White Paper: Evaluating Whether Activities are Servicing or Remanufacturing

Disclaimer: This white paper is for discussion purposes only and does not represent draft or final guidance. It is not intended to propose or implement policy changes regarding servicing and remanufacturing or the applicable statutory and regulatory requirements for entities conducting these activities.

The Food and Drug Administration (FDA) is holding a public workshop to gather feedback and comments concerning the distinction between servicing and remanufacturing. This upcoming workshop, entitled "Medical Device Servicing and Remanufacturing Activities" will be held on December 10-11, 2018. The discussions at the workshop and comments received in the docket will be considered when developing draft guidance as noted in the Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices (FDA Report on Device Servicing) in accordance with section 710 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52).[1] Please submit your comments regarding this white paper and the workshop to https://www.regulations.gov, Docket No. FDA-2018-N-3741 by January 25, 2019. Additional information can be found on FDA's webpage, https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm623283.htm.

1 Introduction

FDA is releasing this white paper and holding a workshop to better inform future draft and final guidance that will aid industry and FDA staff in determining whether an activity is servicing or remanufacturing. The intent of this public workshop is to publicly discuss the potential factors and criteria on which FDA may base its determination of whether an activity is servicing or remanufacturing. The concepts presented in this white paper are intended to guide discussions during the upcoming workshop. This document contains FDA's initial thoughts about guiding principles, a flowchart with accompanying text, a complementary approach for software, considerations for labeling, and examples. FDA is seeking specific input on each of these topics.

In preparation for the upcoming workshop, you may consider how FDA's initial thoughts on these guiding principles apply to your activities and practices. Additionally, FDA is seeking feedback on a flowchart that aims to help distinguish between servicing and remanufacturing by addressing activities performed on a legally marketed device. The flowchart is intended to be considered with the accompanying text in Section 5 of this white paper. The flowchart is intended to be applied to each action performed on the device as well as the actions in aggregate. The decision of whether an activity or activities is/are servicing or remanufacturing should be based on consideration of all applicable decision points in the flowchart and, if applicable, the complementary approach for software in Section 6. FDA has also posed questions concerning labeling in Section 7. Finally, the examples in Section 8 will be discussed during the workshop to evaluate the appropriateness of the draft flowchart and the complementary approach for software. The examples are for illustrative purposes and are intended to represent common scenarios. They may not include all details of each situation that might be

[1] This report, published in May, 2018, is available at https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/UCM607469.pdf.

considered in a decision.

After considering public comments expressed during this workshop and submitted to docket FDA-2018-N-3741,[2] FDA intends to issue draft guidance that will provide proposed recommendations to help distinguish between servicing and remanufacturing. This white paper is not draft or final guidance and is not intended to propose or implement policy changes regarding servicing and remanufacturing or the applicable statutory and regulatory requirements for entities conducting these activities. Rather, the intent of this white paper is to facilitate public discussion on the distinction between servicing and remanufacturing.[3]

2 Background

FDA's conclusions in the FDA Report on Device Servicing were based, in part, on information submitted to a docket from a request for comments,[4] a public workshop held in 2016,[5] and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing. FDA concluded that a majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to adverse events and deaths actually pertain to "remanufacturing," and not "servicing." FDA makes an important distinction between these two activities; which of these two categories an activity falls within may determine the applicability and enforcement of regulatory requirements such as those regarding quality systems, premarket notification, adverse event reporting, and registration and listing. For purposes of the FDA Report on Device Servicing and this white paper, servicing is the repair and/or preventative or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the original equipment manufacturer (OEM) and to meet its original intended use. Remanufacturing is processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[6] For the purposes of this document, we refer to the OEM's legally marketed finished device as the "legally marketed device."

3 Scope

This white paper discusses servicing and remanufacturing activities performed on devices by OEMs and third parties.[7] This white paper addresses activities performed on reusable devices that can be serviced, repaired, refurbished, maintained, and/or remanufactured.

The products included within the scope of this white paper are:

- Devices, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software and electronic products that meet the definition of a device; and

[2] Submit electronic comments on this white paper at https://www.regulations.gov.
[3] For additional background and supporting information, see supra note 1.
[4] 81 FR 11477.
[5] 81 FR 46694.
[6] 21 CFR 820.3(w).
[7] Third party servicers and Independent Service Organizations are entities, other than the manufacturer or healthcare establishments, that maintain, restore, refurbish, or repair a finished device after distribution, for purposes of returning it to the safety and performance specifications established by the manufacturer and to meet its original intended use.

- Combination products, as defined in 21 CFR 3.2(e), for which CDRH is the lead Center.[8]

In general, the concepts discussed in this white paper are meant to apply to all devices, including those subject to PMA. This white paper is not intended to describe the specific regulatory requirements for remanufacturing or servicing.

FDA notes there is overlap between the regulatory definition of remanufacturing (altering a finished device in a way that significantly changes its performance or safety specifications, or intended use) and the standard for when a 510(k) is required for a change to a legally marketed device (a change that *could* significantly affect safety or effectiveness or a major change in intended use).[9] However, the concepts in this document are not intended to alter or supersede existing policies related to the regulatory threshold for submitting a new 510(k) for a device.

4 Guiding Principles for Discussion

The following section includes FDA's initial thoughts on guiding principles and recommendations that FDA is considering proposing in draft guidance. These guiding principles are designed to help FDA and entities determine whether activities are servicing or remanufacturing.

1. **Servicing does not significantly change the safety or performance specifications of a device** – Activities that significantly change the performance or safety specifications, or intended use of the device are remanufacturing and are not servicing. 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 change significantly affects device performance and safety specifications, or intended use.

2. **Evaluate whether any changes to a device require a new 510(k)** – Regardless of whether changes made to a cleared device are servicing or remanufacturing, such changes should be considered pursuant to 21 CFR 807.81(a)(3) and the concepts in the FDA guidances Deciding When to Submit a 510(k) for a Change to an Existing Device[10] and Deciding When to Submit a 510(k) for a Software Change to an Existing Device.[11]

3. **Assess component/part/material[12] dimensional and performance specifications** – Assessment of changes to dimensional and performance specifications can inform whether the activity

[8] Although the scope of the white paper does not include combination products with device-constituent parts for which other FDA Centers have primary jurisdiction, we believe these concepts could apply to device-constituent parts of all combination products.
[9] See the FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771, and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.
[10] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771.
[11] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.
[12] 21 CFR 820.3(c) defines a component as any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device. In this white paper, "component" and "component/part/material" are used interchangeably. Due to the nature of software and firmware, consideration of whether activities involving them may be remanufacturing or servicing is discussed separately from components/parts/materials.

performed is servicing or remanufacturing. Consequences of component/part/material changes can be evaluated by comparison to OEM components/parts/materials specifications and/or through testing. Deviations in component/part/material specifications from the OEM counterpart may result in significant changes to the legally marketed device's performance or safety specifications, or intended use, and may necessitate closer evaluation. When there are no deviations in component/part/material dimensional or performance specifications from the OEM counterpart, there would likely be no significant changes to the legally marketed device's performance and safety specifications, or intended use, in the absence of other types of changes.

4. **Employ a risk-based approach** – FDA is considering recommending that entities employ a risk-based approach, such as one that conforms to or is consistent with ISO 14971: *Medical devices – Application of risk management to medical devices* when assessing whether an activity they perform is servicing or remanufacturing. A risk-based assessment, as referred to throughout this document, is based on the combination of multiple risk concepts that are important for managing the risks of medical devices. Risk estimation, risk acceptability, risk control, risk/benefit analysis, assessment of hazards and hazardous situations, and overall risk evaluation are all concepts that can be applied during servicing and remanufacturing activities. The concept of risk, as defined in ISO 14971, is the combination of the probability of occurrence of harm and the severity of that harm. Although the risk terminology used in this document is primarily derived from ISO 14971, we recognize that an individual entity's terminology may differ.

   For the purposes of this white paper, an activity performed on a device is likely remanufacturing when a risk-based assessment identifies any new risks or significantly increases known risks, and thus significantly changes performance or safety specifications, or intended use, in comparison to the legally marketed device.

5. **Adequately document decision-making** – When deciding whether an activity is servicing or remanufacturing, FDA is considering recommending that the rationale for the determination be documented with sufficient detail to explain why the determination was made. Specifically, FDA is considering proposing that the documentation specify why the activities performed on the device do or do not significantly change the performance or safety specifications, or intended use of the legally marketed device. Effective documentation can facilitate sound decision-making and evaluation of adverse events, and provide necessary information for an entity to justify their decision-making in the event that an inspection is conducted by FDA or this information is otherwise requested.

FDA is seeking feedback on whether stakeholders agree with these guiding principles and whether any principles or considerations should be added or removed. Additional considerations to address in feedback include:

- **Are there additional considerations that may help entities distinguish between servicing and remanufacturing activities?**
- **What are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing?**
- **What are the pros and cons of the risk-based approach discussed in this white paper?**

5 Flowchart for Distinguishing Servicing from Remanufacturing

For activities involving components/parts/materials, FDA is considering the flowchart detailed below for helping entities distinguish servicing from remanufacturing. The flowchart (Figure 1) is a visual aid intended to be used in concert with the accompanying text and guiding principles. The flowchart and accompanying text are intended to address the most common and important considerations that should be evaluated, but is not meant to capture *all* necessary considerations that an entity should evaluate in distinguishing servicing from remanufacturing. Rather, they are intended to guide entities in determining when additional evaluation (such as testing or conducting a risk assessment) is necessary. The flowchart and accompanying text are intended to be consulted after it is determined that there is no significant change to intended use.

Under this flowchart, each change (e.g., physical change or change to safety control) should first be assessed individually to determine whether the action represents servicing or remanufacturing. With each additional change being evaluated, the cumulative changes should be assessed to determine whether the collective changes represent servicing or remanufacturing. FDA is also considering a complementary approach for changes involving software (see Section 6). Throughout these approaches, the legally marketed device should be used as the basis for comparison.

FDA is considering identifying certain types of activities that, in general, significantly change the legally marketed device's performance or safety specifications, or intended use. These changes would typically represent remanufacturing and evaluation using the flowchart, accompanying text, and guiding principles would not be necessary.

The following activities are examples that FDA is considering identifying as generally not constituting servicing:[13]

- Changes to sterilization methods;
- Changes to reprocessing instructions;[14]
- Changes to the control mechanism,[15] operating principle,[16] or energy type;[17] and
- Significant changes to intended use (e.g., changing a single-use device to become reusable).

Stakeholders should consider whether they agree with this list or whether any activities should be added or removed to represent examples of changes that do not constitute servicing.

[13] These activities would generally be considered remanufacturing; however, it is possible that in limited circumstances, such an activity may not be servicing or remanufacturing.

[14] See the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.

[15] A control mechanism is the manner by which the actions of a device are directed. One example of a control mechanism change would be a change from analog to digital control of a medical device.

[16] An operating principle is the mode of operation or mechanism of action through which a device fulfills (or achieves) its intended use. An example of a new operating principle would be changing the image reconstruction algorithm used in a computed tomography x-ray system from simple back projection to a new, more radiation-efficient method.

[17] Energy type is the type of power input to or output from the device. These changes include both energy output and input changes. A change from emitting microwave energy to radiofrequency (RF) energy would be an example of an energy output change; this type of change would likely be part of a significant redesign.

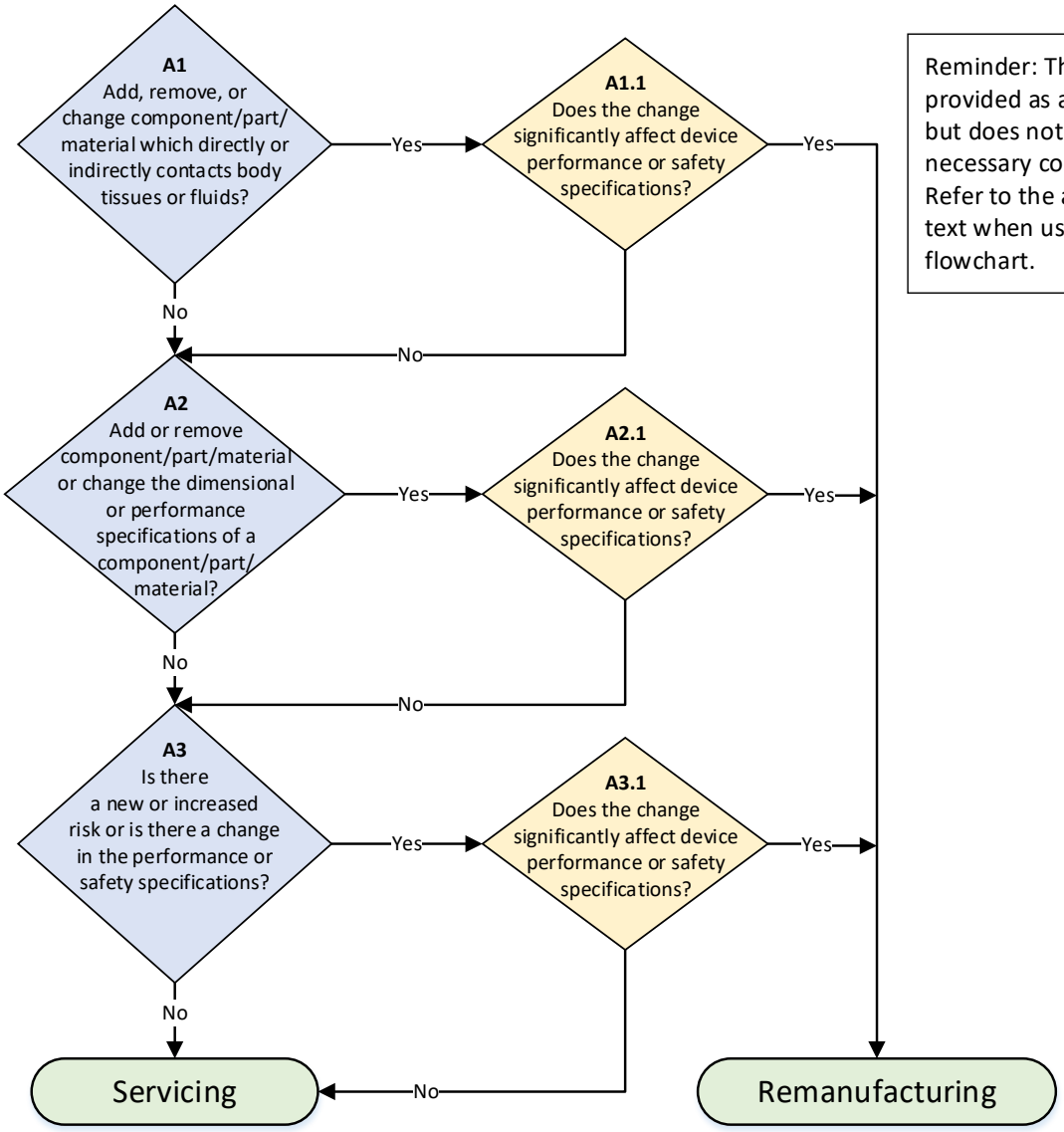

Figure 1. Flowchart proposed to distinguish whether activities performed are servicing or remanufacturing.

The following introduces accompanying text for the flowchart in Figure 1 that FDA is considering proposing to distinguish servicing and remanufacturing for changes to components/parts/materials.

A1. Add, remove, or change a component/part/material which directly or indirectly contacts body tissues or fluids?

This portion of the flowchart is designed to assess whether the activity impacts the biocompatibility of the device. Consistent with FDA's 2016 guidance on biocompatibility,[18] direct contact is when a component/part/material comes into physical contact with body tissue. A component/part/material has indirect contact when a fluid or gas passes through it prior to the fluid or gas coming into physical contact with body tissue (i.e., the device or component/part/material itself does not physically contact body tissue). For example, materials in a catheter hub (the part of the catheter that is external to the patient) can indirectly contact the patient when fluids or drugs are infused through the hub and into the patient. Both direct and indirect contact should be considered in answering this question.

If there is any addition or removal of a component/part/material to the finished device, and that component/part/material directly or indirectly contacts body tissue, the answer to this question should be "yes." Additionally, if there is any change in material type, formulation, or chemical composition that directly or indirectly contacts body tissue, the answer to this question should be "yes." If the entity is uncertain how to respond to this question, the answer should be "yes." If the answer to this question is "yes" that does not necessarily mean that the activity is remanufacturing. Rather, when an entity makes such changes, it should analyze the impact of the change on the device's performance or safety specifications using A1.1.

If no component/part/material is added or changed or any added or changed component/part/material does not contact body tissue, the answer should be "no" and then proceed to A2.

A1.1 Does the change significantly affect device performance or safety specifications?

If the added or changed component/part/material directly or indirectly contacts body tissue, or the removal of a component/part/material exposes a previously unexposed component/part material to body tissue either directly or indirectly, a risk-based assessment should be conducted. The assessment should be conducted to determine whether the change significantly affects the biocompatibility of the legally marketed device and thus may be considered remanufacturing. Depending on the magnitude of the change and the nature of the component/part/material, a more thorough biocompatibility risk assessment or testing may be necessary. Entities should incorporate factors that affect the biocompatibility of a device in their risk-based assessment and testing where appropriate. These factors may include the materials of construction, the processing of the materials, methods (including the sterilization process), and any residuals from aids used during the process.

If the answer to this question is "yes," then the change would likely be remanufacturing. If the answer is "no," then proceed to A2.

[18] See the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

Add component/part/material? If there is any addition of a material or component to a legally marketed device that was not originally part of the legally marketed device, the answer should be "yes." Examples include adding an adhesive to mend a break in the device or fasteners to secure a component/part/material.

Remove component/part/material? If there is any removal of a material or component to a legally marketed device that is not replaced in the legally marketed device, the answer should be "yes." Examples include removing a fastener or barrier without replacement.

Change or replace component/part/material? If there is any change or replacement of a component/part/material of the legally marketed device, that affects the component/part/material's dimensional or performance specifications, the answer to this question should be "yes."

If a component/part/material is not being added or removed, or the dimensional or performance specifications on a replacement component/part/material are not being changed, the answer should be "no." If uncertain, the answer should be "yes."

When an entity makes a change that has a "yes" answer to A2, the entity should analyze the impact of the change on the device's performance or safety specifications using A2.1. If the answer is "no," then proceed to A3.

A2.1 Does the change significantly affect device performance or safety specifications?

Does the added or removed component/part/material significantly change the device performance or safety specifications? When evaluating whether an addition or removal 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. For instance, many reusable devices are reprocessed numerous times within their intended use life. Applicable considerations include whether the added component will withstand repeated reprocessing cycles or whether the removed component exposes previously unexposed components that will withstand repeated reprocessing cycles. If not, the addition or removal of the component may significantly change the legally marketed device's performance and safety specifications.

Do the changed dimensional specifications of the component/part/material significantly affect the device performance or safety specifications? In determining whether an activity is remanufacturing for these types of changes, you should consider not only the magnitude of the dimensional specification change, but the criticality of the modified dimension. 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 specifications. If dimensional specifications are within the acceptable range, the answer would likely be "no"; however, for changes that are outside the acceptable range of dimensional specifications, the answer would likely be "yes."

Do the changed performance specifications of the component/part/material significantly affect the device performance or safety specifications? When evaluating if the change significantly affects performance or safety specifications, you should consider whether performance outputs meet a

minimum or maximum specification (i.e. temperature within chamber cannot exceed 25 ºC 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). 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."

If the answer to this question is "yes," then the change would likely be remanufacturing. If the answer is "no," then proceed to A3.

A3. Is there a new or increased risk or is there a change in the performance or safety specifications?

The entity should perform an assessment to determine whether there are new or increased risks or a change in the safety specifications of the legally marketed device occurs as a result of the activity being performed on the device. A risk-based assessment can identify whether there are new risks or increased likelihood of existing risks in comparison to the legally marketed device. Additionally, both the individual change and cumulative changes performed on the legally marketed device should be considered. While individual changes may not significantly affect the legally marketed device's performance or safety specifications, the cumulative actions may do so. The extent of the assessment should be appropriate considering the nature and extent of the activities being performed. If new risks or increases to existing risks are identified, the answer should be "yes." If uncertain, the answer should be "yes."

When an entity makes a change that has a "yes" answer to A3, the entity should analyze the impact of the change on the device's performance or safety specifications using A3.1. If the answer to A3 is "no," then the change is likely servicing.

A3.1 Does the change significantly affect device performance or safety specifications?

If new or increased risks were identified, evaluate whether they significantly change the legally marketed device performance or safety specifications. Changes that alter or bypass a safety feature (e.g., fuses, alerts, alarms, interlocks) likely significantly affect the legally marketed device's performance or safety specifications. Multiple changes, when considered cumulatively, may inadvertently significantly change the performance or safety specifications of the legally marketed device.

If the answer to this question is "yes," then the change would likely be remanufacturing. If the answer is "no," then the change is likely servicing.

6 Changes Involving Software

Although the servicing and remanufacturing definitions in this document are meant to apply to software changes, the approach described in Section 5 should not be applied to such changes due to the nature of software and the methods used to evaluate changes. Therefore, FDA is considering identifying types of software changes that generally constitute servicing or remanufacturing.

For example, changes to integral software might generally be considered remanufacturing. Entities should also consider the unintended consequences and cumulative effects of the software change(s). **FDA is seeking feedback on what constitutes integral software or suggestions on how to determine what software is integral to the performance, safety, and intended use of a device.**

The following common activities performed on software might generally be considered servicing:

- Implementing OEM provided updates and upgrades;
- Running software diagnostics;
- Assessing for viruses, malware, and other cybersecurity related issues;
- Reinstalling OEM software to restore original performance and safety specifications;
- Reverting software to a previous configuration;
- Installing cybersecurity updates that are authorized by the OEM; and
- Turning on or off connectivity features (e.g. WiFi and Bluetooth connections) consistent with OEM intended use.

At the workshop we will discuss whether this list is sufficiently comprehensive or whether activities should be added to or removed from this list.

7 Considerations for Labeling

This section gives background information on select device labeling requirements and explains the role labeling may have in assuring the safety and effectiveness of devices that undergo servicing. 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. At the upcoming public workshop, we will discuss what information concerning device specifications and servicing should be included in labeling to provide a reasonable assurance of the safety and effectiveness of legally marketed reusable devices throughout their intended use life.

FDA regulates device labeling in several ways. For example, section 502(f)(1) of the FD&C Act requires that labeling include adequate directions for use. Under section 502(a)(1) of the FD&C Act, a medical device is deemed misbranded if its labeling is false or misleading in any particular. Under section 201(n) of the FD&C Act, labeling may be misleading if it fails to reveal facts material with respect to consequences which may result from use of the article under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. *See also* 21 CFR 1.21.

FDA device regulations contain further requirements related to labeling. For example, 21 CFR 801.5 requires that labeling include adequate directions for use, including statements of all conditions, purposes, or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications). Similarly, 21 CFR 801.109(c) requires that prescription device labeling include any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended. Instruments that are part of *in vitro* diagnostic devices must include service and maintenance information.[19] Furthermore, sections of the Quality System regulation also regulate labeling, such as 21 CFR 820.80(b) (verification of incoming product), 21 CFR 820.30 (design controls), and 21 CFR 820.120 (device labeling), among others.

Electronic products with performance standards promulgated in 21 CFR Chapter I, Subchapter J – Radiological Health, under the authority of section 534 of the FD&C Act, generally include requirements

[19] 21 CFR 809.10(b)(6)(ix).

for product manufacturers to provide, at a cost not to exceed the cost of preparation and distribution and upon request, certain information to purchasers, servicing dealers and distributors, or others. These informational requirements for laser products,[20] ultrasonic therapy products,[21] and diagnostic x-ray systems[22] generally include adequate instructions for service adjustments and procedures, clear warnings and precautions to avoid exposure to radiation within certain emission limits, and a schedule of maintenance necessary to remain in compliance with each respective performance standard.

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.[23] 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 submitted to the Agency.

In addition to the topics already mentioned, FDA would also like your comments on the following questions. FDA recognizes that some stakeholders favor detailed, public disclosure of product specifications while others believe certain information should not be publicly available, for example because it may be trade secret or CCI. **At the upcoming workshop, FDA will seek public input about the information relating to servicing that should be available so that patients are assured access to serviced devices that are high quality and have a reasonable assurance of safety and effectiveness. Specifically, the following questions will be discussed:**

1. **Which device technical, performance, or other product specifications should be included in the device labeling to facilitate high quality, safe, and effective servicing?**
2. **Are there any additional component/part/material specifications that should be included in labeling to facilitate high quality, safe, and effective servicing?**
3. **Is there any additional information about software that should be included in labeling?**

8 Examples for Discussion

The following are hypothetical examples of activities that may be performed on medical devices that may constitute servicing or remanufacturing. Each example is presented with multiple alternative scenarios that are intended to facilitate public discussion at FDA's workshop regarding servicing and remanufacturing activities. The most pertinent flowchart decision point(s) are highlighted in each scenario; however, all guiding principles and applicable flowchart questions discussed in this white paper apply to each scenario.

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[20] 21 CFR 1040.10(h)(2)(ii).

[21] 21 CFR 1050.10(f).

[22] 21 CFR 1020.30(h). As described in 21 CFR 1020.30(h)(1), this applies to diagnostic x-rays systems and their components and radiographic, fluoroscopic, and computed tomography equipment.

[23] A trade secret is defined as consisting "of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process." 21 CFR 20.61(a).
Commercial or financial information that is privileged or confidential "means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 CFR 20.61(b).

The following questions are intended to be considered for each scenario, along with the guiding principles, flowchart, and accompanying text discussed above:

I. Using the pertinent accompanying text for each flowchart question, how would you determine whether the change significantly affects the performance or safety specifications, or intended use?
II. Under what circumstances would you consider this activity servicing?
III. Under what circumstances would you consider this activity remanufacturing?
IV. What actions should be performed and documented to support this activity as servicing or remanufacturing?

FDA has purposely omitted information in each scenario to leave these questions unanswered and initiate collaborative discussion at the upcoming workshop and obtain written feedback to the docket. **FDA is seeking feedback on how these questions are addressed using the following scenarios, flowchart, accompanying text, and guiding principles. Stakeholders should comment on whether the accompanying text and flowchart adequately and clearly capture the thought process that would distinguish between servicing and remanufacturing activities.**

1. Infusion Pump

   Infusion pumps, as described in 21 CFR 880.5725, are intended to pump fluids into a patient in a controlled manner.

   Example A: While verifying the accuracy of an infusion pump flow rate, it is determined that the door of the infusion pump has been bent in a way that pinches the administration set. Due to this pinching, the accuracy of the flow rate falls outside the OEMs specified accuracy range.

   Scenario 1: The door is replaced with a non-OEM door that has the same dimensions but is made from a different material of construction. (A2.1)

   Scenario 2: An adequate replacement door cannot be obtained and the existing door is repaired. (A2.1)

   Example B: The stepper motor of a syringe infusion pump, in part, functions to regulate the delivery accuracy of the device. The device labeling states to use a specific model/part number for the stepper motor, however access to this part is no longer available. An off-the-shelf non-OEM motor is used to as a replacement. It is unclear whether the off-the-shelf motor has significantly different performance specifications in comparison to the OEM motor.

   Scenario 1: The entity replaces the original motor with the off-the-shelf motor. (A2.1 and A3; A3.1 if needed)

   Scenario 2: The entity identifies the winding (electromagnetic coils) within the motor as the source of the failure and replaces the winding of the original motor. (A2.1 and A3; A3.1 if needed)

   Example C: A user complains about the frequency of an infusion pump upstream occlusion alarm. It is unclear whether the frequency of the alarm has increased over time.

   Scenario 1: It is determined that the pressure sensors monitoring upstream occlusion are no longer working correctly and are replaced with non-OEM sensors. (A2.1 and A3; A3.1 if needed)

   Scenario 2: It is determined that the occlusion alarm and pressure sensors appear to be working as intended, however the frequency of alarm (based on sensitivity to alarm conditions) does seem higher than comparable

models of the same device. The occlusion alarm sensitivity specification is not publicly available information. The alarm setting is changed to decrease the detection sensitivity without knowing whether the setting is within the OEM's performance specifications. (A3.1 and/or software)

2. Endoscope

An endoscope, as described in 21 CFR 876.1500, is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye.

Example A: The insertion tube cover that covers the length of an endoscope is cracked. An OEM insertion tube cover is not available and the specifications of the component are not publicly available information.

Scenario 1: The insertion tube cover has both non patient-contacting sections and patient-contacting sections. Only a portion of the non-patient contacting insertion tube cover is cracked. This portion is removed and replaced with a non-OEM insertion tube cover. (A2.1)

Scenario 2: The cracked insertion tube cover directly contacts the patient's body tissue. The exact material formulation and/or chemical composition of the insertion tube cover is unknown. It is replaced with a non-OEM insertion tube cover and applied with an adhesive previously used to repair similar medical devices. (A1.1 and A2.1)

Example B: The lens of an endoscope is cracked. The lens is held in place by an epoxy that is not described in the device labeling. Both the lens and the epoxy holding the lens in place is removed and replaced.

Scenario 1: A replacement OEM lens can be obtained, however additional OEM epoxy is no longer available. The original epoxy specifications are unknown. A "medical-grade" epoxy is used to replace the lens. (A1.1 and A3; A3.1 if needed)

Scenario 2: Additional OEM epoxy can be obtained, however a replacement OEM lens is unavailable. The lens is replaced with a comparable lens. (A2.1 and A3; A3.1 if needed)

Scenario 3: A replacement OEM lens and additional OEM epoxy is unavailable. Furthermore, the specifications for both components are not publicly available information. The optical properties of the lens are determined through an engineering analysis, and a replacement lens within those specifications is used as a replacement. A "medical-grade" epoxy is used to replace the lens. (A1.1, A2.1, and A3; A3.1 if needed; multiple changes)

Example C: An endoscope has incurred significant damage to its image quality.

Scenario 1: A section of the fiberoptic bundle has been severely bent and needs replacement, however the fiberoptic bundle of this endoscope is custom made and is no longer manufactured. The fiberoptic bundle is replaced with a different brand. (A2.1)

Scenario 2: The shaft housing the working channels of the endoscope is cracked and bent at the distal end, limiting the articulating angle of the endoscope,

however there is no damage to the fiberoptic bundle. The damaged shaft is replaced with a non-OEM part. (A2.1)

Scenario 3: Multiple components have incurred damage and need to be replaced. OEM replacement components can be obtained for all damaged parts, however during reassembly two of the components which appear similar, but are significantly different, are inadvertently switched. While the device still operates, it is not configured as intended. (A2.1 and A3.1; multiple changes)

3. Magnetic Resonance Imaging Scanner (commonly referred to as MRI)
   A magnetic resonance diagnostic device, as described in 21 CFR 892.1000, is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance.

   Example A: The liquid helium used to quench the magnet has decreased over time indicating a leak in the system.

   Scenario 1: It is determined that there is a large crack in the liquid helium reservoir. The entire reservoir is replaced with a non-OEM reservoir that has a significantly larger volume capacity. (A2.1 and A3; A3.1 if needed)

   Scenario 2: It is determined that there is a small hole in the liquid helium reservoir. The hole is patched with materials that are different than the OEM reservoir. (A2.1 and A3; A3.1 if needed)

   Example B: During an imaging session the gradient coil is significantly damaged and needs to be replaced or repaired.

   Scenario 1: The gradient coil is removed, repaired, and reinstalled into the MRI. (A2.1 and A3; A3.1 if needed)

   Scenario 2: The gradient coil is replaced with a non-OEM gradient coil. The maximum slew rate of the coil matches that of the OEM gradient coil, however the peak gradient strength is significantly larger than the OEM coil. (A2.1)

   Scenario 3: The gradient coil is replaced with a non-OEM gradient coil which has a significantly different design including dimensional specifications and coil design. The performance specifications of the non-OEM coil when compared to the OEM coil are determined to not be significantly different. (A2.1 and A3; A3.1 if needed)

4. Ultrasound Devices
   An ultrasound device, both fetal (21 CFR 884.2660 fetal ultrasonic monitor and accessories) and nonfetal (21 CFR 892.1540 nonfetal ultrasonic monitor), is described as a device designed to transmit and receive ultrasonic energy usually by means of continuous high-frequency sound wave. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

   Example A: Some ultrasound device peripheral equipment has malfunctioned and needs to be replaced.

   Scenario 1: The display monitor can no longer display 30% of its pixels. An OEM display monitor is no longer available and a non-OEM display is used as a replacement. The display is determined to have higher resolution than the OEM display. (A2.1)

Scenario 2: The ultrasound printer is malfunctioning and cannot print and an OEM replacement printer is no longer available. The printer is replaced with a one that is not specifically designed for ultrasound devices, however will interface with the system and print high quality pictures. (A2.1)

Example B: An ultrasound probe has incurred significant damage to the housing and lens.

Scenario 1: Replacement OEM housing can be obtained, however a replacement OEM lens is unavailable. The lens is replaced with a comparable lens. (A2.1 and A3; A3.1 if needed)

Scenario 2: A replacement OEM lens can be obtained, however the OEM housing is no longer available. The original housing specifications are unknown. A non-OEM housing with unknown biocompatibility specifications is used as a replacement. (A1.1 and A3; A3.1 if needed)

Scenario 3: A replacement OEM lens and housing are unavailable. Furthermore, the specifications for both components are not publicly available information. The optical properties of the lens are determined through an engineering analysis, and a replacement lens within those specifications is used as a replacement. A non-OEM housing with unknown biocompatibility specifications is used as a replacement. (A1.1, A2.1, and A3; A3.1 if needed; multiple changes)

5. Non-device Specific Examples

In the following examples, consider if the device type changes the considerations when determining the type of activity being performed.

Example A: Circuit boards can be used to control various functions of a device from display of information to regulating the power of a laser. Circuit boards can have simple or intricate designs (single vs. multilayered) and can contain custom or off-the-shelf components. Circuit boards may have generic input/output specifications and may have multiple suppliers.

Scenario 1: A circuit board that controls the display of information on an intracranial pressure monitor has been damaged beyond repair. There is no reference or serial number associated with the circuit board. The circuit board is replaced with an off-the-shelf circuit board. (A2.1)

Scenario 2: An arm on a robotically-assisted surgical device has stopped responding to commands. A power diode on a circuit board that controls the arm has been damaged and is replaced. (A2.1)

Example B: Some components/parts/materials have a defined intended use life which limits the life expectancy of the device. Activities are performed to extend the device's intended use life.

Scenario 1: A surgical instrument with a sharp and thin blade is labeled as having an intended use life of 30 uses. The labeling instructs the user to discard the instrument after 30 uses as the blade will have become too dull for the specified use. The blade is sharpened and the user is told the blade can be used for another 30 uses. (A2.1 and A3.1)

Scenario 2: A reusable endoscope contains a lumen that significantly deteriorate after 300 reprocessing cycles. After 450 reprocessing cycles, it becomes apparent that the lumen is no longer structurally sound and is leaking. All debris from the corroded lumen is removed and all affected

components/parts/materials are replaced with non-OEM parts. Each non-OEM part is found to be not significantly different than the OEM part. (A3.1; multiple changes)

Example C: The battery of a reusable device has malfunctioned and needs to be repaired or replaced.

Scenario 1: The battery no longer holds a charge and needs to be replaced, however the OEM battery can no longer be obtained. A non-OEM battery is used to replace the damaged battery. (A2.1)

Scenario 2: An entity obtains used, non-rechargeable batteries and restores them for resale. The entity receives the batteries that are due for replacement from their distributors and the lithium cells are replaced with identical, equivalent, or superior cells. (A2.1 and A3; A3.1 if needed)

Scenario 3: The battery is leaking, and significantly damages most device components. Only some of the device's components' safety and performance specifications are publicly available information. The damaged components, including the battery, are replaced with a mixture of OEM and non-OEM parts. (A2.1 and A3; A3.1 if needed; multiple changes)

6. Software

Software includes both software contained in a medical device and software as a medical device (SaMD). Software contained in a medical device includes firmware and other means for software-based control of medical devices, dedicated hardware/software medical devices, and accessories to medical devices that contain or are composed of software.[24] SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[25, 26]

Example A: An infusion pump has an outdated drug library in its software. The OEM has stopped support of the device and does not provide an updated library for this infusion pump model. The library is updated to include newer drugs and modified dosage regimens, consistent with the drug approvals.

Scenario 1: Updated Orange Book information is manually added to modify the drug library. (Software)

Scenario 2: The OEM has an updated drug library that is only compatible with the newer model of the infusion pump. Modifications to the software are made so that it can be installed on the older version of the infusion pump. (Software)

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[24] See the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf.

[25] See the International Medical Device Regulators Forum final document, "Software as a Medical Device (SaMD): Key Definitions," available at: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.

[26] See the FDA guidance, "Software as a Medical Device (SAMD): Clinical Evaluation," available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf.

Example B: A device which connects to a facility's network contains software that runs within a Microsoft Windows operating system (OS).

Scenario 1: The device is no longer supported by the OEM. A cybersecurity vulnerability, specifically related to breach of information, has been identified by Microsoft. Microsoft has provided an update to address the vulnerability. The extent of the vulnerability is assessed and the Microsoft update to the OS is installed. (Software)

Scenario 2: The device is an infusion pump which validates patients' records accessed through the intranet by the drug delivery information input on the device to avoid complications with treatment. A cybersecurity vulnerability is identified for which the OEM has not yet provided an update. The device is isolated from the intranet until a cybersecurity update can be implemented. (Software)

Scenario 3: The necessary adjustments are made to allow the device to run using a Linux OS. (Software)

Appendix A: Definitions

The following definitions, taken from the FDA Report on Device Servicing, apply only for the purposes of this document. Wherever possible, existing terminology originate from relevant regulations or FDA guidance documents.

Manufacturers ("Manufacturers," "Original Equipment Manufacturers" (OEMs), or "Remanufacturers"): A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device.[27] A remanufacturer is 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 are considered to be manufacturers.[28] Note that, for electronic products, a manufacturer is any person engaged in the business of manufacturing, assembling, or importing electronic products.[29]

Recondition/Refurbish/Rebuild: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair of components, installation of software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

Remanufacture: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[30]

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.

Reprocessing: Validated processes used to render a medical device which has been previously used or contaminated fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.[31]

Service: Repair and/or preventative or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that change the intended use of the device from its original purpose, or change the safety or performance specifications. FDA considers servicing to include refurbishing, reconditioning, rebuilding, repairing, and remarketing, but not remanufacturing.

Third Party Servicers and Independent Service Organizations (ISOs) ("Third Party Servicers," "ISOs," or "Third Party Entities"): These are entities, other than the manufacturer or healthcare establishments,

[27] 21 CFR 820.3(o).
[28] 21 CFR 820.3(w).
[29] 21 CFR 1000.3(n).
[30] See 21 CFR 820.3(w).
[31] See the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.

that maintain, restore, refurbish, or repair a finished device after distribution, for purposes of returning it to the safety and performance specifications established by the manufacturer and to meet its original intended use.