

February 25, 2019

Division of Dockets Management Staff (HFA-105)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 208552

Re: *Docket No. FDA-2018-N-3741: Request for Comments on Medical Device Servicing and Remanufacturing Activities; Public Workshop*
Docket No. FDA-2018-N-3741-0001: White Paper: Evaluating Whether Activities are Servicing or Remanufacturing

Dear Sir/Madam:

On behalf of the Advanced Medical Technology Association (AdvaMed), we are pleased to submit these comments on the Food and Drug Administration's (FDA or Agency) request for comment on medical device servicing and remanufacturing activities and the associated Public Workshop and White Paper entitled "*Evaluating Whether Activities are Servicing or Remanufacturing.*"

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. These members range from the smallest to the largest medical technology innovators and companies. AdvaMed's nearly 400 members manufacture the vast majority of all medical technology products sold in the U.S. 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.

Please see AdvaMed's general and specific comments below.

GENERAL COMMENTS

AdvaMed supports FDA's efforts to clarify remanufacturing activities as distinct from servicing activities via development of draft guidance (subject to our general and specific comments below) since many third-parties are, in effect, remanufacturing devices when they service them. In order to appropriately distinguish servicing from remanufacturing, it will be necessary for all third-party servicers and remanufacturers to have processes in place to determine if their actions are changing the device's performance or safety specifications or intended use, if the change is reportable to FDA or requires prior clearance or approval, and to document the decision.



Collaborative Communities

A substantial portion of the December 10-11, 2018 Public Workshop on Medical Device Servicing and Remanufacturing Activities focused on the topic of the potential development of collaborative communities (CCs) around the topic of device servicing. During the panel discussion on day two, AdvaMed outlined the criteria it would use to prioritize participation in servicing collaborative communities. These included:

- collaborative communities in which FDA participates and for which information about the CC (e.g., membership roster, mission statement, etc.) is on FDA's website to ensure transparency;
- Includes all representatives from relevant and key stakeholders;
- Seeks input from stakeholders on agendas and publicizes agendas in advance of meetings;
- Lists times and locations of meetings in advance and includes web conference and dial-in options; and
- Maintains publicly available records and minutes of meetings, participants and decisions.

We also believe that FDA should ensure basic principles of fairness and inclusion in any collaborative community which FDA decides to join or participate in. Thus, for FDA to join a collaborative community, it should ensure the criteria listed above are followed and also ensure that: there is a clearly-defined leadership and decision-making structure for the CC; that the CC is subject to a publicly available charter; that FDA maintains an open docket to permit stakeholders to comment on the collaborative communities in which the Agency participates; and that FDA maintains a publicly-accessible list of the collaborative communities in which it participates. By following these steps, FDA will signal that collaborative communities should be open to all interested participants and that they will operate with transparency, predictability, and accountability.¹

Statutory Issues Related to Third-Party Servicing

AdvaMed greatly appreciated FDA's acknowledgement at the Public Workshop that FDA is prohibited from disclosing the confidential commercial business information or trade secrets of Original Equipment Manufacturers (OEMs). As noted in the White Paper, "Trade secrets and confidential commercial information (CCI) are protected from public disclosure by the Trade Secrets Act, 18 U.S.C. § 1905, Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. §552(b)(4), and 21 CFR 20.61. Additionally, it is a prohibited act under section 301(j) of the FD&C Act to disclose trade secrets to unauthorized parties. FDA must comply with applicable statutory and regulatory requirements regarding the protection of trade secrets and CCI that are

¹ Notably, the assurances of transparency and other protections provided by law and regulations for advisory committees apply whether such groups are established by FDA or simply utilized by it, whenever the Agency intends to obtain advice or recommendations. *See*, 21 CFR 10.3 and 21 CFR Part 14.

submitted to the Agency.” We believe most service manuals, particularly the complex service manuals companies use to repair their own products, diagnostic or specialized software, specialized tools or hardware and routine service or maintenance (as distinct from user manuals) fall into the category of protected intellectual property which FDA cannot compel manufacturers to provide.

We would note that to the extent FDA were to seek to require sponsors to provide information to customers and device users that is not device labeling under section 201(k) of the Food, Drug, and Cosmetic Act (FDCA), the agency would need new statutory authorities. If FDA were to contemplate mandating the inclusion of such information *within* the device labeling, the Agency would need to make a determination that such information is necessary to provide adequate directions for the intended uses of these devices. Notably, however, the Agency has already classified these device types through a notice and comment process, and the marketed versions of these devices have already been cleared or approved. While the FDCA does allow FDA to make a determination that labeling must address conditions of use that are shown to be “customary or usual,” neither the servicing of a device to meet its original intended use, nor the remanufacturing of a device to significantly change the device’s intended use, are themselves “uses” of the device for these purposes. The “uses” contemplated are the intended uses to treat, prevent, mitigate or diagnose a disease or condition. More broadly, the Agency is bound by constitutional limitations in seeking to compel the distribution of specific information by device sponsors, absent a demonstrated interest in correcting or preventing misleading information. *See, e.g., R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1214 (D. C. Cir. 2012) (*citing Ibanez v. Florida Department of Business and Professional Regulation*, 512 U.S. 136, 146 (1994)).

Thus, device-specific technical, performance, or other product/component/part/material specifications for device servicing is beyond what is intended for the user and is outside the scope of device labeling.

A number of participants at the public workshop argued that OEMs should share Software Bill of Materials (SBOMs). Based on conversations our industry has had with health care providers, including those during roundtables hosted by the House Energy & Commerce Committee, the extent to which an SBOM would benefit customers is unclear. In fact, some health care delivery organizations have indicated that sharing SBOM information would be unmanageable for the thousands of devices operating in their environment. Similarly, and as noted above, FDA needs new authority to require this type of information to be provided to customers and device users because an SBOM is not product labeling under Section 201(k) of the Federal Food, Drug and Cosmetics Act.

It should be noted – consistent with quality system requirements, security and other concerns – OEMs currently do not distribute OEM manuals and specialized tools to non-affiliated or non-authorized third-party servicers for the following reasons:

- Security concerns (e.g., cybersecurity concerns);
- HIPAA and patient privacy concerns;
- Safety and efficacy concerns;

- OEMs have processes in place to alert purchasers and OEM authorized/affiliated third parties when significant device changes have occurred, however, it is impossible to notify unauthorized/unaffiliated third-party servicers when significant device changes have occurred since OEMs have no information on which 3rd parties are servicing their devices; and/or
- OEMs cannot verify if third-party servicer(s) have acceptable device maintenance processes in place.

As stated in previous AdvaMed docket comments, provision of servicing manuals to third parties will not ensure appropriate servicing given the training needed to ensure proper servicing of most devices. For certain devices, up to two years of training may be required with ongoing intermittent training required thereafter. Additionally, without a requirement to follow basic quality management practices (e.g., such as ensuring training of personnel, evaluating parts suppliers, calibrating tools and maintaining records of such, and maintaining device service and preventive maintenance records, etc.), provision of servicing manuals will not by itself ensure proper servicing. This is especially true as devices continue to become more complex and technologically advanced.

Quality System Regulation (QSR) and Third-Party Servicing and Remanufacturing

Many OEMs act as third-party servicers to other OEMs and comply with QSR. OEMs also rely on contracted third-party servicers to meet their own servicing needs. As a reminder, OEMs are required to have purchasing controls and required to conduct supplier oversight over any entity that performs servicing on behalf of the OEM (21 CFR 820.50). As FDA itself has said, “*proper servicing is critical to the ongoing safety and effectiveness of many devices, particularly those used on numerous patients over long periods of time; poor quality servicing may lead to poor device performance, malfunction, and adverse events. Further, FDA believes it could interpret certain activities to which certain statutory requirements apply to include servicing. Given these, and that the requirements of the FD&C Act continue to apply after a device is sold, for example, to a hospital or other user facility, FDA believes it has statutory authority to regulate device servicing.*”² AdvaMed believes high-quality third-party servicers – that are required to follow the QSR – are needed to ensure sufficient device servicing capacity.

The QSR covers the entire device lifecycle from device design, manufacturing and installation to servicing. Importantly, the QSR is risk-based, scalable and feasible for any company to meet. It applies to all device manufacturers – no matter their size – from the very smallest to the largest company. Small device companies – some with extremely limited numbers of staff – are not allowed to exempt themselves from QSR compliance. Importantly, QSR compliance is understood to be a required fundamental of doing business in the device sector. FDA has stated “quality systems ... help ensure that ...products consistently meet applicable requirements and

² May 2018, FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices: In accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA); p. 4.

specifications.” For these reasons, we believe all companies, OEMs and third-party servicing entities alike, should be QSR-compliant and that a claimed lack of resources by third-party servicers should not serve as an argument to avoid compliance with such minimum requirements.

Specifically, to ensure patient safety, AdvaMed believes FDA should issue formal regulations vis-a-vis third-party servicing requiring compliance with the following:

- Require third-party servicers to register and list with FDA (including publication of which OEM equipment they service) ;
- Require third-party servicers to establish a Quality Management System that is appropriately scaled to the products and types of servicing they conduct as required by the QSR;
- Clarify that FDA will routinely inspect third-party servicers for compliance with the QSR;
- Require third-party servicers to report MDRs to FDA and OEMs; and
- Ensure that MDR codes include identifiers for third-party servicers

Harm to Competition from Discriminatory Application of Quality Standards

FDA applies rigorous quality standards to repair entities that are controlled by OEMs but has not applied these standards to independent third-party repair entities. FDA has acknowledged that it has the authority to regulate independent third-party repair entities but has decided to defer rulemaking regarding these entities.^{3,4} This discriminatory application of quality standard requirements harms manufacturers, their buyers, patients, and competition generally by creating an environment of unfair competitive advantage conferred to some entities over others in the medical device market.

Ideally, buyers of devices can have choices of vendors who offer repair services as long as these vendors comply with quality standards. As we have demonstrated, manufacturers have no interest in acquiring a dominant position in the repair market. Their interest is ensuring that any servicing and repairs of their products are done according to strict specifications and do not result in harming the patient and undermining the reputation of the manufacturer. Since manufacturers are required by regulation to control the quality of service and repair providers, FDA’s failure to apply quality standards to third-party service entities introduces a significant and harmful distortion in the market.

³ Ibid, p. 4.

⁴ During the May 2, 2017 Energy and Commerce Health Subcommittee hearing titled “Examining Improvements to the Regulation of Medical Technologies,” Dr. Jeff Shuren, Director, Center for Devices and Radiological Health, responded to Representative Gene Green’s question about the rules and requirements that currently apply to third party service providers, stating “So, in our regulation on quality systems, we had made clear that third-party servicers are manufacturers, but they have been subject to *enforcement discretion* [emphasis added]. We have not enforced those requirements.”

Failing to impose quality standards on independent service and repair entities means that these entities have a competitive advantage in the market. They can lower their costs by using unregulated parts and service methods that may lead to owners of these devices choosing them over regulated service providers. Use of these devices on patients could result in poorly performing or unsafe devices.

SPECIFIC COMMENTS ON THE WHITE PAPER

Although many of our specific comments relate to the white paper, the majority of the comments below will also be applicable to any draft guidance FDA prepares in this area.

Comments on Part 3: Scope

In general, AdvaMed sees value in outlining principles and identifying quality system requirements for *all* servicing in the draft guidance.

The draft guidance should include a brief discussion about the distinction between maintaining or returning a device to specification (i.e., service or repair) versus remanufacturing in which the specifications of the device are altered to create new specifications or to accommodate a new intended use of the device.

The proposed draft guidance should also address the fact that preventative maintenance and servicing helps establish device reliability and service life. The guidance should advise on how component replacement should be evaluated within the context of service interval or device life.

Comments on Part 4: Guiding Principles for Discussion

Principle 1

Principle 1 should be changed to clarify that this process does not apply to OEMs servicing their own legally marketed devices or to OEM-affiliated or authorized third-party servicing entities. This should also be reflected in the scope of the proposed draft guidance and in the draft guidance flow chart. It is unnecessary for an OEM to assess impact to the device for each service call the OEM makes on its own legally marketed device. By definition, servicing does not significantly change the safety or performance specifications, so when an OEM services a device it does not trigger the evaluation under 820.30(i) “Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation;” 814.39(a) “After FDA’s approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA ...;” or 807.81(a)(3) “The device is one that the person currently has in commercial distribution ... but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use.” The OEM is not changing elements of the device design and is not about to significantly change one of its devices in the field because the action, by definition, is servicing. Due to lack of knowledge of commercially protected design control information, activities conducted by third-party servicing

entities that are *not intended to* significantly change the performance, safety, specifications or intended use of a device should still be evaluated to determine whether the change significantly affects device performance, safety, specifications or intended use.

In addition to the above paragraph, given the continued growing complexity and technological advancements associated with devices, the bolded subtitle of Principle 1 should be amended to state, “Servicing by appropriately trained personnel does not significantly change the safety or specifications of a device.” The first sentence of Principle 1 should be changed to: “Activities that could significantly change the performance or safety specifications, or intended use of the device are remanufacturing and are not servicing.” The last sentence of Principle 1 should be amended to say: “Activities that are not intended to significantly change the performance or safety or specifications, or intended use of a device, however, should still be evaluated to determine whether the activities change could significantly affects- device performance and safety specifications, or intended use.” In general, with respect to the term “significant,” we believe FDA’s planned draft guidance to distinguish servicing from remanufacturing should align with FDA’s regulation in 21 CFR 807.81(a)(3) and FDA’s guidance on “Deciding When to Submit a 510(k) for a Change to an Existing Device.” In both the regulations and the guidance, the term “significant” is always preceded by the word “could.” We see no reason the more stringent standard of “*could significantly* change the performance or safety specification or intended use of the device” would not apply in this context.

Principle 2

As noted above in the first paragraph under Principle 1, Principle 2 should be changed to clarify this process does not apply to OEMs servicing their own legally marketed devices. This should be reflected in the scope of the draft guidance and in the draft guidance flow chart.

Principle 2 fails to mention PMA. This principle needs to be expanded to include reference to PMAs and guidance which lays out when a change to a PMA requires a submission.

Additionally, all OEMs have a detailed assessment process and/or flow chart to determine if a change is reportable to FDA or requires prior clearance or approval, and to document the decision. As a result, this principle should clarify that all third-party servicers and remanufacturers are expected to have an equivalent process in place. Consistent with this, since the changes third-party servicers make should not “significantly change device performance or safety specifications,” it will be important for all third-party servicers to evaluate and document that there is no change.

Principle 3

It is unclear how unauthorized, unaffiliated third-party servicers or remanufacturers will be able to assess changes to components, parts, materials, software, integrated systems and dimensional and performance specifications without access to the OEMs’ design specifications which is protected trade secret, confidential, intellectual property. For example, extremely small dimensional changes could impact safety but may not be picked up by mere “comparison to OEM

components/parts/materials specification and/or through testing.” In many instances, to ensure that components, materials, etc. are acceptable substitutions, it will require stress testing, pull tests, electrical tests, etc.

It should be noted that at the workshop, some of the working group discussions assumed third-party servicers would perform a finished device performance test to demonstrate that the device met performance specifications. This assumes these servicers have the device specific equipment to perform the testing, know the test method and know the acceptance criteria. FDA frequently requires OEMs to obtain approval prior to making changes to test methods and acceptance criteria. FDA also expects OEMs to use quality system practices to validate components and qualify suppliers. A change to a component supplier for a PMA product typically requires prior approval, even when there is no change to specifications. OEMs also are required to have a change assessment process to assess whether a component change alters the device performance or risk profile. We assume the future draft guidance will hold all service providers to the same standards.

Future draft guidance will need to consider when component changes require retesting by a certified test laboratory, such as UL. During design verifications, OEMs will frequently have a Nationally Recognized Testing Laboratory (NRTL) assess and test a device to components of known specification and issue a 60601 test report and certificate. Changes to critical components may require the test laboratory to update and re-issue the report. FDA’s draft guidance needs to address how third-party servicers will complete this requirement.

Future guidance will also need to factor in replacement components/parts that perform the same function but perform differently than the original part (i.e., risk may not be increased but the specifications are different from the original device such as greater memory capacity). An OEM would look at this change in the context of whether the change could significantly affect safety and efficacy of the product. However, if a third-party servicer changed the specifications, they could be considered a manufacturer. It is unclear how servicers could make this determination without having the information and knowledge known by the OEM (i.e., having access to design specification, design history files and other information).

Principle 4

We do not believe the guidance can actually be implemented unless FDA is willing to require registration and listing of third-party servicers and a concomitant requirement that they follow the quality system management. Since many third-party servicers are not registered and/or do not currently comply with quality system management approaches, they will not be able to apply the principles in the proposed draft guidance. They will be inclined to say they are simply servicing when, in fact, they are remanufacturing the device. To prevent this, FDA must be willing to inspect third-party servicers and enforce any violations committed by third-party servicers.

As noted above, third-party servicers will need to have access to the OEM’s original protected risk assessment if they are going to evaluate the impact of their activities which FDA does not have authority to disclose or to require its disclosure. The guidance will also need to address how

FDA expects third-party servicers to evaluate changes to Design Failure Mode Effects Analysis (DFMEA), Use Failure Mode Effects Analysis (UFMEA), Process Failure Mode Effects Analysis (PFMEA), and overall risk-benefit determinations without access to protected, confidential OEM risk documents. Third-party servicers should also be required to have qualified, trained staff performing risk evaluation which OEMs are required to have.

Principle 5

OEMs are required by quality management requirements to have a process to assess changes to components, test methods, device performance, and to use validated methods for servicing. This assessment is documented within the change management system. For this type of documentation, OEMs are subject to audit by the FDA. FDA should also require third-party servicing organizations to be held to the same quality management requirements and to inspect all third-party servicers to ensure servicers are not remanufacturing.

We believe the draft guidance should clearly state expectations for remanufacturers to include the following the requirements:

Maintain a scalable Design History File, with supporting testing.

1. Obtain device clearance/approval.
2. Remove OEM markings and labeling and place their own marks and labels on the device(s) and provide new Instructions for Use (IFUs) for the device(s).
3. Meet all Unique Device Identifier (UDI) requirements including GUDID entries, and assigning Global Trade Item Numbers (GTINs) to device(s).
4. Establish a new 'service life' for the device(s).
5. The device performance, safety and effectiveness and all liability is transferred to the Remanufacturer.
6. Required Registration and listing for each device they are remanufacturing to facilitate FDA inspection.

The draft guidance should also address device end of life issues. OEMs typically determine end of life due to an inability to source parts and components so as to ensure good quality servicing. When an OEM notifies customers that a product has reached end of life, including end of manufacturing, end of sale and end of effective service and support, and third-party servicers continue to service the devices, OEMs should no longer be required to provide complaint documentation and conduct MDR investigations. The device is, in effect, being remanufactured.

Response to Select FDA Questions

Question: What are the pros and cons of the risk-based approach discussed in this white paper?

Response: As noted above, one of the obstacles to this approach is that a risk-based approach needs to consider both the design of components and finished device, user interaction and the process of servicing / repair. Third-party servicers will need access to the original risk assessment and other protected OEM information to conduct their risk evaluation. Because this information is protected trade secret commercial intellectual property held by the OEM, it is unclear how this obstacle can be overcome unless the third-party servicer is authorized or affiliated by the OEM.

Comments on Part 5: Flow Chart for Distinguishing Servicing from Remanufacturing

AdvaMed agrees with FDA that any changes to sterilization methods would constitute remanufacturing. In addition to the list of activities cited as examples that FDA believes do not constitute servicing, we believe the items below go beyond servicing, repair or maintenance and are remanufacturing:

- Changes to the validated reprocessing instructions including methods, sterilization or materials/cleaning agents;
- Changes to device design to diagnose or treat a different anatomy from the original intended use;
- Changes that adversely affect human factors;
- Changes to materials that could affect biocompatibility;
- Changes that could affect expected device life or service life (i.e., reliability);
- Changes that could affect interaction / interoperability with other devices or accessories that are designed by the OEM to be used as a ‘system’; and
- Changing the integrity of any seal of a finished device (hermetic or otherwise). As an example, many seals are intended to act as a barrier to prevent contamination of the surgical site from internal device components such as mechanical lubricants and to prevent internal components from contact with bodily fluids and/or wastes.

Comments on the Flow Chart

- As noted in Principles 1 and 2, the flow chart assessment should begin with a new box containing the question: “Are the activities performed by or on behalf of the OEM to the OEM’s legally marketed device?” The OEM assesses product changes continually through its design control and product change procedures. It is unnecessary to conduct an assessment prior to each service call. If the response is “Yes,” then it is servicing. If “No,” continue to the question in A1 and proceed through the rest of the flow chart.
- The questions in A2 and A1 should be reversed and should follow the question regarding whether the activities are performed on or on behalf of the OEM to the OEM’s device. The questions in A2 focus on distinguishing between remanufacturing and servicing. Assessing whether the change is significant to device performance or safety specifications

would apply when there is a “Yes” to one of the questions in A2, not before. Each of the questions in A2 should be asked separately.

- The draft guidance should address the question of who is qualified to answer the questions raised in the flow chart. There will be an inherent risk to patient safety if an unqualified person makes these determinations and is not aware of all the performance specifications of parts, software and integrated systems. The answers must be documented and available for inspection.
- As noted above in our comments on the Principles, a third-party servicing entity will not be able to answer Questions A1.1, A2.1 and A3.1 without access to OEM’s protected confidential intellectual property or without being an authorized or affiliated third-party servicing entity. As discussed above, in our general comments, required publication of detailed product specifications; component, part or material specifications; software; or a requirement to publish manuals or other service information exceeds FDA’s statutory mandate. FDA’s discriminatory application of quality system requirements is also harming competition.
- The flow chart should address changes that might adversely impact human factors.
- For the Remanufacturing conclusion, the flow chart should include criteria regarding when FDA clearance or approval is required, along with expectations for updated labeling. This includes updated device labels and directions for use (DFUs) and operators’ manuals for remanufactured devices. In addition, these updated instructions should state the re-established service life of the remanufactured device.
- All of the questions in the flowchart should be broken into separate questions to ensure clarity and ease of use of the flowchart.
- The flow chart should include finished device ‘acceptance testing’ to demonstrate the serviced device meets requirements. Most OEM’s include some type of calibration, final test or recurrent safety test to document the device meets performance specifications. During the public workshop, many of the groups assumed that a “final test” could be performed to demonstrate device performance. This requires using the validated test method, equipment and acceptance criteria. This OEM information is protected trade secret, proprietary intellectual property.

Comments on the Accompanying Flow Chart Text

In addition to the changes recommended to the flow chart discussed above which will require corresponding changes to the accompanying flow chart text, we have specific comments on the flow chart text below.

A1.1 – Add biocompatibility to the title such that it reads “Does the change significantly affect device biocompatibility, performance or safety specifications?”

When OEMs make biocompatibility assessments, they review previously completed ISO 10993 testing and then identify which tests warrant repeating. Third-party servicers should perform a similar assessment along with development of a rationale for when and what type of particular testing is required.

In addition to biocompatibility, the material assessment needs to consider how the change affects the validated cleaning and reprocessing instructions to ensure there is no change to cleanliness and/or sterility claims. Third-party servicers must also consider whether the number of validated uses must be changed when a new part or material is used. In recognition of the importance of these issues, FDA has issued a variety of safety communications associated with new parts, materials or changes to cleaning and reprocessing instructions such as the [duodenoscope reprocessing safety communication](#).

A2 – Add “or replace” to the title such that it reads “Add, ~~or~~ remove, or replace component/part/materials or change the dimensional or performance specifications of a component/part/material? As stated above in our comments on the flowchart, we believe all the questions in the accompanying flow chart text should be asked separately for clarity and ease of use.

A2.1 – First paragraph

Add “or replaced” to the first sentence so that it reads: “Does the added, ~~or~~ removed, or replaced component/part/material significantly change the device performance or safety specifications?”

Add “or replacement” to the second sentence so that it reads: “When evaluating whether an addition, removal or replacement of a component/part/material will significantly change the performance or safety specifications, you may consider the intended use life of the legally marketed device.

Add “..., including assessment of whether the changed components alters the validated useful life/service life” to the fifth sentence so that it reads: “If not, the addition or removal of the component may significantly change the legally marketed device’s performance and safety specifications, including assessment of whether the changed component(s) alters the validated useful life/service life.”

Second Paragraph

Add “tolerance” to the third sentence so that it reads: “You should consider whether dimensional specifications meet a minimum or maximum specification (i.e., outer diameter cannot exceed 3.0 mm) or are within a range of acceptable tolerance specifications.”

Third Paragraph

Add “and/” to the second sentence so that it reads: “When evaluating if the change significantly affects performance or safety specifications, you should consider whether performance outputs meet a minimum and/or maximum specification (i.e., temperature

within chamber cannot exceed 25 °C and pressure cannot be less than 150 kPa) or are within a range of acceptable specifications (pump flowrate must be between 2 and 20 mL/h).”

In the third sentence, strike the second “likely” and add a new sentence at the end so that it reads: “If performance specifications are within the acceptable range, the answer would likely be “no”; however, for changes that are outside the acceptable range of performance specifications, the answer would ~~likely~~ be “yes.” Due to patient safety concerns, anything less than a complete assessment would be yes.”

A.3 – This section should also consider Medical Electrical Equipment (MEE) that was previously tested for EN ISO 60601 compliance and/or other relevant standards. If there were changes to components (i.e., critical components) that affect the validity of the previous report/certificate, the remanufactured device may need new electrical safety testing by a Nationally Recognized Testing Laboratory. With respect to performance, please note the last bullet in our comments on the flow chart.

Comments on Part 6: Changes Involving Software

Add “/Firmware” to the title and add “/firmware” each time “software” appears. As an example, the title would read: “Changes Involving Software/Firmware”. Issues associated with changes to OEM firmware must be addressed in the draft guidance. During the workshop, third-party servicers discussed cases of replacing printed circuit boards (PCBs). PCBs may contain firmware which, if removed or replaced, could change device performance.

We recommend that the bullet “Reverting software to a previous configuration” be revised to the following: “Reverting software to a previous configuration following a detailed risk/impact analysis.” OEMs develop new configurations for a reason – to correct software bugs, to address safety fixes, etc. In addition, hardware changes may have been tied to the software change (e.g., new handpiece may not be recognized; a new motherboard may have been added to support the software; a new printer driver added for a new printer). Reverting software to previous configurations can also open up ports for cybersecurity breaches. In these instances, reverting the software to a previous configuration goes beyond servicing.

Revise the last bullet to read: “Turning on or off connectivity features (e.g., WiFi and Bluetooth connections), as long as this does not change OEM intended use.”

The draft guidance should also specifically address the topic of cybersecurity and related cybersecurity patches that are not authorized by the OEM. There is an assumption that patches can be applied without specific knowledge of the device and device software and that no servicing or diagnostic testing is needed after a patch is applied. However, our companies have had to service their devices after customers applied network security patches without working with the OEM on testing or coordination of the activity, causing unnecessary device down time, and affecting patient safety.

Although FDA's white paper does not directly address this, AdvaMed also wants to reiterate our concern and disagreement with any possible suggestion that OEMs should be required to share hard-coded passwords with non-affiliated third-party servicers. Any suggestion toward this end would be directly contrary to advice FDA has provided in its guidance entitled: ***Content of Premarket Submissions for Management of Cybersecurity in Medical Devices***. The guidance states: "Limit access to devices through the authentication of users (e.g., user ID and password, smartcard, biometric);" and "Strengthen password protection by avoiding "hardcoded" password or common words (i.e., passwords which are the same for each device, difficult to change, and vulnerable to public disclosure) and limit public access to passwords used for privileged device access...." It would also be contrary to the advice of the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team (ICS-CERT) which cites FDA's advice: "Take steps to limit unauthorized device access to trusted users only, particularly for those devices that are life-sustaining or could be directly connected to hospital networks.

- Appropriate security controls may include: user authentication, for example, user ID and password, smartcard or biometric; strengthening password protection by avoiding hard-coded passwords and limiting public access to passwords used for technical device access; physical locks; card readers; and guards."

Comments on Part 7: Considerations for Labeling

The white paper appears to suggest that FDA is contemplating requiring OEMs to provide third-party servicers access to device specifications: 1) "Access to device specifications may be needed by entities performing servicing to assure that the work being performed returns the device to its proper state. While some product specifications may be provided in the product labeling or other publicly available information, other specifications may not be available" and 2) the question FDA posed "Which device technical, performance or other product specifications should be included in the device labeling?" FDA is prohibited under the statute from requiring OEMs to share device specifications and would have to seek additional statutory authority in order to require OEMs to share device specifications.

As we noted in our general comments above, such information is trade secret, confidential commercial information and we do not believe FDA has statutory authority to require expansion of labeling to include or otherwise share such information. Further, forcing disclosure would reduce the value of this information and harm manufacturers' ability to compete. Manufacturers currently provide certain specifications to device users in the instructions, for the safe and effective use of the device for its intended use and by the intended user population. The information provided is based on the device, its design and the associated risk, and the detail necessary for routine maintenance and service by the intended user of the device as contemplated by device design. A requirement to publish to the general public all device specifications not only presents intellectual property and statutory authority concerns but introduces patient safety issues by providing a roadmap to the unintentional and intentional tampering of medical devices.

Further manufacturers have a legitimate need to restrict the persons who are authorized to repair devices because servicing is highly technical and a failure to properly service or repair a device

will be harmful to patients and device operators and damage the manufacturer's reputation. The manufacturer already provides repair information to persons authorized to repair devices so there is no need for this information to be included in labeling. Requiring manufacturers to disclose repair and service information to everyone, for example through labeling, will undermine the efforts of manufacturers to ensure their devices are maintained properly and continue to be safe and effective. It may also, as an example, facilitate servicing of devices by those who may have little or no training (e.g., patients servicing their own home-use devices).

The proposed guidance should make clear that if a labeling change is required due to activities carried out by the third-party service entity, they have remanufactured the device. It should also discuss requirements for removing the OEM mark, labeling and instructions for use (IFUs) and replacing these with the mark, labeling and IFUs of the remanufacturer. In searching the Centers for Devices and Radiological Health (CDRH) website, remanufactured device labeling does not seem to be defined in other guidance. Remanufacturers would need to relabel the device to support the revised performance and intended use of the device and to ensure that users understand that the remanufacturer is the new manufacturer of the device. For example, the remanufacturer may need to update the EMC (electromagnetic compatibility) safety testing and separation distances listed in user manuals. Further, since the remanufacturer is a different entity than the OEM, FDA should identify a requirement in the draft guidance that the remanufacturer must obtain a new establishment registration and device listing and new UDIs and GTIN.

Lastly, we recommend adding a note to the flow chart that "Servicing does not require labeling updates."

Comments on Part 8: Examples for Discussion

AdvaMed does not have specific comments on the examples. However, based on discussions held at the public workshop, many of the examples required layer upon layer of assumptions which is indicative of the complexity of devices. Indeed, many of the assumptions made by third-party servicing representatives about the device examples were incorrect. In addition, many of the examples were not cost-effective; it would have been better to simply replace the device. For the proposed draft guidance, we recommend that the examples be updated based on the experience from the workshop and the following:

- Examples should represent real-world scenarios for the device type;
- Examples should include assumptions on the criteria used during the assessment;
- Provide an example of the 'risk-based assessment' to illustrate the connection to design risk, usability risk and processing/servicing risk;
- State the conclusion reached (servicing, remanufacturing);
- State when prior PMA or 510(k) submission is warranted;
- Add examples for when labeling changes are warranted; and
- Add IVD examples.

In closing, thank you for this opportunity to provide comments on FDA's medical device servicing and remanufacturing activities and the associated Public Workshop and White Paper entitled "*Evaluating Whether Activities are Servicing or Remanufacturing.*" Please don't hesitate to contact me if I can help respond to any questions.

Sincerely,

/s/

Tara Federici
Vice President
Technology and Regulatory Affairs