agency believes significantly change the legally marketed device's performance or safety specifications:

- Changes to the device's sterilization methods;
- Changes to the device's reprocessing instructions; and
- Changes to the device's control mechanism, operating principle, or energy type.

MITA agrees that these activities constitute remanufacturing. MITA also believes that the following activities or device changes also significantly change the legally marketed device's performance, intended use, or safety specifications and should be referenced in the guidance document:

- **Safety Interlock**: The installed safety measures (interlocks) that ensure the safe operation and service of a device by an operator or service provider. They may also ensure patient safety by ensuring that devices limit exposure to unsafe conditions (e.g., excess radiation) and/or 'fail' safely (e.g., unrequested motion).
- **Energy Amount**: The amount of power input to or output from the device
- **Biocompatibility**: Materials that come into contact with patients must be tested to confirm biocompatibility (e.g., patient-contacting surfaces like endoscope tubing or ultrasound transducer lens). These materials must also be validated to properly endure the OEM approved cleaning materials and procedures that are used for high level disinfection or to sterilize the device. Changes in the materials used, method of sterilization, cleaning, or high-level disinfection have the potential to change material or performance characteristics of a reusable device.
- **Cybersecurity and Data Privacy**: Entities should assess whether changes to the device affect its cybersecurity, including diminishing the confidentiality, integrity, and accessibility of the device and its associated data—including protected patient data—and systems. Unauthorized changes to

a device that alter the device's Manufacturer Disclosure Statement for Medical Device Security (MDS2) likely alter the device's cybersecurity, and therefore likely constitute remanufacturing.

- **Design**: If a design change significantly affects how a device may be used, the activity likely constitutes remanufacturing.
- **Physical Configuration**: Changes in the physical construction or installation location can significantly affect the safety and performance of a device. For example, seismic-certified devices require specific testing and mounting hardware. Additionally, devices designed and intended for fixed installation cannot always be converted to mobile installations (trailers), even if conversion kits, testing, and certifications exist.
- **Non-Conforming Parts**: Replacing parts in a medical device does not necessarily constitute remanufacturing. Replacement parts, however, need to undergo verification and validation to ensure that they meet the device's original specifications and do not significantly affect the safety or performance of the device.
- **Device Listing**: Changes which violate the National Recognized Test Lab listing of the device significantly alter the safety of the device and likely constitute remanufacturing.
- **Parts and Module Compatibility**: OEMs assure compatibility of components and modules used in the equipment and the interaction with each other. Exchange of components and modules used in the originally released equipment may lead to incompatibilities and subsequent unintended behavior or failure.
- **Software**: Unqualified parties should not be accessing or modifying device software of any kind. Changing software can impact system performance or create cybersecurity or patient privacy issues. Software changes can impact a variety of safety factors, including, but limited to duration of exposure, position of exposure, underpowering or overpowering operation, or unexpected or uncontrolled movement. Software is complex and can operate on many levels and with many branches. Making a software change in one area can have unknown or unclear consequences in another portion of the operating system.

Considerations for Labeling

In the draft guidance, FDA discusses its recommendation that medical device OEMs include certain information in product labeling. This section raises a number of concerns.

This section should be removed from the guidance document. Any updates to product labeling should be reflected in product-specific guidance documents issued by FDA.

It is our position that documentation already required by regulation or contractual agreement and provided to the owner/operator is sufficient to determine whether an activity constitutes remanufacturing and successfully return a device to safe and effective condition after servicing.

FDA states "Unintentional remanufacturing can occur when entities do not have the instructions necessary to return a device to its original performance and safety specifications. The lack of adequate servicing instructions can also create challenges in the availability of quality, safe, and effective devices." The implication of these statements is that manufacturers are largely or solely responsible for the ability of entities outside their control to determine whether an activity constitutes remanufacturing and that manufacturers are responsible for inadequate servicing caused by unregulated third-party servicers. MITA strongly disagrees with this implication.

In fact, adequate performance of medical device servicing activities is not dependent only on possession of certain materials. Safe and effective servicing is not merely the acquisition of certain documentation or materials—it is the implementation of and adherence to a set of policies, practices, and procedures that

consistently return the device to a state of safe and effective operation. Knowledge of and compliance with FDA regulatory requirements is essential to performance of medical device servicing and remanufacturing activities in a way that results in the safe and effective operation of the medical device. Operating within a quality management system as codified by FDA in 21 CFR 820: Quality System Regulation ensures that medical devices consistently meet applicable specifications and requirements.

We are also deeply concerned that the documentation recommendations contained in this section would eliminate OEM intellectual property protections and allow for uncontrolled wide release of proprietary servicing materials, creating an irrevocable loss of trade secret protection for manufacturers.

As voluntary entrants into the market, Third Party Servicers and ISOs should be required to accept responsibility for ensuring the return of medical devices to safe and effective operation and can do so by adopting appropriate quality systems and investing in the development of their own valid servicing protocols, tools, and training. Many non-OEM servicers also already make these kinds of investments in servicing tools, training, and protocols for the same reasons that OEMs do.

Requiring regulated medical device manufacturers who have made significant investments in regulatory compliance and development of servicing processes to provide company confidential or proprietary information to competitors will have significant negative consequences for innovation and competition in this industry. Forcing one device manufacturer to turn over company confidential information or trade secrets to a competing manufacturer when acting as a third-party servicer would be disastrous for competition and innovation.

Even beyond the impact on competition and innovation, the more relevant issue is that Third Party Servicers and ISOs may misuse OEM intellectual property without proper quality system controls to create unsafe, unreliable, or ineffective alternatives to the OEM-designed service strategies.

Implementation and Enforcement

As determined in the 2018 report on medical device servicing, "A majority of comments, complaints, and adverse event reports alleging that inadequate 'servicing' caused or contributed to clinical adverse events and deaths actually pertain to 'remanufacturing' and not 'servicing'." These remanufacturing activities are, in general, currently unknown to and uncontrolled by FDA. This is due to both a lack of visibility into the depth and breadth of service activities taking place and a lack of consistent regulation and discretionary oversight of the medical device servicing industry.

FDA must have a robust, proactive plan for implementation and enforcement of this guidance and associated regulatory requirements. In particular, the Agency will need to establish processes for:

- Educating stakeholders about remanufacturing and its associated regulatory requirements,
- Detecting instances of uncontrolled remanufacturing, and

Enforcing regulatory requirements on uncontrolled remanufacturers.In addition, to ensure this guidance achieves the intended outcome and is effective in driving appropriate regulation and oversight of medical device remanufacturing activities, FDA must clearly communicate how and when the Agency will enforce this guidance. This will ensure Third Party Servicers and ISOs understand the timeframe available to establish processes to assess their activities and implement the necessary requirements.

Education

Entities that provide servicing for medical devices will need to be educated the existence and contents of this guidance, as well as the corresponding regulatory requirements. Expedient finalization and publication of this guidance document will be an important first step.

After finalization of this guidance, we recommend that the Agency:

- Work with industry groups and professional societies to develop educational materials and programs for stakeholders involved in aftermarket technical support of medical devices,
- Directly alert those stakeholders that are known to the Agency of the distinction between servicing and remanufacturing and the associated regulatory requirements,
- Hold local educational programs via FDA field district offices and state-level professional and industry groups, and
- Provide educational programs at industry trade shows and annual meetings.

Surveillance

As part of its surveillance activities, and in parallel to its educational activities, we recommend that the Agency:

- Require that all entities engaged in servicing of medical devices make themselves known to the FDA via registration. Without registration and reporting to the Agency, Third Party Servicers and ISOs that may be unknowingly performing remanufacturing activities are not likely to proactively categorize their activities as remanufacturing nor proactively seek the Agency's guidance to help determine whether their activities might constitute remanufacturing.
- Commit to inspecting a certain number of servicing entities each year to confirm that the activities being performed are in conformance with applicable regulations
    - The Agency should apply a risk-based approach to selecting inspection sites, taking into account device type, complaints and adverse events associated with a site and/or entity, and other relevant factors, as it would for any OEM
- Conduct audits of Third Party Servicers and ISOs to determine compliance with documentation prescribed by this guidance document
- Establish a portal on the FDA website in which any concerned stakeholder, including, but not limited to OEMs, healthcare providers, patients, and servicers can report suspected remanufacturing
- Add additional fields to reporting forms to assist in detection of remanufactured medical devices, similar to recent additions to the 3500A reporting form
- Publish periodic reports containing findings from inspections, audits, and reporting forms regarding the quality, safety and effectiveness of medical device servicing as prescribed in the May 2018 report

Action

It is our position that all medical device servicing businesses should be required to adopt a quality management system conformant with 21 CFR 820, register with the FDA, and report deaths, serious injuries, and major malfunctions. Shifting away from discretionary and enforcement toward proactive application of these requirements by FDA to medical device servicing businesses is the most appropriate way to protect patient safety and ensure ongoing device performance.

FDA must align accountability measures for remanufacturers with OEMs. FDA must:

- Ensure remanufacturers register and list;

- Ensure remanufacturers have a quality management system in place;
- Ensure remanufacturers are filing premarket submissions for remanufactured products;
- Conduct for-cause inspections as appropriate
- Take appropriate enforcement actions (e.g., issue Warning Letters) against remanufacturers who are out of compliance

Line-Item Edits to Guidance Document

In addition to the comments included above, we have included an appendix with certain proposed line-item edits to the draft guidance document.

* * * *

If you have any questions, please contact Peter Weems, Senior Director, Policy & Strategic Operations, at 703-841-3238 or by email at pweems@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.

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Appendix: Line-Item Proposed Edits to Draft Guidance

Line Number(s)	Current Text	New Proposed Text	Reasoning/Comment
Red Text = proposed change to text in Guidance Yellow Highlight = General comment made on existing Guidance text			
General Comment			FDA has acknowledged and used its power and responsibility to regulate third party servicers and ISOs using enforcement discretion. This draft guidance creates new requirements for third party servicers and ISOs that would be ineffectual without a level of oversight greater than what enforcement discretion provides, as currently implemented by the Agency. FDA should consistently enforce the new requirements set forth in the draft guidance with all third party servicers and ISOs.

136-138	Repair: A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.	Repair: A type of servicing that returns a component to OEM's original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.	Adding "OEM's original specifications" to be consistent with the other defined terms in guidance document. Important to specify that Repair brings device back to OEM original specifications.
169-170	Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device –	Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications established by the OEM of a finished device –	Adding "established by the OEM" to be consistent with the defined terms in the guidance document and to emphasize the importance of OEM specifications.
173-176	Activities that are not intended to significantly change the performance or safety specifications, however, should still be evaluated to determine whether they do significantly change the finished device's performance and safety specifications. Multiple changes, when considered cumulatively, may significantly change the performance or safety specifications of the legally marketed device and should be evaluated.	Activities that are not intended to significantly change the performance or safety specifications, however, should still be evaluated to determine whether they do significantly change the finished device's performance and safety specifications. Multiple changes, when considered cumulatively, may significantly change the performance or safety specifications of the legally marketed device and should be evaluated and documented.	It is not clear who will conduct this evaluation and how FDA will enforce this requirement for entities **that are currently subject to regulation by FDA only through enforcement discretion and may be unknown to the agency**. **Third party servicers and ISOs may not have the qualified individual(s) with the expertise to conduct this type of evaluation for regulatory impact.** In addition, how is this evaluation documented and reviewed by the FDA?

181-185	Regardless of whether changes made to a legally marketed device are remanufacturing, such changes should be evaluated to determine whether a premarket notification (510(k)) or other marketing submission is required pursuant to the FD&C Act and applicable regulations, and entities should consult relevant guidance for FDA's recommendations on the topic.	Regardless of whether changes made to a legally marketed device are remanufacturing, such changes should be evaluated and documented to determine whether a premarket notification (510(k)) or other marketing submission is required pursuant to the FD&C Act and applicable regulations, and entities should consult relevant guidance for FDA's recommendations on the topic.	A third-party servicer or ISO required to perform this evaluation under this draft guidance may not have the qualified individual(s) to determine whether a 510(k) or other marketing submission is required.
247-250	Conversely, replacing an internal capacitor with one that has the same specifications (e.g., same capacitance, working voltage, temperature range, and footprint) is not likely to significantly change device performance or safety specifications and therefore, is likely not remanufacturing.	Conversely, replacing an internal capacitor with one that has the same specifications (e.g., same capacitance, working voltage, temperature range, and footprint) is not likely to significantly change device performance or safety specifications and therefore, is likely not remanufacturing.	The verification testing that is performed to confirm device performance and safety is critically important. A replacement that seemingly has the same specifications must be tested after installation to ensure device performance and safety These replacement parts may only be available through qualified suppliers.
263-264	Therefore, as discussed in Guiding Principle 1, any change to the intended use should be evaluated to determine whether the activity is remanufacturing.	Therefore, as discussed in Guiding Principle 1, any change to the intended use should be evaluated to determine whether the activity is remanufacturing.	It is not clear who will conduct this intended use evaluation and how FDA will enforce this requirement for entities that are currently subject to regulation by FDA only through enforcement discretion and may be unknown to the agency. Third party servicers and ISOs may not have the qualified individual(s) with the expertise to conduct this type of evaluation for regulatory impact.

295-297	FDA does not recommend evaluation with Figure 1 when an activity is performed on behalf of, or otherwise explicitly authorized by, the OEM and the activity returns the legally marketed device to its original performance and safety specifications, and intended use.	N/A	This text should be reflected in the "Scope" section at line 97 of the guidance document since it clearly defines the audience of the guidance document.
304-306	The documentation should be prepared in a way that an FDA investigator or other third party can understand what the change was and the rationale underlying the conclusion.	The documentation should be prepared in a way that an FDA investigator or other third party can understand what the change was and the rationale underlying the conclusion.	Third party servicers and ISOs may not have the qualified individual(s) with the expertise to create documentation that meets FDA requirements . How will FDA identify all entities performing these evaluations? Who is required to document this evaluation? Does the documentation follow the device, owner of the device, or the 3rd Party Servicer/ISO? Who is the "other third party" referenced here?

443-445	*Is there a new or modified risk*? A risk-based assessment can identify whether there are new risks or modified existing risks in comparison to the legally marketed device. If a new risk is created or an existing risk has been modified based on the activity being performed, the answer VII.	*Is there a new or modified risk*? A risk-based assessment can identify whether there are new risks or modified existing risks in comparison to the legally marketed device. If a new risk is created or an existing risk has been modified based on the activity being performed, the answer VII.	3rd Party Servicers and ISOs may not have the appropriate qualified individual(s) to conduct a regulatory risk analysis to determine if a new or modified risk exists based on the activity being performed. Requiring compliance with ISO 14971 would address this.
474	**VII. Changes involving software**		FDA has provided a list of changes to software it believes are likely *not* remanufacturing. It would be helpful for FDA to provide a list of software changes that would constitute remanufacturing. Many of the items listed could be open to interpretation by third party servicers or ISOs without the qualified individual(s) to conduct this type of evaluation for regulatory impact.
487-488	Running software-based hardware diagnostics; assessing for viruses, malware, and other cybersecurity related issues	~~Running software-based hardware diagnostics; assessing for viruses, malware, and other cybersecurity related issues~~	OEMs have experienced challenges updating or patching device software when a health care provider, through its third party service provider or ISO, installs a third party software program (e.g. McAfee) to a device. The installation of such a program may inhibit the return of the device to original safety and performance specifications in the event of a required

			software patch or update. Additionally, the use of any OTS diagnostic needs to be within the OEM support strategy for a given software or hardware medical device.

490	Reverting software to a previous configuration;	~~Reverting software to a previous configuration;~~	FDA is including "reverting software to a previous configuration" in a list of activities that are presumed not to be remanufacturing. Very few systems run on a single software - often many programs work together and if one software is reverted to a previous configuration without consideration of others, this could post major issues within the device. The context and facts surrounding the reason for reverting software is very important in conducting an analysis for remanufacturing - especially considering the emerging technology in this space (artificial intelligence, FDA cybersecurity requirements, OEM updates to software, support of software configurations, etc.). Therefore, this should be removed from the list and a further analysis should be required. In addition, there are concerns with changing hardware/firmware conditions (such as ports, addresses, etc.) to revert software to a previous configuration.

512-539	**VIII. Considerations for labeling**	~~**VIII. Considerations for labeling**~~	Remove this section from the guidance document. This section on labeling is misplaced and should not be included in a FDA Guidance Document addressing Remanufacturing and Servicing. Any updates to labeling should be reflected in product-level guidance documents issued by the FDA.
647-650	A2.1 Is there a significant change to device performance or safety specifications? No. The new gradient coil only differs by small changes in design and dimensional specifications. There are no significant changes to the performance and safety specifications (e.g., slew rate, peak gradient strength, power).	A2.1 Is there a significant change to device performance or safety specifications? No. The new gradient coil only differs by small changes in design and dimensional specifications. There are no significant changes to the performance and safety specifications (e.g., slew rate, peak gradient strength, power).	This analysis requires a 3rd Party Servicer/ISO to decide the impact of a "small change" to the performance or safety specifications. The verification testing that is performed to confirm device performance and safety is critically important. A replacement that seemingly has the same specifications must be tested after installation to ensure device performance and safety. 3rd Party Servicers and ISOs may not have the appropriate qualified individual(s) to conduct verification testing to ensure device performance and safety.