



U.S. FOOD & DRUG
ADMINISTRATION

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)

Executive Summary

The Food and Drug Administration Reauthorization Act (FDARA) became law on August 18, 2017. Section 710 of FDARA charges the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing.

FDA has considered information including but not limited to the information presented at a public workshop, responses to a request for comments, and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing in the compilation of this report.

Stakeholders have differing views about the quality, safety, and effectiveness of servicing performed by original equipment manufacturers (OEMs) and third party entities, and the need for imposing additional regulation. Based on the available information, we have concluded:

- The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
- Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;
- A majority of comments, complaints, and adverse event reports alleging that inadequate “servicing” caused or contributed to clinical adverse events and deaths actually pertain to “remanufacturing” and not “servicing”; and
- The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.

We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time. Although we do not believe that additional, formal regulatory action is warranted, based on the available information and findings, we intend to pursue the following actions:

1. Promote the Adoption of Quality Management Principles;
2. Clarify the Difference Between Servicing and Remanufacturing;
3. Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
4. Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.

As part of its 2018-2020 strategic priorities, FDA’s Center for Devices and Radiological Health (CDRH) has committed to establishing “Collaborative Communities.” The hallmark of a Collaborative Community, is a continuing forum where public and private sector members proactively work together to solve both shared problems and problems unique to other members in an environment of trust and openness, where participants feel safe and respected to communicate their concerns. Members share a collective responsibility to help each other obtain what they need to be successful. We believe there may be value in the creation of a public-private forum, such as a Collaborative Community, to address the challenges associated with delivering high quality, safe, and effective servicing of medical devices. If there is sufficient interest and broad willingness to participate by stakeholder groups, we would facilitate the creation of such a community.

Table of Contents

Preface	iii
1 Introduction	1
2 Existing Authorities and Regulations	3
2.1 FDA's Authority and Regulatory History	3
2.1.1 Electronic Product and Radiation Control.....	5
2.1.2 Medical Device Reporting	6
2.2 Centers for Medicare and Medicaid Services and the Joint Commission.....	8
2.3 U.S. Federal Trade Commission	10
2.4 State Regulations	10
3 Review of Responses to FDA's March 2016 Federal Register Request for Comments.....	11
3.1 Quality Management System	12
3.2 Training	12
3.3 Availability and Use of Quality Replacement Parts.....	13
3.4 Access to Device-Specific Service Information	13
4 Public Workshop	14
4.1 Stakeholder Presentation Summaries	15
4.2 Panel Discussion Summaries.....	17
5 Summary of Evidence Pertaining to Medical Device Servicing.....	19
5.1 Number of Service and Repair Entities	19
5.2 Literature Review.....	19
5.3 ECRI Institute Analysis.....	20
5.4 Medical Device Reports (MDRs)	21
5.5 Complaints	22
6 Summary of Key Issues and On-Going Activities	23
6.1 Promote the Adoption of Quality Management Principles by Medical Device Servicers	23
6.2 Clarify the Difference Between Servicing and Remanufacturing	24
6.3 Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices.....	25
6.4 Foster Evidence Development to Assess the Quality, Safety, and Effectiveness of Medical Device Servicing.....	25
7 Conclusion.....	26

Preface

The Food and Drug Administration Reauthorization Act of 2017 (FDARA)¹ became law on August 18, 2017. Not later than 270 days after enactment, section 710 of FDARA charges the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to post on the Food and Drug Administration (FDA) internet website a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing.² The report shall contain:

- (1) the status of, and findings to date, with respect to, the proposed rule entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments” published in the Federal Register by the Food and Drug Administration on March 4, 2016 (81 Fed. Reg. 11477);
- (2) information presented during the October 2016 public workshop entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers”;
- (3) a description of the statutory and regulatory authority of the Food and Drug Administration with respect to the servicing of devices conducted by any entity, including original equipment manufacturers and third party entities;
- (4) details regarding how the Food and Drug Administration currently regulates devices with respect to servicing to ensure safety and effectiveness, how the agency could improve such regulation using the authority described in paragraph (3), and whether additional authority is recommended;
- (5) information on actions the Food and Drug Administration could take under the authority described in paragraphs (3) and (4) to assess the servicing of devices, including the size, scope, location, and composition of third party entities;
- (6) information on actions the Food and Drug Administration could take to track adverse events caused by servicing errors performed by any entity, including original equipment manufacturers and third party entities;
- (7) information regarding the regulation by States, the Joint Commission, or other regulatory bodies of device servicing performed by any entity, including original equipment manufacturers and third party entities; and
- (8) any additional information determined by the Secretary (acting through the Commissioner) to be relevant to ensuring the quality, safety, and effectiveness of devices with respect to servicing.

This report is intended to fulfill the requirements of Section 710. Appendix A contains a cross reference between the congressionally mandated report elements and the corresponding sections in this document.

¹ Public Law No. 115-52.

² Section 710(c) of FDARA defines servicing to include, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, remanufacturing, or other servicing of the device. As discussed later in this report (see p. 3), and as set forth in FDA regulations, FDA does not consider remanufacturing to be a type of servicing. Nevertheless, given the definition in section 710(c) of FDARA, unless otherwise specified in this report (e.g., when expressly describing the differences in FDA regulation concerning servicing and remanufacturing), references to “servicing” throughout this report generally include all of the activities identified in section 710(c).

1 Introduction

Medical devices encompass a vast array of different products, from patient examination gloves, stethoscopes, infant warmers, and powered wheelchairs to implantable cardiac pacing devices, magnetic resonance imaging scanners, large volume infusion pumps, and ventilators. The technologies, product lifecycles, device complexity, intended users, and environment of use are similarly diverse. While many devices are disposable and intended to be used a single time on a single patient, others have long lifespans, are used repeatedly on multiple patients, and necessitate preventive maintenance and repair during their service life. For these device types, such as medical imaging equipment, automated external defibrillators, endoscopes, and ventilators, proper servicing is critical to the continued safe and effective use of these products. The availability of timely, cost effective, quality maintenance, and repair of medical devices is critical both to the successful functioning of the United States (U.S.) healthcare system and to the continued quality, safety, and effectiveness of marketed medical devices in the U.S.

Over the years, some have expressed concerns about the quality of servicing provided by some third party entities who refurbish, recondition, rebuild, remarket, service, and repair medical devices (collectively, referred to as “servicing activities”). These concerns have related to allegations regarding third party entities’ use of poor quality replacement parts, inadequately trained personnel, poorly documented servicing, and servicing that fails to restore the device to its specifications. Some have tied these alleged problems to third party entities’ difficulty in obtaining necessary device servicing manuals, technical specifications, quality replacement parts, and access to training from original equipment manufacturers. These and other concerns impact the ability of entities to perform high quality, safe, and effective medical device servicing. Poor quality servicing may lead to poor device performance, device malfunction, and clinical adverse events.

Three key entities perform or participate in the servicing of medical devices, each playing an essential role. They are:³

Manufacturers (“Manufacturers,” “Original Equipment Manufacturers,” “OEMs” or “Remanufacturers”): A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device.⁴ 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.⁵ Regulatory requirements for medical device manufacturers are covered in Section 2 of this report. Note that, for electronic products, a manufacturer is any person engaged in the business of manufacturing, assembling, or importing electronic products.⁶

Healthcare Establishments and Hospital Based Service Providers (“Healthcare Establishments”): Healthcare establishments are entities that provide clinical care to patients, and receive products and services from OEMs and other entities. Healthcare establishments may directly employ professionals (biomedical and clinical engineers, healthcare technology

³ The definitions contained herein are for the purposes of this report only. They are not intended to imply any specific regulatory requirements and do not replace or supercede existing definitions or requirements.

⁴ 21 CFR 830.3(o).

⁵ 21 CFR 820.3(w).

⁶ 21 CFR 1000.3(n).

management professionals, etc.) that perform servicing activities, including maintenance and repair.

Certain healthcare establishments are subject to oversight by other governmental organizations such as the Centers for Medicare and Medicaid Services (CMS), state governments, or independent organizations such as The Joint Commission (TJC). These are described in more detail in Section 2 of this report. In addition, some healthcare establishments are subject to FDA medical device adverse event reporting requirements.

Third Party Servicers and Independent Service Organizations (ISOs) (“Third Party Servicers,” “ISOs,” or “Third Party Entities”):⁷ These 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.

The applicability and enforcement of regulatory requirements by FDA depends on the type of entity and the specific activities performed. An individual entity may be categorized into multiple roles based on the activities it performs. For example, an entity could be both an OEM and a third party servicer by manufacturing their own product, and servicing another company’s product, respectively. Specific FDA authorities are described in Section 2 of this report.

Numerous definitions have been used and proposed for key terms associated with servicing, including refurbishing, reconditioning, rebuilding, remarketing, and remanufacturing. FDA used the following working definitions as part of its October 2016 public workshop:^{8, 9}

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.

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. As FDARA section 710(c) includes “remanufacturing” in its definition of servicing, this report includes discussion of both activities. However, it is important to note that FDA considers remanufacturing to be a distinct activity from servicing that raises different concerns, and is thus regulated differently. See 21 CFR 820.3(w). FDA considers

⁷ Historically, FDA has included healthcare establishments who service medical devices in its definition of third party servicers. For the purposes of this report, the terms third party servicer and third party entity exclude healthcare establishments.

⁸ 81 FR 11477.

⁹ Working Definitions; available at: <http://wayback.archive-it.org/7993/20171114130552/https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM529024.pdf>.

servicing to include refurbishing, reconditioning, rebuilding, repairing, and remarketing, but not remanufacturing.

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.

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.¹⁰

Remarket: The act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift, or lease.

This report summarizes FDA's existing rules and regulations, the responses to FDA's public outreach, the available evidence pertaining to the quality, safety, and effectiveness of medical device servicing, key issues, and on-going activities. The FDA continues to receive information related to these topics. This report reflects the information received through December 31, 2017.

2 Existing Authorities and Regulations

2.1 FDA's Authority and Regulatory History

FDA's authority to regulate the servicing of medical devices by any entity, including OEMs and third party servicers, is grounded in the agency's authority to regulate medical devices and radiation-emitting electronic products under the FD&C Act. The Medical Device Amendments (MDA)¹¹ to the FD&C Act, enacted on May 28, 1976, directed the FDA to issue regulations that classify all devices into one of three regulatory control categories, Class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of the device. In addition, the Radiation Control provisions of the FD&C Act¹² authorized FDA regulation of electronic products to protect the public health and safety from electronic product radiation. Some products meet both the definition of a "device"¹³ and "electronic product."¹⁴

Under this statutory scheme, the safety and effectiveness of all medical devices is assured at least in part through general controls, which include the adulteration and misbranding provisions of the FD&C Act as well as requirements related to manufacturer registration and device listing, applicable good manufacturing practices, medical device reporting, reports of corrections and removals, unique device identification, and others described in FD&C Act section 513(a)(1)(A). The safety and effectiveness of class II and class III devices is also assured through special controls and premarket approval, respectively. Special controls may include performance standards, postmarket surveillance, patient registries,

¹⁰ See 21 CFR 820.3(w).

¹¹ Public Law 94-295.

¹² These were originally enacted as the Radiation Control for Health and Safety Act of 1968 (Pubic Law 90-602).

¹³ FD&C Act § 201(h).

¹⁴ FD&C Act § 531(2). Although FDARA section 710 applies only to devices, FDA includes in this report some discussion of its regulation of electronic products that are also devices as it relates to servicing.

guidelines, and other actions deemed necessary by FDA to provide a reasonable assurance of safety and effectiveness of the device.¹⁵

Thus the FD&C Act mandates that all devices have a reasonable assurance of safety and effectiveness and gives FDA the authority to establish regulatory controls to provide such. As discussed above, 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.¹⁶ 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,¹⁷ FDA believes it has statutory authority to regulate device servicing.

Although FDA generally has not enforced FD&C Act requirements with respect to servicing activities, FDA has consistently interpreted FD&C Act provisions to apply or potentially apply to servicing activities. Specifically—

- In 1987, FDA issued a Compliance Policy Guide (CPG) (7124.28) stating that reconditioners and rebuilders of medical devices were subject to requirements for establishment registration, premarket notification, labeling, FDA inspection, good manufacturing practices, and medical device reporting. The CPG identified a “reconditioner/rebuilder” as a person or firm that acquires ownership of a used device and, for purposes of resale or commercial distribution, “restores” or “refurbishes” the device to the manufacturer’s original or current specifications or new specifications.¹⁸
- Following passage of the Safe Medical Devices Act in 1990, FDA began a rulemaking process to amend its regulations to “replace quality assurance program requirements with quality system requirements that include design, purchasing, and servicing controls.”¹⁹ At the time, “servicers” and “refurbishers” were included in the proposed rule, which explained: “FDA finds, as a result of reviewing service records, that the data resulting from the maintenance and repair of medical devices provide valuable insight into the adequacy of the performance of devices. Thus, FDA believes that service data must be included among the data manufacturers use to evaluate and monitor the adequacy of the device design, the quality system, and the manufacturing process. Accordingly, FDA is proposing to add general requirements for the maintenance of servicing records and for the review of these records by the manufacturer. Servicing controls will apply to servicing conducted or controlled by or for finished device manufacturers (e.g., conducted by a manufacturer, employee, agent or contractor). Manufacturers must ensure that the performance data is obtained as part of servicing are fed back into the manufacturer’s quality system for evaluation as part of the overall device experience data.”

¹⁵ FD&C Act § 513(a)(1)(B)-(C) and (a)(2).

¹⁶ See, e.g., section 510(a)-(j), establishing registration and listing requirements for those engaged in the manufacture, preparation, propagation, compounding, or processing of a device, and section 520(f), authorizing FDA to promulgate regulations requiring the methods used in, and the facilities and controls used for, the manufacture, design validation, packing, storage, and installation of a device to conform to current good manufacturing practice. But see section 519(g)(3) of the FD&C Act, specifically exempting routine servicing from correction and removal reporting requirements.

¹⁷ See, e.g., section 301(k) of the FD&C Act, prohibiting the adulteration or misbranding of a device while held for sale after shipment in interstate commerce, and section 519(b) of the FD&C Act, requiring device user facilities to submit certain adverse event reports.

¹⁸ 63 FR 67076.

¹⁹ 58 FR 61952.

- In 1996, FDA ultimately excluded servicers and refurbishers, as those terms relate to entities outside the control of the original equipment manufacturers, from the final quality system (QS) regulation.²⁰ In doing so, FDA explained that although “it believes that persons who perform such functions meet the definition of manufacturer,” the nature of servicing involved “a number of competitive and other issues” that would be worked through in a separate rulemaking.²¹ FDA has not undertaken such rulemaking. However, the 1996 final rule did establish certain requirements for manufacturers with respect to servicing²² and make “remanufacturers” subject to the QS regulation by including them in the definition of manufacturer.²³ The rule defined remanufacturer as “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications, or intended use.”²⁴
- In 1997, FDA published an advanced notice of proposed rulemaking announcing its intention to consider identifying the used device market, for regulatory purposes, in terms of “refurbishers,” “as-is remarketers,” and “servicers” whose activities do not significantly change the safety, performance, or use of a device, and to examine alternative approaches for regulating these firms. The Agency explained that it was reconsidering its approach to regulating these activities in light of “evolving industry practices” and “in order to ensure that particular remarketed devices [including refurbished, reconditioned, serviced, and as-is devices] meet suitable performance requirements for their intended uses, and are as safe as the originally marketed finished device.” The agency identified certain general controls with which, at a minimum, compliance might be expected including representations of quality,²⁵ false or misleading labeling,²⁶ notification and recall,²⁷ reporting of corrections and removals,²⁸ medical device reporting,²⁹ device tracking,³⁰ and radiological health requirements.³¹
- In 1998, FDA revoked CPG 7124.28, which pertained to “reconditioners/rebuilders” as it overlapped with, and was inconsistent with, the 1996 rulemaking.³²

Note that, with respect to devices subject to premarket approval, once a device has received marketing authorization, the FD&C Act generally requires changes that affect safety or effectiveness to be submitted to FDA for review and approval.³³

2.1.1 Electronic Product and Radiation Control

The Electronic Product and Radiation Control (EPRC) regulation, issued under authority of the Radiation Control for Health and Safety Act of 1968, applies to electronic products, which include some products that are also medical devices. Per 21 CFR 1000.3(j), an electronic product is defined as (1) any manufactured or assembled product which, when in operation: (i) contains or acts as part of an

²⁰ 61 FR 52602.

²¹ 61 FR 52602.

²² See 21 CFR 820.200.

²³ 21 CFR 820.3(o).

²⁴ 21 CFR 820.3(w).

²⁵ FD&C Act § 501(c).

²⁶ FD&C Act § 502 and 21 CFR 801.

²⁷ FD&C Act § 518 and 21 CFR 810.

²⁸ FD&C Act § 519(f) and 21 CFR 806.

²⁹ FD&C Act § 519(a) and 21 CFR 803 and 804.

³⁰ FD&C Act § 519(e) and 21 CFR 821.

³¹ FD&C Act §§ 532-542.

³² 63 FR 67076.

³³ FD&C Act § 515(d)(6)(A)(i) and 21 CFR 814.39.

electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (2) any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation. Per 21 CFR 1000.3(k), electronic product radiation is defined as (1) any ionizing or non-ionizing electromagnetic or particulate radiation, or (2) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Some activities regulated under the EPRC regulation may also be considered servicing. 21 CFR 1020.30(b) defines an assembler as any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services. Under 21 CFR 1020.30(d), assemblers who install certified components are required to follow the instructions of their respective manufacturers. All assemblers who install diagnostic x-ray systems and certified components must submit reports of assembly to FDA, the purchaser, and the State agency, per 21 CFR 1020.30(d)(1). Assemblers are also required to retain these reports of assembly for a period of 5 years from its date, per 21 CFR 1002.1(c)(4).

Manufacturers of diagnostic x-ray systems must provide assemblers with adequate instructions for assembly, installation, adjustment, and testing of their component sufficient to assure the product will comply with all applicable performance standards when their instructions are followed, per 21 CFR 1020.30(c). The instructions must also provide specifications for other components that are compatible with the component to be installed when compliance of the component or system depends on such compatibility. The specifications may describe physical characteristics of compatible components and/or may list, by manufacturer's name and model number/designation, specific components that are compatible, per 21 CFR 1020.30(g).

Under 21 CFR 1020.30(g), manufacturers of diagnostic x-ray systems and components listed in 21 CFR 1020.30(a)(1) are subject to information disclosure obligations so that assemblers or other interested parties may obtain, upon request, information regarding the assembly, installation, adjustment, and testing (AIAT) of an x-ray system to ensure it meets federal performance standards. The AIAT information shall be provided at a cost not to exceed the cost of publication and distribution.

Generally, manufacturers of diagnostic x-ray equipment must provide the purchaser of such equipment and, upon request, others with manuals and instructions describing specific technical specifications of the equipment and any necessary safety precautions and procedures at a cost not to exceed the cost of publication and distribution. This information must include a recommended maintenance schedule required to keep the equipment in compliance with all applicable performance standards.³⁴

2.1.2 Medical Device Reporting

FDA also has implemented its authority via the Medical Device Reporting (MDR) regulation.³⁵ Medical device reporting helps FDA assess significant adverse events and detect emerging problems that are associated with the use of medical devices. Medical device reporting requirements apply to

³⁴ 21 CFR 1020.30(h).

³⁵ 21 CFR part 803.

manufacturers, importers of devices manufactured outside the United States, user facilities, and in some instances to distributors.

The MDR regulation requires manufacturers to report to FDA when their devices may have caused or contributed to a death or serious injury, or their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. A serious injury is an injury or illness that is: (1) life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.³⁶

Certain malfunctions are also required to be reported by manufacturers. A malfunction means the failure of a device to meet its performance specifications or otherwise perform as intended.

Performance specifications include all claims made in the labeling for the device and the intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in 21 CFR 801.4.³⁷ A malfunction is reportable when it is likely to cause or contribute to a death or serious injury if the malfunction occurs again.

If any one of the following is true, the malfunction is reportable:³⁸

- The chance of a death or serious injury occurring as a result of a recurrence is not remote;
- It affects the device in a catastrophic manner that may lead to a death or serious injury;
- It causes the device to fail to perform its essential function and compromises the therapeutic, monitoring, or diagnostic effectiveness of the device, which could cause or contribute to a death or serious injury;
- The device involves a long-term implant, or a device that is considered to be life-supporting or life-sustaining; or
- The manufacturer takes or would be required to take action to reduce a risk to health as a result of the malfunction.

The MDR regulation requires device user facilities to report to FDA and to the manufacturer when a device may have caused or contributed to a death and to the manufacturer only when their devices may have caused or contributed to a serious injury.³⁹ A “device user facility” (UF) is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office. UF’s must also submit an annual summary of death and serious injury reports to FDA.⁴⁰ Reports submitted to the FDA are done so using the Form FDA 3500A (MedWatch) for mandatory reports.

There is no obligation for UFs or manufacturers to notify third party entities about adverse events related to the servicing of the device. Manufacturers, UFs, device users, and others may choose to inform third party servicers voluntarily.

³⁶ 21 CFR 803.3(w).

³⁷ 21 CFR 803.3(k).

³⁸ FDA Guidance document – Medical Device Reporting for Manufacturers; available at:

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf>.

³⁹ 21 CFR 803.10(a).

⁴⁰ 21 CFR 803.10(a), 803.33.

Most reports do not include detailed information concerning the servicing history of the medical device, such as:

- Who serviced the device and what service was done;
- When the device was serviced;
- How often the device was serviced;
- What parts were replaced or repaired; and
- What testing was completed after the device was serviced.

Without this information, it is difficult to establish a definitive link between the servicing of a device and the reported event. FDA has not applied reporting requirements to third party servicers, though they can submit voluntary reports.

Although medical device reports (MDRs) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use.

2.2 Centers for Medicare and Medicaid Services and the Joint Commission

The Centers for Medicare and Medicaid Services (CMS) is involved in the regulation of the maintenance and repair of medical devices through requirements regarding conditions for receiving federal payments for health services.⁴¹ For example, 42 CFR 482.41(c)(2) requires that hospital facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. CMS pronounced in 2011 that alternate equipment maintenance methods were not permitted; hospitals must continue to follow the manufacturer's recommended techniques for maintaining equipment, even if the hospitals alter the frequency of maintenance activities.⁴²

In 2013, CMS issued updated guidance to clarify that medical "equipment" refers to all devices intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by a hospital. Hospitals comply with the regulation when they perform equipment maintenance in accordance with the manufacturer's recommendations. In certain circumstances, it also may be consistent with the CMS regulatory requirements for a hospital to use an alternative maintenance schedule. Specifically, a

⁴¹ As noted on TJC public website (https://www.jointcommission.org/facts_about_federal_deemed_status_and_state_recognition/), in order for a healthcare organization to participate in and receive federal payment from Medicare or Medicaid programs, one of the requirements is that a healthcare organization meet the government requirements for program participation, including a certification of compliance with the health and safety requirements called Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations. The certification is achieved based on either a survey conducted by a state agency on behalf of the federal government, such as CMS, or by a national accrediting organization, such as TJC, that has been approved by CMS as having standards and a survey process that meets or exceeds Medicare's requirements. Healthcare Facilities Accreditation Program, Det Norske Veritas Healthcare, and Center for Healthcare Improvement have also been approved by CMS to accredit facilities. Healthcare organizations that achieve accreditation through a "deemed status" survey are determined to meet or exceed Medicare and Medicaid requirements. Accreditation is required for advanced diagnostic imaging services, durable medical equipment, prosthetics, and orthotics and supplies (DMEPOS) suppliers.

⁴² CMS Memo: S&C: 12-07-Hospital: Clarification of Hospital Equipment Maintenance Requirements; available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter12_07.pdf

hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment, based on a risk-based assessment by qualified personnel, unless other Federal or state law or hospital Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements, the equipment is a medical laser device, or new equipment without a sufficient maintenance history has been acquired.⁴³

As stated in the 2013 guidance, hospitals electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their alternative equipment management (AEM) program. They must adhere strictly to the AEM activities and/or frequencies they establish. Notably, the determination of whether it is safe to perform facility or medical equipment maintenance in an alternate manner must be made by qualified personnel, regardless of whether they are hospital employees or contractors.⁴⁴

Revised standards for medical equipment maintenance were announced by TJC in 2014,⁴⁵ aligning TJC's accreditation with updates from CMS. All medical equipment under 2014 standards had to be on the facility's medical equipment inventory when using TJC accreditation process for CMS deemed status. A risk assessment would first determine whether the medical equipment served a life support function and whether non-life support equipment would be considered "high-risk." In the context of the 2014 EC.02.04.01 standard, the term "high-risk" means those items for which there is a risk of serious injury or even death to a patient or staff member should they fail.

In accordance with standard EC.02.04.01, to determine activities and frequencies of maintenance, organizations had to comply with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program, as long as the AEM did not reduce safety and was based on accepted standards of practice.⁴⁶ Although an AEM strategy could include reduced or altered maintenance tasks, relaxed frequencies of maintenance, run-to-fail strategies, etc., assessments for AEM strategies had to be documented in accordance with EC.02.04.01 and high-risk medical equipment had to be maintained at 100% of schedule. However, in January 2017, TJC interpreted CMS's requirements for hospitals to strictly adhere to manufacturer recommendations or to their AEM policy for scheduled maintenance activities and frequencies to mean a "100 percent completion rate" for all equipment.⁴⁷ Recently, TJC enacted a new element of performance (EP) that dictates that hospitals maintain servicing manuals on all devices.⁴⁸ This may facilitate access to servicing manuals by ISOs, contracted by these hospitals.

⁴³ CMS Memo: S&C: 12-07-Hospital Superceded: Hospital Equipment Maintenance Requirements; available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-07.pdf>

⁴⁴ Id.

⁴⁵ The Joint Commission. Standards Revisions and Clarifications Related to Medical Equipment and Utility System Maintenance. Issued July 1, 2014; available at: http://www.jointcommission.org/assets/1/18/hap_equip_maint_revisions_july2014.pdf

⁴⁶ Trade organizations such as American Society for Healthcare Engineering (ASHE), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), etc. may provide further information with regard to establishing alternative equipment maintenance strategies. For medical equipment, accepted standards may be found in the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.

⁴⁷ TJC Prepublication Requirements October 2016; available at:

https://www.jointcommission.org/assets/1/6/PrepublicationRpt_HAP_LSC.pdf

⁴⁸ Changes to Environment of Care and Life Safety Chapters Related to Life Safety Code Updates; available at:

https://www.jointcommission.org/assets/1/6/Life_Safety_Code_Prepub_HAP_Jan2018.pdf

2.3 U.S. Federal Trade Commission

The U.S. Federal Trade Commission (FTC) is a government agency charged with protecting consumers through preventing anticompetitive, deceptive, and unfair business practices, while enhancing informed consumer choice and public understanding of the competitive process. The FTC encourages government agencies to consider the impact on competition when deciding regulatory activities, and avoid unneeded or burdensome barriers to competition that lack compensating benefits. Similar to FDA, FTC aims to complete their mission without unduly burdening legitimate business activity.⁴⁹ FTC enforces a number of antitrust laws including the Sherman Act of 1890⁵⁰ and the Clayton Antitrust Act of 1914.⁵¹

Antitrust laws affect a variety of “vertical” relationships — those involving firms at different levels of the supply chain — such as manufacturer-dealer or supplier-manufacturer. Restraints in the supply chain are tested for their reasonableness, by analyzing the market in detail and balancing any harmful competitive effects against offsetting benefits. In general, the law views most vertical arrangements as beneficial overall because they can reduce costs and promote efficient distribution of products. A vertical arrangement may violate the antitrust laws, however, if it reduces competition among firms at the same level (say among retailers or among wholesalers) or prevents new firms from entering the market. This is particularly a concern in markets with few sellers or those dominated by one seller.⁵²

2.4 State Regulations

Some regulation of medical device servicing at the state level focuses primarily on protecting the public from radiation emitting devices, such as X-Ray machines, medical lasers and fluoroscopy imaging equipment. Generally, states do not regulate servicing of devices that do not emit radiation. Nearly all states have issued specific regulations about servicing radiation emitting equipment. Regulations include state registering of entities that service radiation emitting equipment and/or obtaining a license issued by a state control entity, such as a Radiation Control Board.^{53, 54, 55, 56, 57}

As of December, 2017, a number of states have proposed bills to expand access of parts and servicing manuals to non-OEM entities across various manufacturing industries. Several of the “Right to Repair” bills do not specifically call out medical devices however may still apply to them. Others specifically

⁴⁹ FTC Public Website; available at: <https://www.ftc.gov/about-ftc>

⁵⁰ 15 U.S.C. §§ 1-7.

⁵¹ 15 U.S.C. §§ 12-27.

⁵² FTC Public Website; available at: <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealing-supply-chain>

⁵³ Florida Statutes: 404.22(2) - Radiation machines and components; inspection; available at:

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0404/Sections/0404.22.html

⁵⁴ New Mexico Administrative Code (NMAC) 20.3.2.204 – Application for Registration of Servicing and Services; available at: <http://164.64.110.239/nmac/parts/title20/20.003.0002.htm>

⁵⁵ Illinois Compiled Statutes (ILCS): 420 ILCS 40/25.2 - Radiation Protection Act of 1990; available at: <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1622&ChapterID=37>

⁵⁶ Minnesota Administrative Rules: 4732.0280 - Service Provider’s Responsibility; available at: <https://www.revisor.mn.gov/rules/?id=4732.0280>

⁵⁷ Pennsylvania Code § 216.2a. Registration of radiation-producing machine service providers; available at: <https://www.pacode.com/secure/data/025/chapter216/chap216toc.html>

exclude or limit the applicability to medical devices. For example, the Illinois bill⁵⁸ would require that OEMs shall “(i) make available to any independent repair provider or owner of equipment manufactured by the original equipment manufacturer the same diagnostic and repair documentation in the same manner as that information is made available to the manufacturer’s authorized repair providers; and (ii) make available for purchase by the owner, his or her authorized agent, or any independent repair provider, parts, inclusive of any updates to the embedded software of the parts, upon fair and reasonable terms.”

Similarly, the Missouri bill⁵⁹ would require OEMs “to openly provide all of their diagnostic repair tools to both consumers and independent repair providers on fair and reasonable terms. Consumer products sold for security-related purposes may not be programmed to exclude diagnostic, service, or repair methods to reset a security-related electronic function. Manufacturers are not legally responsible for the content and functionality of such diagnostic repair tools so long as the manufacturers comply with the rest of the bill, but nothing in the bill requires the divulgence of a trade secret.”

The New Jersey bill⁶⁰ would require that “an OEM of equipment sold, offered for sale, or used in this State shall make available for purchase by independent repair providers and owners all diagnostic repair tools incorporating the same diagnostic, repair, and remote communications capabilities that the OEM makes available to its own repair or engineering staff or any authorized repair provider.”

The New York bill⁶¹ “excludes medical devices covered by federal law.” Similarly, the Massachusetts bill⁶² does “not include a class III medical device as established by 21 U.S.C. § 360c.”

3 Review of Responses to FDA’s March 2016 Federal Register Request for Comments⁶³

On March 4, 2016, FDA published in the Federal Register a notice requesting comments from interested persons, such as those engaged or otherwise interested in the “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices,” including radiation-emitting devices subject to EPRC provisions of the FD&C Act.⁶⁴ FDA took this action, in part, because of concerns expressed about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by OEMs, third parties, and healthcare establishments. The notice sought comments on proposed definitions of specific terms pertaining to servicing activities, and the evaluation of benefits and risks associated with them.

⁵⁸ Illinois bill HB3030; available at:

<http://www.ilga.gov/legislation/billstatus.asp?DocNum=3030&GAID=14&GA=100&DocTypeID=HB&LegID=104597&SessionID=91>

⁵⁹ Missouri bill HB 1178; available at: <https://house.mo.gov/billtracking/bills171/hlbillspdf/2172H.01I.pdf>

⁶⁰ New Jersey bill A4934; available at: http://www.njleg.state.nj.us/2016/Bills/A5000/4934_I1.HTM

⁶¹ New York bill S618B; available at: <https://www.nysenate.gov/legislation/bills/2017/s618/amendment/b>

⁶² Massachusetts bill H.143; available at: <https://malegislature.gov/Bills/190/House/H143>

⁶³ Section 710(b)(1) requires FDA to provide the status of, and findings to date, with respect to, the proposed rule entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments” published in the Federal Register by the Food and Drug Administration on March 4, 2016. Although the header in the Federal Register was labeled “Proposed Rules,” the action was “Notification; Request for Comments.”

⁶⁴ 81 FR 11477.

FDA received feedback in response to the March 2016 request for comments.⁶⁵ Stakeholders that provided input included OEMs, ISOs, healthcare establishments, biomedical and clinical engineers, healthcare technology management (HTM) professionals, and professional and trade associations. In total, FDA received 186 comments through the time the docket closed on June 3, 2016.

Healthcare establishments identified three leading factors that contribute to their decision to use a particular service provider: quality, cost, and timeliness. Comments also identified several common elements that significantly influence the quality of Medical Device Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing. These included, but were not limited to the presence of a quality management system; training of service providers; the availability and use of quality replacement parts; and access to device-specific information.

3.1 Quality Management System

Some comments, across all stakeholder groups, provided feedback to FDA that the presence of a quality management system can have a positive influence on service quality. Comments discussed quality systems broadly or suggested that third party entities that are certified to a standard such as ISO 9001⁶⁶ or ISO 13485⁶⁷ are better suited to perform these services. Other comments focused on specific aspects of a quality management system such as supplier validation, design controls, process validation for servicing procedures, and documentation of the service provided. Some commented that servicing performed under an appropriate quality system can facilitate device servicing, updating, and performance tracking. OEMs also communicated that lack of service history records can negatively impact the ability to troubleshoot or identify the root cause of device performance concerns, provide future servicing, and track device performance. Some third party entities and healthcare establishments communicated that the lack of instructions and procedures for performing service activities can negatively impact a servicer's ability to provide high quality product updates or service to the device.

In total, commenters noted that high quality service under a quality management program can help maintain device conformance with specifications and performance standards. These specifications include mechanical safety, electrical safety, and other functional specifications. Servicing, if performed properly, can address unintended or improper device function and does not contribute to future malfunction.

3.2 Training

Medical devices vary considerably with regard to technological complexity, mode of action, materials, and design. As a result, some personnel may not be adequately trained to service certain products or to perform certain types of servicing. FDA received comments from all stakeholder groups indicating that it is critical that personnel performing servicing be adequately trained to recognize the scope of work that needs to be performed and to work only on those devices for which they have adequate knowledge, skill, training, and experience. Some OEMs expressed concerns that third party servicers do not have the adequate knowledge or expertise to provide high quality servicing of their devices. Conversely, some third party servicers stated that their expertise and experience matches and sometimes exceeds that of an OEM servicer. It was also

⁶⁵ Docket No. FDA-2016-N-0436.

⁶⁶ ISO 9001 – Quality management systems -- Fundamentals and vocabulary.

⁶⁷ ISO 13485 – Medical devices -- Quality management systems -- Requirements for regulatory purposes.

noted that there is limited access to device-specific training, and that few accredited training programs exist to address the training needs of the ecosystem.

3.3 Availability and Use of Quality Replacement Parts

All stakeholders stressed the importance of using quality replacement parts that are reliable and compatible with the product being serviced. The use of out of specification parts may lead to repeated or additional device malfunction, and the need for re-service or repair sooner. While there seems to be a consensus about the importance of using quality replacement parts, some expressed concern about limited availability.

3.4 Access to Device-Specific Service Information

Another element identified as influencing the ability to provide high quality service is access to device specifications and service equipment. The availability of device specifications is typically needed by the servicer to ensure that the work being performed returns the device to its proper state. Participants noted that while some product specifications can be obtained from information provided with the original equipment or test records, not all specifications are available in labeling, other publicly available documents, or can be measured with generally available test equipment. In addition, some specifications may require specialized test equipment to assess, and the equipment may not generally be available. Similarly, there may be device-specific test procedures needed to verify that the service performed has in fact resulted in a device that meets its specifications. This issue applies to a number of medical devices that undergo servicing, including radiological devices subject to the EPRC regulation.

In addition to these specific topics, all stakeholders also shared their experiences providing and receiving servicing. These experiences included positive and negative examples of service by OEMs and third party entities. Some emblematic examples of alleged improper servicing include:

- An x-ray film developer began to smoke during use. As the technician unplugged the device, it caught fire. Upon investigation of the incident, it was determined that the internal fan was not functioning and the thermal safety fuse had been improperly wired by a third party servicer to bypass the device's safety feature.⁶⁸
- During an invasive urology procedure, the insulation sleeve from a flexible ureteroscope separated from the device and lodged in the patient's kidney. A resulting investigation revealed that the scope had been repaired by a third party entity using non-OEM materials.⁶⁹
- A malfunctioning ventilator contributed to two deaths outside the U.S. The device's internal components were contaminated with a significant amount of dust and dirt because, after undergoing servicing by a third party entity, the main compressor inlet filter was missing, multiple components were replaced with non-OEM parts, and the device was improperly assembled.⁷⁰
- An infusion pump device was repaired by a non-OEM entity using non-OEM parts. When used on a patient the device delivered unregulated flow (over infusion) causing serious harm to the patient.⁷¹

⁶⁸ Docket No. FDA-2016-N-0436-0126.

⁶⁹ Docket No. FDA-2016-N-0436-0134.

⁷⁰ Docket No. FDA-2016-N-0436-0141.

⁷¹ Docket No. FDA-2016-N-0436-0141.

- Multiple anesthesia machines were improperly maintained and serviced by the OEM, contributing to mold growth on the internal breathing circuits.⁷²

FDA has not confirmed the veracity of these allegations or the investigative findings.

4 Public Workshop

On October 27-28, 2016, FDA held a public workshop – Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.⁷³ The public workshop consisted of introductory stakeholder presentations followed by four sessions covering the general themes pertaining to servicing of medical devices. Specifically, FDA, stakeholder presenters and panel members discussed the benefits and risks of servicing associated with these activities; the characteristics of good servicing entities; the challenges that stakeholders face in performing high quality servicing activities; and best practices and future recommendations.⁷⁴

FDA presented an overview of the Agency's history in regulating remarketers, refurbishers, reconditioners, rebuilders, servicers, and remanufacturers. FDA also presented the working definitions for these terms, and summarized the comments received in advance of the public workshop through the Federal Register.⁷⁵ These comments were consistent with the viewpoints expressed during the two-day workshop.

FDA appreciated the broad stakeholder participation and varying perspectives on these topics from OEMs, third party entities, healthcare establishments, and hospital based service providers. The speakers represented a diversity of backgrounds and viewpoints, and included the following presenters (in the order of presentation):^{76, 77}

- Peter Weems, Director of Policy and Strategy, Medical Imaging & Technology Alliance (MITA)
- David Anbari, Vice President & General Manager, Mobile Instrument Service and Repair, Inc.
- Tara Federici, Vice President, Technology and Regulatory Affairs, Advanced Medical Technology Association (AdvaMed)
- Barbara Maguire, Vice President, Quality and Geisinger Clinical Engineering, ISS Solutions, representing the American College of Clinical Engineering (ACCE)
- Robert Kerwin, General Counsel, International Association of Medical Equipment Remarketers and Servicers (IAMERS)
- Mark Leahey, President and CEO, Medical Device Manufacturers Association (MDMA)

⁷² Docket No. FDA-2016-N-0436-0142.

⁷³ 81 FR 46694.

⁷⁴ Workshop Agenda; available at: <http://wayback.archive-it.org/7993/20171114130552/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm511411.htm>

⁷⁵ Issue Overview; available at: <http://wayback.archive-it.org/7993/20171114130552/https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM525760.pdf>

⁷⁶ Day 1 Transcript; available at: <http://wayback.archive-it.org/7993/20171114130552/https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM532679.pdf>

⁷⁷ Day 2 Transcript; available at: <http://wayback.archive-it.org/7993/20171114130552/https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM532680.pdf>

- Tim McGeath, Senior Vice President and General Counsel, TriMedx
- Katie Ambrogi, Attorney Advisor, Office of Policy Planning, U.S. Federal Trade Commission
- Mary Logan, President, Association for the Advancement of Medical Instrumentation (AAMI)

Stakeholders presented differing views about the quality, safety, and effectiveness of servicing performed by OEMs and third party entities, and the need for imposing additional regulation. OEM representatives emphasized the need for mandatory regulatory requirements on third party entities performing servicing, including portions of the 21 CFR 820 QS regulation. ISO representatives cited a lack of evidence that current voluntary implementation of quality systems and best practices by third party entities were resulting in improper servicing of medical devices. Further, they expressed concerns that the imposition of an FDA QS regulation on ISOs would create a significant financial burden and reduce healthcare providers' choice and availability of medical device servicing. Both OEMs and ISOs presented examples of quality system best practices which have been or could be adopted by entities who perform servicing of medical devices.

The workshop participants expressed general agreement on the importance of quality medical device service. Quality servicing maintains and/or restores device conformance with specifications and performance standards; resolves unintended, inappropriate, or improper device function and does not contribute to a recurrence of problems; and produces sufficient information for the facility and those servicing the device in the future to know the service history and current device configuration. All stakeholders presenting and participating in the panel discussions emphasized the importance of and their commitment to patient safety, and agreed that quality medical device service is essential to ensuring patient safety. Participants also spoke of patients' and healthcare providers' shared interest in ensuring that a medical device continues to perform according to its original design and intended use.

4.1 Stakeholder Presentation Summaries

The first workshop day included formal presentations from various stakeholders. Common themes arising from these presentations were: the importance of collaboration amongst stakeholders, the value provided by ISOs, that regulatory decision making should be evidence based, and that patient safety is of primary importance.

Peter Weems (MITA), summarized OEM concerns that improper third party entity servicing may present significant challenges including but not limited to interfering with future OEM servicing activities, presenting a potential for patient harm, and creating difficulties for OEMs to provide future field upgrades if a device has been improperly altered. Mr. Weems also noted that a lack of mandatory adverse event reporting by third party entities and an incomplete device service history impedes tracking and a complete root cause investigation of adverse events. Finally, he expressed concerns that improper servicing could create liability concerns if a device were to cause injury or damage. Mr. Weems presented three cases of alleged improper servicing of medical imaging devices which posed a potential risk to patient or operator safety.

David Anbari spoke as a representative of a company who repairs surgical equipment. He emphasized a commitment to patient safety first. He presented that such safety is achieved in the current paradigm by the FDA, CMS, TJC, in conjunction with standard developing organizations such as AAMI and the International Organization for Standardization. He emphasized that a 2016 ECRI report⁷⁸ indicated that there is no evidence of anything other than isolated adverse outcomes arising from improper servicing,

⁷⁸ Docket No. FDA-2016-N-0436-0126.

and that the continued use by hospitals and other healthcare providers of independent servicing entities was evidence of this quality servicing. Advamed's concerns included: device repairs may currently be performed by untrained personnel with inappropriate equipment and testing; replacement of parts or components of unknown provenance can result in an adulterated device; and repairs are performed without compliance to servicing standards such as those followed by OEMs. She emphasized that the lack of mandatory MDR reporting by ISOs creates a gap in MDR data, masking adverse events that are caused by improper servicing. Advamed supported FDA oversight of medical device repairs performed by any entity, and that these activities should be subject to key portions of the QS regulation.

Tara Federici, Advamed, summarized concerns relating to the safe and effective performance of medical devices serviced by third party entities. Advamed's concerns included: device repairs may currently be performed by untrained personnel with inappropriate equipment and testing; replacement of parts or components of unknown provenance can result in an adulterated device; and repairs are performed without compliance to servicing standards such as those followed by OEMs. She emphasized that the lack of mandatory MDR reporting by ISOs creates a gap in MDR data, masking adverse events that are caused by improper servicing. Advamed supported FDA oversight of medical device repairs performed by any entity, and that these activities should be subject to key portions of the QS regulation.

Barbara Maguire spoke on behalf of ACCE and also as a representative of an organization that provides clinical engineering and IT services to healthcare establishments, including in-house and independent clinical engineering and servicing. She summarized ACCE's efforts to gather evidence and information on the state of independent and in-house servicing of medical devices today. The evidence she cited included: the ECRI Institute's MAUDE analysis (1998),⁷⁹ UK MHRA outcomes of adverse event investigation (2008-2010),⁸⁰ a survey of the Joint Commission conducted by AAMI (2012),⁸¹ an analysis of the Joint Commission sentinel event data (2013),⁸² Aramark's decade incident data analysis (2014),⁸³ and the ECRI Institute's MAUDE data analysis (1998 and 2016 reports).⁸⁴ ACCE concludes that this existing data does not represent a sufficient level of evidence of improper servicing-related patient incidents to justify additional FDA regulation. She noted that most servicers are regulated through CMS and other agencies, and that when servicers work with healthcare establishments, they are indirectly subject to the same requirements of those organizations. Because of existing oversight, it was ACCE's position that further regulation would be redundant and counterproductive to patient safety. Downsides to unnecessary further regulation would be higher healthcare costs, decreased competition, and reduced service choices that could delay patient care from equipment service and repair delay. ACCE instead recommended that FDA encourage collaboration between manufacturers and third party entity servicers on education and training, standardization of maintenance documentation, and voluntary reporting.

Robert Kerwin spoke on IAMERS's unanimous adoption of recommendations for best practices on meeting customer requirements and patient safety. IAMERS encourages all members of the organization to pursue best practices in medical device servicing and compliance with international standards such as ISO 9001 and ISO 13485, and expects the application of quality management principles in their members' organizational structure, policies, procedures, processes, and records. He noted that many healthcare establishments require cost effective options other than the purchasing of new equipment, and that IAMERS members provide options to maintain medical devices and capital equipment which

⁷⁹ Docket No. FDA-2016-N-0436-0111.

⁸⁰ <https://www.fdanews.com/ext/resources/files/archives/c/con129234.pdf>

⁸¹ Survey not publicly available, but can be obtained from TJC. A presentation summarizing the survey can be found in Docket No. FDA-2016-N-0436-0111.

⁸² <https://www.ncbi.nlm.nih.gov/pubmed/23432570>

⁸³ Data not publicly available. A presentation by Aramark describing the study can be found in Docket No. FDA-2016-N-0436-0111.

⁸⁴ Docket No. FDA-2016-N-0436-0126.

does not compromise patient safety or device performance. The continued availability of independent servicing entities therefore was described as a necessary and important part of the healthcare ecosystem.

Mark Leahey represented MDMA, a trade group of small to midsize medical technology companies. He stressed the importance of upholding elements of a quality system for OEMs and third party servicers, and that FDA's decision in this area should be based on safety and efficacy, not market dynamics that are outside the Agency's jurisdiction. He concluded that earlier workshop presentations demonstrated a consensus that high quality servicing, whether by OEMs or third parties, is performed by organizations with an established quality system, where adequate and appropriate training is in place, and where validated parts are used for repair and service.

Tim McGeath of TriMedx emphasized that there is a need in the market for third party service organizations as they are capable of quality service and repair, and increased collaboration amongst all parties is essential to preserving cost effective and high quality care. He stated that TriMedx follows a holistic equipment management and repair program that is provider centric, allowing healthcare providers to work with a single point of contact for device maintenance. TriMedx's position is that in-house service providers and ISOs are more accountable and available because of an onsite presence, and their lower cost is important in maintaining a competitive market to keep down healthcare costs. However, he emphasized that for ISOs and in-house providers to be successful, collaboration on access to training, parts and service manuals/keys must increase.

Katie Ambrogi of the U.S. FTC spoke of the significant benefits of market competition, including lower price, improved access, and better service quality. The FTC primarily acts as a law enforcement agency, but is also concerned with how competition could be effected by the actions of legislators and regulators. She reminded the audience of Presidential Executive Order 13725 signed in April 2016,⁸⁵ stating the federal government's priority in promoting competitive markets. Thus, she suggested that FDA consider the impact on competition when deciding regulatory activities, and avoid unneeded or burdensome barriers to competition that lack compensating benefits. Last, she encouraged consideration of alternative actions that might fulfill public health goals without impacting competition or creating burden.

Mary Logan spoke for AAMI, a standards development organization. AAMI submitted a comment to the public docket discussing the results of a survey they performed at the request of TJC. In addition, AAMI has both facilitated the development of standards relating to servicing, and had recently formed a new committee to develop definitions for servicing, refurbishing, and other related terminology.⁸⁶ AAMI identified the need for this committee as a result of the Federal Register notice, related public comments, and the observation that their organization could address the need for standardized definitions.

4.2 Panel Discussion Summaries

Panel 1 covered the benefits and risks of servicing associated with refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing activities. The OEM panel representatives stated that if devices receive quality servicing, then the benefits will include extended device lifespans with fewer occurrences of device downtime that could delay patient care. Patient safety hazards and

⁸⁵ 81 FR 23417.

⁸⁶ <http://www.aami.org/productspublications/articledetail.aspx?ItemNumber=4160>

poor product performance are risks that can occur due to inappropriate servicing, incomplete service documentation, the use of improper replacement parts, or unintended design changes. The hospital end user and in-house service representatives mentioned the benefits of quality servicing, including extended device lifespan, but also cited the risks that arise from adverse event reporting systems that fail to cover the entire device lifespan and service ecosystem, and risks that may arise when comprehensive service manuals are unavailable to the parties performing the servicing. Finally, the ISO panel representatives emphasized the benefits of reduced healthcare costs, and that access to timely repair and regular preventative maintenance is essential to patient safety. Meanwhile, they stated that the risk of unnecessary regulation could jeopardize the existence of ISOs and marketplace competitiveness which generates end user and patient benefits.

Panel 2 covered the characteristics of good refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing entities. The panel members representing hospital end users and engineers emphasized the importance of service engineers with appropriate qualifications, adequate training, appropriate and calibrated test equipment, and the availability of field service reports and maintenance records. They noted the apparent overlap between TJC oversight and FDA QS regulation requirements, in such areas as quality audits, personnel, document control, inspection, acceptance, and records. To maintain quality, the hospital end users rely on support from OEMs to provide service manuals, parts and access to training programs. The panel members from ISOs agreed that high quality servicing entities share the following core characteristics: a patient safety focus, strong quality management system, alignment within users of serviced equipment, commitment to scheduled preventative maintenance, and a local presence important to end users. The panel members representing OEMs spoke of the importance that an appropriate quality management system, such as that described by QS regulation 21 CFR 820, be followed by all OEMs and all independent service providers, not just those parties present at the public workshop who voluntarily implement those systems. Additionally, the closed loop process of continuous improvement of a quality management system is essential.

Panel 3 addressed the challenges faced in performing high quality refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing activities. The panel representatives from ISOs identified many challenges, such as: OEMs who limit training seminar attendance by ISO employees and charge high fees; lack of access or affordable access to parts, manuals, and service software; and lack of information on recalls and safety information directly from OEMs. The OEM panel representatives, however, explained that their own service activities are challenged by the impact of poor service performed by other entities, which present patient and operator safety hazards, and liability concerns. The panel representatives for end users and clinical engineers stated their biggest challenge was a lack of information about the harms arising from servicing. They suggested a risk-based approach to oversight predicated on servicing complexity. They also requested that more robust data be obtained to allow assessment of the current servicing ecosystem.

Panel 4 covered current best practices and future recommendations. Hospital groups described accounts from several hospital engineers in which repair activities were urgently needed during the delivery of patient care and prevented major health or patient crises. They also described incidents in which device manufacturers refused to provide service manuals or training. Finally, they noted that the required support for clinical engineers is different than in the past due to more complicated and cyber-sensitive equipment and environments. OEM panel members stated that their current best practices are summarized by the QS regulation in 21 CFR 820, but that most also certify to ISO 9001 or ISO 13485. The OEMs do not advocate new, broader regulations by FDA but instead that existing medical device

regulations be extended to apply consistent minimum requirements for all device service providers. The third party entity panel members described an example of quality system best practices in place at one company – certification to ISO 9001 and ISO 13485 – and noted the range of voluntary applicable standards that can apply to third parties. They encouraged the FDA to compel OEMs to provide documentation and better ‘after-sale’ support needed to service and maintain equipment to all users, which would benefit patient safety.

5 Summary of Evidence Pertaining to Medical Device Servicing

5.1 Number of Service and Repair Entities

The precise number of entities that perform servicing of medical devices in the U.S. is not known. Therefore, the total number of medical device servicing firms in the U.S. was estimated. Dun and Bradstreet (D&B) is a private company that curates and manages a database of companies and company records worldwide. For each company in the database, D&B assigns a unique identifier and one or several Standard Industrial Classification (SIC) codes based on the industry in which they operate and services/products are offered.

All firms in the D&B database that were classified using at least one of the following SIC codes were identified:

SIC Code	SIC Description
76990700	Hospital equipment repair services
76990701	Medical equipment repair, non-electric
76990702	Surgical instrument repair
76990703	X-ray equipment repair
76290101	Hearing aid repair
76990102	Dental instrument repair

In total, this search yielded 4,791 firms in the U.S. Identified firms may also perform original equipment manufacturing or remanufacturing. States with the highest number of servicing firms were California, Florida, Texas, New York, and Pennsylvania.

To determine the capture rate of medical device servicing firms using the SIC codes above, a sample group of 130 medical device servicers was compiled using publicly available information independent of the D&B database. The sample group represented a heterogeneous group of medical device servicers across device types. Using this sample set of firms, 34 out of 130 (26%) were captured by the SIC code search. By extrapolating this rate to the entire U.S. market and estimating the statistical error, we conclude that the estimated total number of firms performing medical device servicing in the U.S. is between 16,520 and 20,830.

5.2 Literature Review

FDA conducted a literature review on January 17, 2018 to assess what peer-reviewed published evidence is available on the quality, safety, and effectiveness of medical device servicing. The search was conducted using PubMed and EMBASE and was limited to English language articles published on or after January 1, 2008. The search returned articles that included at least one term from each of the following

lists in the title or abstract. Terms listed included hyphenated variants of each and used the truncation symbol “*” to catch all suffixes of the terms.

List 1	List 2	List 3
<ul style="list-style-type: none"> • Furbish* • Servic* • Refurbish* • Recondition* • Rebuil* • Remarket* • Remanufactur* • Device Maint* • Device Repair* • Calibrat* 	<ul style="list-style-type: none"> • “Equipment and supplies”[MeSH Terms] • Medical Device* • Device* 	<ul style="list-style-type: none"> • Third Part* • 3rd Part* • Independent Service Organization* • Equipment Manufacturer* • Device Manufacturer* • OEM

The review excluded articles if they did not provide quantitative evidence relating to the quality, safety, and effectiveness of third party or original manufacturing servicing. Case reports, review articles, editorials, and animal studies were also excluded. In total, the search strategy identified 502 articles. 476 articles were excluded after reviewing the title and abstract. The remaining 26 articles were reviewed in full. Among them, 25 articles were further excluded because, after further review, they met one of the exclusion criteria listed above or because they did not address the question of interest. Only one study (Worobey, L., et al, 2014) attempted to address the question by assessing the frequency of device repairs (for power wheelchair) and adverse consequences reported among patients with spinal cord injury by device manufacturers. However, this study lacked detailed information on the nature of the repair, who provided the service, and the number and timing of adverse consequences, and thus, did not provide sufficient information to address the quality, safety, and effectiveness of medical device servicing. Based on this literature review, no definitive conclusions can be drawn about the safety and effectiveness of medical device servicing in general or about the servicing of specific medical devices due to the lack of studies with sufficient, high-quality data.

In summary, a systematic literature review did not produce robust quantitative evidence to support an evaluation of the quality, safety, or effectiveness of servicing of medical devices.

5.3 ECRI Institute Analysis

In response to FDA’s public request for information pertaining to the quality, safety and effectiveness of servicing of medical devices, ECRI Institute submitted a summary of their research and analysis.⁸⁷

ECRI Institute searched:

- FDA’s MAUDE database from 2006-2015 (2,114,303 records);
- ECRI Institutes Health Devices Alerts (HDA) Tracker Database 2006-2015 (limited to search of ECRI-generated Hazard Reports and User Experience Network Articles) (528 records); and
- ECRI Institutes confidential contracted accident investigations 2006-2015 (692 investigations).

The search was limited to capital equipment by excluding records that related to prostheses, implants, reagents, in vitro diagnostics, and disposable/single-use medical devices, and the search strategy

⁸⁷ Docket No. FDA-2016-N-0436-0126.

incorporated specific terms and search phrases pertaining to the servicing, repair, and maintenance of medical devices.

Relevant reports were reviewed and excluded if the problem described in the record was caused by:

- Disposables or single use devices;
- Manufacturing errors;
- Operator or use error in setup, assembly, adjustment, or routine use of the device;
- Unauthorized service/repair errors or equipment modifications performed by the patient or lay users;
- Routine maintenance operations performed by the user such as calibration, cleaning, sterilization, lubrication, or battery replacement; or
- No maintenance was performed at all on the incident device.

In total, the analysis identified 86 MDRs (0.004% of MDRs analyzed), 4 ECRI Health Devices Alerts Tracker reports (0.8% of HDA Tracker reports) and 6 ECRI Institute contracted accident investigations (0.9% of investigations). Based on the results of their analysis, ECRI Institute concluded that they do not believe that a safety problem exists with the servicing, maintenance, and repair of medical devices by either third party organizations or OEMs.

5.4 Medical Device Reports (MDRs)

Each year, the FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries, and malfunctions submitted by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as healthcare professionals, patients, and consumers. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. MDRs can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type; and
- Detect actual or potential device problems used in a “real world” setting/environment, including:
 - Rare, serious, or unexpected adverse events;
 - Adverse events that occur during long-term device use;
 - Adverse events associated with vulnerable populations;
 - Off-label use; and
 - Use error.

As previously stated, although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA’s several important postmarket surveillance data sources. Important limitations of MDRs include:⁸⁸

- The data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be

⁸⁸ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.

- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MDRs are subject to reporting bias, attributable to potential causes such as reporting practice, increased media attention, and/or other agency regulatory actions.
- MDRs do not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.

All MDRs received and publicly posted since March 1992 in the Manufacturer and User Facility Device Experience (MAUDE) database as of June 30, 2017 were evaluated. Text-based searches and manual review of candidate MDRs were performed to identify 4,301 reports that mentioned a third party servicer who repaired a device. This does not include reports of repair by the OEMs or hospital personnel. It only includes reports where it explicitly states that a device or device component was repaired, replaced, or maintained by a third party servicer.

The 4,301 MDRs included 40 deaths, 294 serious injuries, 3,791 malfunction reports, and 176 reports classified as “other.” Of these reports, 4,240 came from manufacturers, 16 from distributors, 25 from user facilities, and 20 from voluntary sources.

Device types associated with more than one death report included: automated external defibrillators (6), duodenoscopes (5), ventilators (4), intra-aortic balloon systems (4), and infusion pumps (2). Of the death reports, only 3 contained sufficient information to definitively conclude that servicing caused or contributed to the death:

- A fatality occurred to a Field Service Engineer while servicing a Computed Tomography scanner;
- A fatality occurred to a Field Service Engineer while servicing an MRI scanner; and
- A death occurred after a patient lift rail was reinstalled incorrectly.

A fourth death was due to the malfunction of a remanufactured imaging system that lacked FDA clearance or approval. The camera fell on and killed a patient.

Due to the limited information contained in the 334 MDRs of death or serious injury, we were not able to establish a conclusive relationship between device third party entity servicing and the subsequent adverse event.

5.5 Complaints

FDA searched all complaints and allegations of regulatory misconduct (collectively “complaints”) received by the Center for Devices and Radiological Health (CDRH) since 2009 for those related to servicing of medical devices and radiation-emitting products. Complaints that did not involve device servicing or remanufacturing, or complaints that were duplicates were excluded. A total of 68 potentially relevant complaints were identified. Of those, 28 were related to device remanufacturing, including the replacement of parts not consistent with OEM specification. The remaining 40 complaints alleged inadequate servicing, ranging from customers being charged for repair services, OEMs not providing service manuals, and OEMs not providing critical replacement parts to poor technician

training, knowingly falsifying service records and device serial numbers, and repairs using broken replacement parts. One complaint alleged an end user was neglecting maintenance, 29 complaints alleged inadequate servicing by OEM's, and 10 complaints alleged inadequate servicing by ISOs. Of the 40 complaints, 18 alleged that the inadequate servicing could lead to a serious adverse event. Only one complainant reported that adverse events occurred. In that complaint, two patients were injured due to an ISO repairing an infusion pump with allegedly defective parts.

In total, similar to the anecdotes provided as feedback in response to FDA's March 2016 request for comments, complaints and allegations of regulatory misconduct related to the servicing of medical devices and radiation-emitting products received by FDA demonstrate that there may be isolated instances of poor quality servicing by OEM's or third party entities.

6 Summary of Key Issues and On-Going Activities

Based on the available information, including but not limited to the public meeting, response to the request for comments, and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing, we have concluded:

- The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
- Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;
- A majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing"; and
- The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.

However, based on the available information and findings, we intend to pursue the following actions:

1. Promote the Adoption of Quality Management Principles by Medical Device Servicers;
2. Clarify the Difference Between Servicing and Remanufacturing;
3. Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
4. Foster Evidence Development to Assess the Quality, Safety, and Effectiveness of Medical Device Servicing.

Each of these actions is explained in more detail below.

6.1 Promote the Adoption of Quality Management Principles by Medical Device Servicers

Quality management principles and processes, as part of a quality system, have been adopted and implemented by more than 1 million companies and organizations worldwide to improve quality, efficiency, safety and reliability.⁸⁹ The selective adoption and application of existing quality management principles and processes to medical device servicing has been advocated by OEMs and third party

⁸⁹ See International Organization for Standardization (ISO), ISO 9000 – Quality Management; available at: http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm

servicers, and some, but not all, medical device servicers already adopt at least some quality management principles.

Different approaches to quality management exist, and they share certain common, underlying principles. Quality management principles help to identify, prevent, track, and monitor safety hazards and to reduce risks. They are flexible, scalable, and adaptable so organizations can tailor the application of these standardized processes to their individual circumstances and needs. Quality management principles provide a quality framework for companies and organizations to ensure that:

- Their services consistently meet their customer's needs and requirements;
- Risk management principles are applied to identify, evaluate, mitigate, and remediate hazards;
- Personnel performing servicing are appropriately qualified and trained;
- Replacement parts meet the design requirements of the initial device design;
- Servicing activities are appropriately documented;
- Technical and service manuals are accurate, understandable, and available to those providing service and maintenance; and
- Overall quality is continually improved.

A number of efforts to create or update existing voluntary consensus standards and best practices pertaining to the quality servicing of medical devices are ongoing.

The selective adoption and application of quality management principles and processes to medical device servicing contributes to the quality, safety, and effectiveness of these activities. FDA intends to work with entities performing medical device servicing to identify the essential elements of a voluntary medical device servicing quality framework, leveraging new and existing quality management standards, best practices and principles, and identifying areas where they can be most impactful. We view this strategy, rather than a formal regulatory approach mandating adoption of FDA's QS regulation by all entities performing medical device servicing, as the appropriate approach at this time for advancing the quality of medical device quality servicing.

6.2 Clarify the Difference Between Servicing and Remanufacturing

A significant portion of the comments, complaints, and adverse event reports alleging inadequate servicing pertain to activities more accurately described as remanufacturing. FDA makes an important distinction between these activities. Servicing returns or maintains a finished device's safety and performance specifications and intended use whereas remanufacturing significantly changes the finished device's performance, safety specifications, or intended use.^{90, 91} Because remanufacturing can have a significant impact on the safety and effectiveness of the device, FDA has interpreted regulatory requirements such as those under the QS regulation to apply to remanufacturers and has actively regulated them as manufacturers. FDA is currently and will continue to enforce existing requirements for those third parties engaged in remanufacturing.

Because of the apparent confusion we have heard from stakeholders concerning the difference between servicing and remanufacturing activities, FDA intends to publish guidance to assist in differentiating these activities to allow more consistent interpretation and categorization. In turn, this will clarify

⁹⁰ 21 CFR 820.

⁹¹ Federal Register Vol 81; No. 42; March 4, 2016: 11477-11479.

regulatory responsibilities for entities performing these activities and allow FDA to focus its regulatory oversight on those activities that have the greatest impact on the quality, safety, and effectiveness of medical devices. In accordance with good guidance practices,⁹² FDA intends to publish the guidance in draft form and accept public comments before issuing final guidance.

6.3 Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices

Effective cybersecurity practices are essential for the continued safety and effectiveness of medical devices, particularly with the increasing use of wireless, internet-, and network-connected devices. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient illness, injury, or death. FDA has issued guidance outlining the approaches device manufacturers should follow in the premarket design and development of medical devices, and during their surveillance and response to identified cybersecurity vulnerabilities and exploits of marketed products.^{93, 94} FDA has recommended that manufacturers address cybersecurity risks throughout the product lifecycle.

The security industry has established resources including standards, guidelines, best practices, and frameworks to assist in adopting a culture of cybersecurity risk management. Recommended approaches include limiting privileged access to operating systems and applications, instituting user authentication and appropriate controls before permitting software or firmware updates, and ensuring only trusted content is permitted by restricting software or firmware updates to authenticated code only. Best practices also include collaboratively assessing cybersecurity intelligence information for risks to device functionality and clinical risk.

The servicing of medical devices by entities other than the OEM raises specific cybersecurity challenges related to the servicer's need, in many cases, for privileged access to perform the necessary diagnostic, maintenance and repair functions. Servicers may also play an important role in reducing cybersecurity risks by ensuring that the latest security patches and software updates have been successfully installed.

Although FDA has clarified requirements associated with the cybersecurity of medical devices, many OEMs, healthcare establishments, and third party servicers lack the necessary cybersecurity expertise, policies, and practices necessary to ensure the appropriate level of cybersecurity resilience associated with the servicing of medical devices. The development and application of standards and best practices for all entities engaged in the servicing of medical devices could further mitigate cybersecurity risks.

6.4 Foster Evidence Development to Assess the Quality, Safety, and Effectiveness of Medical Device Servicing

The creation of an environment of learning and continual improvement is central to a medical device servicing industry that delivers quality, safe, and effective service. Currently, the available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements. Efforts to systematically collect evidence on

⁹² 21 CFR 10.115.

⁹³ FDA Guidance document – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; available at: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356190.pdf>

⁹⁴ FDA Guidance document – Postmarket Management of Cybersecurity in Medical Devices; available at:

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482022.pdf>

the number, rate, and type of servicing errors would be of value. However, several factors inhibit the utility of isolated adverse event reporting as the mechanism for identifying and sharing important safety concerns associated with medical device servicing. These include persistent underreporting of patient safety events and device malfunctions even when there are well-established programs in place to encourage adverse event reporting; failure to recognize adverse events as related to the servicing of the medical device at the time of their occurrence; poor documentation of the service history of the device impeding root cause analysis of device malfunctions and adverse events; and difficulty in reaching conclusions about the existence, severity, or frequency of problems associated with the servicing of the devices.

Because of these and other shortcomings related to adverse event reporting, we do not believe that extending MDR reporting to third party servicing entities would be likely to yield the information necessary to assess the quality, safety, or effectiveness of medical device servicing. Therefore, we do not intend to modify our current approach to reporting by third party medical device servicers at this time. FDA continues to encourage voluntary MDR reporting by servicers, patients, and healthcare providers. Similarly, while some have advocated for FDA to use its authority to require registration of entities or persons performing servicing activities, we do not believe this information alone would address the outstanding fundamental questions regarding the quality, safety, and effectiveness of servicing, and we do not intend to apply registration and/or listing requirements to persons or entities engaged solely in servicing at this time.

As noted previously, we have concluded that the available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify additional/different burdensome regulatory action. To evaluate the servicing ecosystem more fully would require more than limited, anecdotal adverse event reports, but robust, systematically-collected, quantitative data addressing the rates of servicing-related errors, malfunctions, and adverse events, across different device types and different servicers.

Entities engaged in servicing activities (including OEMs, healthcare establishments, and ISOs) have access to, or could collect comprehensive information on device types, number of devices serviced, frequency of servicing, frequency of service-related complaints, frequency of service-related adverse events, and characteristics of the servicing entity. FDA believes that any concerted data collection and analysis effort should be a multi-stakeholder enterprise.

7 Conclusion

This report includes information and evaluation with respect to the quality, safety, and effectiveness of medical device servicing, as required by Section 710 of the FDA Reauthorization Act of 2017.⁹⁵

We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time. Although we do not believe that additional, formal regulatory action is warranted, based on the available information and findings, we intend to pursue the following actions:

⁹⁵ A docket has been opened to receive comments regarding this report. Please submit your comments to www.regulations.gov, Docket No. FDA-2018-N-1794.

1. Promote the Adoption of Quality Management Principles;
2. Clarify the Difference Between Servicing and Remanufacturing;
3. Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
4. Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.

As part of its 2018-2020 strategic priorities, CDRH has committed to establishing “Collaborative Communities.” The hallmark of a Collaborative Community, is a continuing forum where public and private sector members proactively work together to solve both shared problems and problems unique to other members in an environment of trust and openness, where participants feel safe and respected to communicate their concerns. Members share a collective responsibility to help each other obtain what they need to be successful. We believe there may be value in the creation of a public-private forum, such as a Collaborative Community, to address the challenges associated with delivering high quality, safe, and effective servicing of medical devices. If there is sufficient interest and broad willingness to participate by all stakeholder groups, we would facilitate the creation of such a community.

Appendix A – Cross Reference between the Congressionally Mandated Report Elements and the Corresponding Section in this Document

FDARA 710	Charge	Section(s) in report which address(es) the charge	Page No.
(b)(1)	the status of, and findings to date, with respect to, the proposed rule entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments” published in the Federal Register by the Food and Drug Administration on March 4, 2016 (81 Fed. Reg. 11477)	Section 3 - Review of Responses to FDA’s March 2016 Federal Register Request for Comments	11
(b)(2)	information presented during the October 2016 public workshop entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers”	Section 4 - Public Workshop	14
(b)(3)	a description of the statutory and regulatory authority of the Food and Drug Administration with respect to the servicing of devices conducted by any entity, including original equipment manufacturers and third party entities	Section 2.1 - FDA’s Authority and Regulatory History	3
(b)(4)	details regarding how the Food and Drug Administration currently regulates devices with respect to servicing to ensure safety and effectiveness, how the agency could improve such regulation using the authority described in paragraph (3), and whether additional authority is recommended	Section 2.1 - FDA’s Authority and Regulatory History and Section 6 - Summary of Key Issues and On-Going Activities	3 23
(b)(5)	information on actions the Food and Drug Administration could take under the authority described in paragraphs (3) and (4) to assess the servicing of devices, including the size, scope, location, and composition of third party entities	Section 2.1 - FDA’s Authority and Regulatory History and Section 6 - Summary of Key Issues and On-Going Activities	3 23
(b)(6)	information on actions the Food and Drug Administration could take to track adverse events caused by servicing errors performed by any entity, including original equipment manufacturers and third party entities	Section 2.1 - FDA’s Authority and Regulatory History and Section 5.4 - Medical Device Reports (MDRs)	3 21
(b)(7)	information regarding the regulation by States, the Joint Commission, or other regulatory bodies of device servicing performed by any entity, including original equipment manufacturers and third party entities	Section 2.2 - Centers for Medicare and Medicaid Services and the Joint Commission and Section 2.3 - U.S. Federal Trade Commission and Section 2.4 - State Regulations	8 10 10