



The New FDA Request for Comments on Medical Device Servicing: A Review of Past History and An Analysis of Current Status

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Summary

- ▶ On 12/23/1997 the FDA issued an Advance Notice of Proposed Rulemaking (ANPR) announcing its intent to regulate refurbishers, rebuilders, reconditioners, servicers, and "as is" remarketers of medical devices because of the concerns raised in the process of establishing the Quality System (QS) regulation (aka cGMP) in 1996. After receiving extensive feedback, including from ACCE, convening a public conference in 1998, and reviewing evidence of extremely small amount of serious patient injuries and deaths caused by those stakeholders, FDA decided not to issue new regulatory requirements.
- ▶ On 3/4/2016 the FDA issued a Request for Comments (RfC) for the same activities (plus remanufacturing) with the deadline of 5/3/16. FDA stated this RfC was issued "because various stakeholders have expressed concerns 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 both original equipment manufacturers (OEM) and third parties, including health care establishments."
- ▶ This webinar will review additional evidence of risks from those activities collected since 1998 and discuss potential impacts of additional regulation on costs for healthcare organizations and safety for patients and users. Actions are then suggested to stakeholders in preparing their comments to the FDA, including analyzing their own data, alerting the executive leadership and other device users, purchasers, and managers in their respective organizations, and communicating with their parts, service, and training providers.

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Acknowledgement

- ▶ The following expert panel contributed to this presentation and most of them are available during Q&A (in alphabetic order of last name):
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Goals

- ▶ Motivate all stakeholders, especially clinical engineering professionals, to provide **data and comments** to the FDA so it can decide what changes, if any, are needed to enhance patient safety and care.
- ▶ Stimulate **innovative, disruptive ideas** that can enhance the safety and effectiveness of medical devices through **cooperation** among stakeholders.

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The FDA Proposed Rule/Request for Comments

- ▶ **Title:** Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers
- ▶ Available at: <https://www.federalregister.gov/articles/2016/03/04/2016-04700/refurbishing-reconditioning-rebuilding-remarketing-remanufacturing-and-servicing-of-medical-devices>.
- ▶ **Summary:** The Food and Drug Administration (FDA or we) is announcing the establishment of a docket **to receive information and comments** on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices (hereafter termed “third-party entity or entities”), including radiation-emitting devices subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA is taking this action, in part, **because various stakeholders have expressed concerns 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 both original equipment manufacturers (OEM) and third parties, including health care establishments**. We are seeking comments from the widest range of interested persons, including those who are engaged in one or more of the activities noted previously or who utilize refurbished, reconditioned, rebuilt, remarketed, remanufactured, or third-party serviced and repaired medical devices.
- ▶ **Comment Deadline: May 3, 2016**



FDA Rationale

- ▶ “Stakeholders have expressed concerns that some third-party entities who refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices may use **unqualified personnel** to perform service, maintenance, refurbishment, and **device alterations** on their equipment and that the work performed **may not be adequately documented**. Possible public health issues arising from these activities include **ineffective recalls**, **disabled device safety features**, and **improper or unexpected device operation**.”
- ▶ “OEMs have also requested clarification of their responsibilities when their **devices have been altered** by a third-party entity.”
- ▶ “Federal Agencies other than FDA address service and maintenance activities as well.” (CMS 2011 and 2013 S&C letters)

FDA Proposed Definitions

1. **Recondition**
2. **Service:** "Maintenance or repair of 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 cannot change the intended use(s) of the device from its original purpose(s)."
3. **Repair:** "Return the device or component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device."
4. **Refurbish**
5. **Remanufacture**
6. **Remarket:** "The act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift, or lease."

Refurbish + Recondition + Remarket + Repair + Service = R⁴S

FDA Questions on Risk Evaluation

- 1) Who are the different stakeholders...?
- 2) What evidence exists regarding actual problems...?
- 3) What are the potential risks (patients/users) and failure modes (devices)...?
- 4) Are the risks different depending on who performs the previously mentioned activities?
- 5) Are these activities more difficult or riskier to perform on certain devices versus others?
- 6) What information do third-party entities need...?
- 7) What additional challenges do stakeholders encounter with devices that result from these activities?

History of Prior FDA Actions

- ▶ FDA stated in preamble of Quality System (QS) regulation (aka cGMP) - 21 CFR 808, 812, and 820 issued on Oct 7, 1996, did not include servicers “... **even though it believes that persons who perform such functions meet the definition of manufacturer.** Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee at the September 1995 meeting, FDA has elected to address application of the CGMP requirements ... in a separate rulemaking later this year...”
- ▶ FDA published **ANPR** on Dec 23, 1997, saying “FDA is announcing its intention to review and, as necessary, to revise or to amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and **the persons who refurbish, recondition, rebuild, service, or remarket such devices**”

History of Prior FDA Actions (cont.)

- ▶ After receiving and reviewing extensive feedback (including from ACCE) and participating in a public meeting, FDA announced on Dec 4, 1998 that “FDA currently believes that it may be appropriate for the agency to apply certain regulatory controls to certain used-device processors, using **alternative regulatory approaches**, if their processing activities do not result in significant changes in the used device's safety or performance specifications, or intended use.”

Lessons from 1997 ANPR

- ▶ Confusion between reprocessing of single-use devices (SUDs) and R⁴S until SUD reprocessing was segregated. Refurbish + Recondition + Remarket + Repair + Service = R⁴S
- ▶ FDA is willing to read, listen and learn but lots of input (factual data) must be provided
- ▶ Although a consensual alternative to regulation was proposed,* FDA did not implement it
- ▶ Above all, **there must be evidence of risk to public health and safety for FDA to devote attention as it has limited resources**

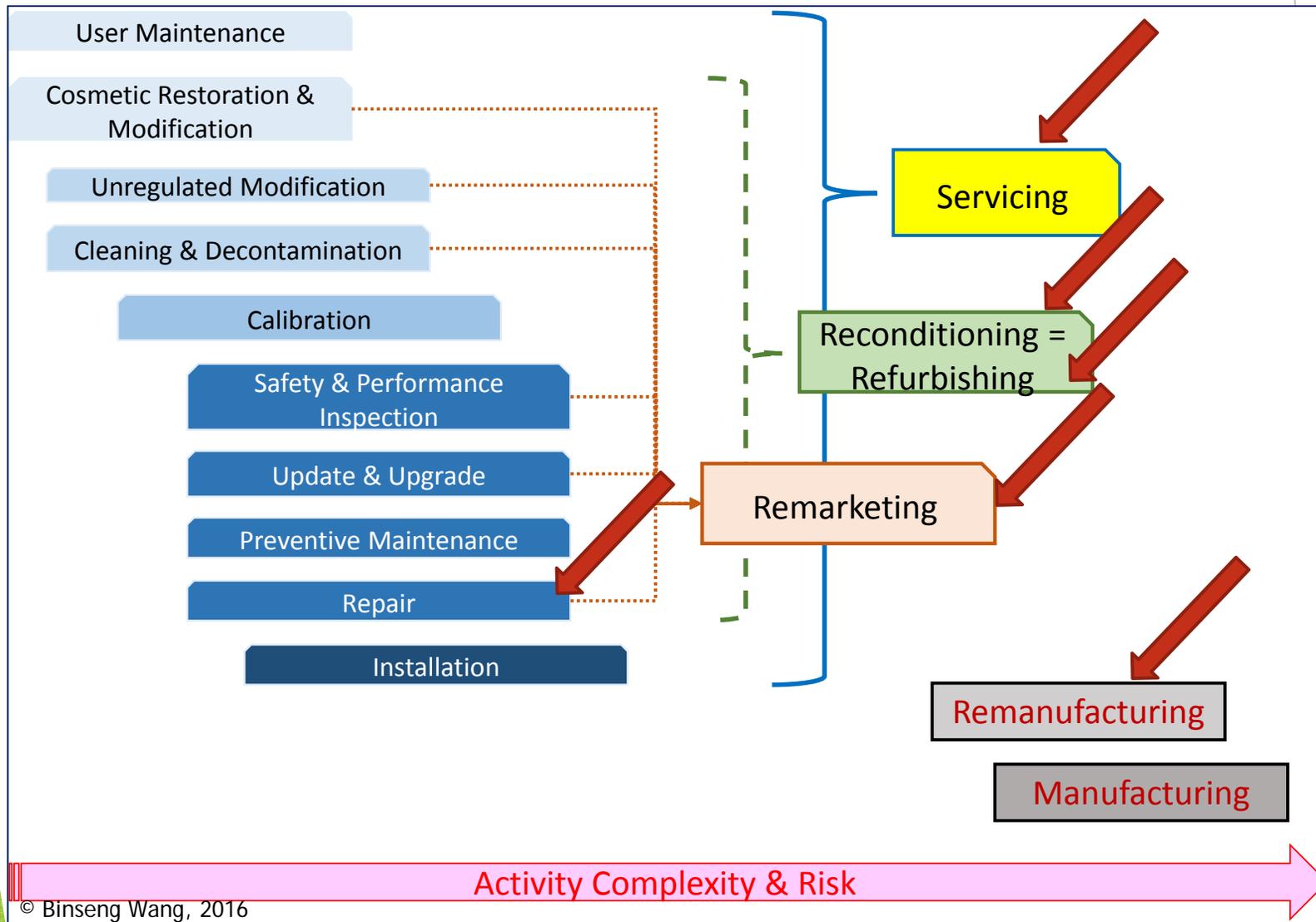
*ACCE, ASHCS, ASHE, AAMI, ECRI, HIMA, IAMERS, MDMA, NEMA & SIA, 1999

Some Background Information for Consideration on the FDA Questions

- 0) Proposed definitions of activities
- 1) Who are the different stakeholders...?
- 2) What evidence exists regarding actual problems...?
- 3) What are the potential risks (patients/users) and failure modes (devices)...?
- 4) Are the risks different depending on who performs the previously mentioned activities?
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0) Definitions of Activities

(In addition to the 6 listed by FDA)



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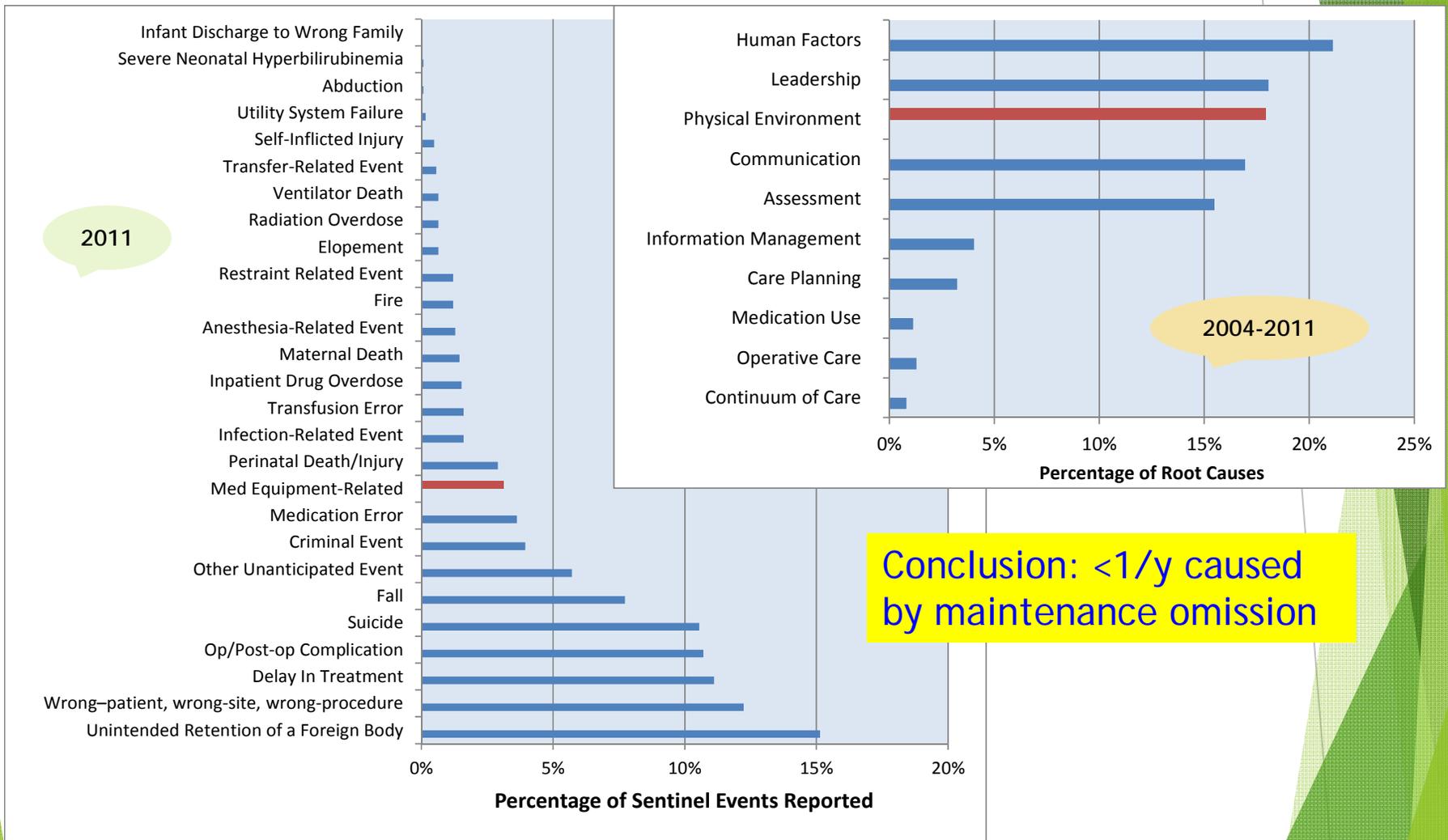
1) Who are the stakeholders?

- ▶ Referenced in FDA RfC
 - ▶ OEM
 - ▶ Healthcare organizations
 - ▶ Remanufacturers
 - ▶ Those that perform R⁴S (Refurbish + Recondition + Remarket + Repair + Service)
- ▶ **Not referenced** (see previous slide)
 - ▶ Patients & non-professional care givers
 - ▶ Home care providers
 - ▶ Doctors, nurses, technologists, allied health professionals (e.g., Central Processing/Sterilization and EMT staff)
 - ▶ Clinical Engineering & Facility Management professionals
 - ▶ Material Management/Supply Chain Management professionals
 - ▶ Alternate parts providers
 - ▶ Lessors of leased and owners of rental equipment

2) What evidence exists regarding actual problems?(Please share others you have)

- ▶ M. Bruley presented at the 1998 AAMI/FDA Conference an analysis of ~137,500 FDA-MAUDE reports involving equipment collected 1977-1997 and found **241 incidents potentially related to R⁴S**, i.e., 0.17%. **ECRI Institute is analyzing data collected since 1998.**
- ▶ Wang, Rui & Balar published in BI&T (2013) an analysis of **Sentinel Events collected by TJC** for year 2011 and root causes for the period 2004-2011 and found 7 (0.6%) and 24.6 (0.4%) related to equipment failure, respectively, in the worst case. Of these, **less than one/year is likely due to maintenance omission**. Maintenance omission is estimated to be 0.024-0.286 per million equipment uses (or 6.5-6.96 sigma).
- ▶ AAMI conducted a **survey in 2011** for TJC with 1,526 respondents. Twelve adverse events were reported, but **none due to maintenance omission**.
- ▶ Fedele & Wang presented at the 2014 MD Expo an analysis of a **decade of incidents** collected by Aramark and found 6 out of 476 incidents were related to maintenance omission (**0.6/year**), with an average inventory of almost 1 M/y and >1.1 M services/y (or ~6.5 sigma).

TJC Sentinel Events 2011 and Root Causes 2004-2011 (Wang, Rui & Balar - BI&T, 2013)



Aramark Internal Incidents Analysis

(presented at 2014 MD Expo by Fedele & Wang)

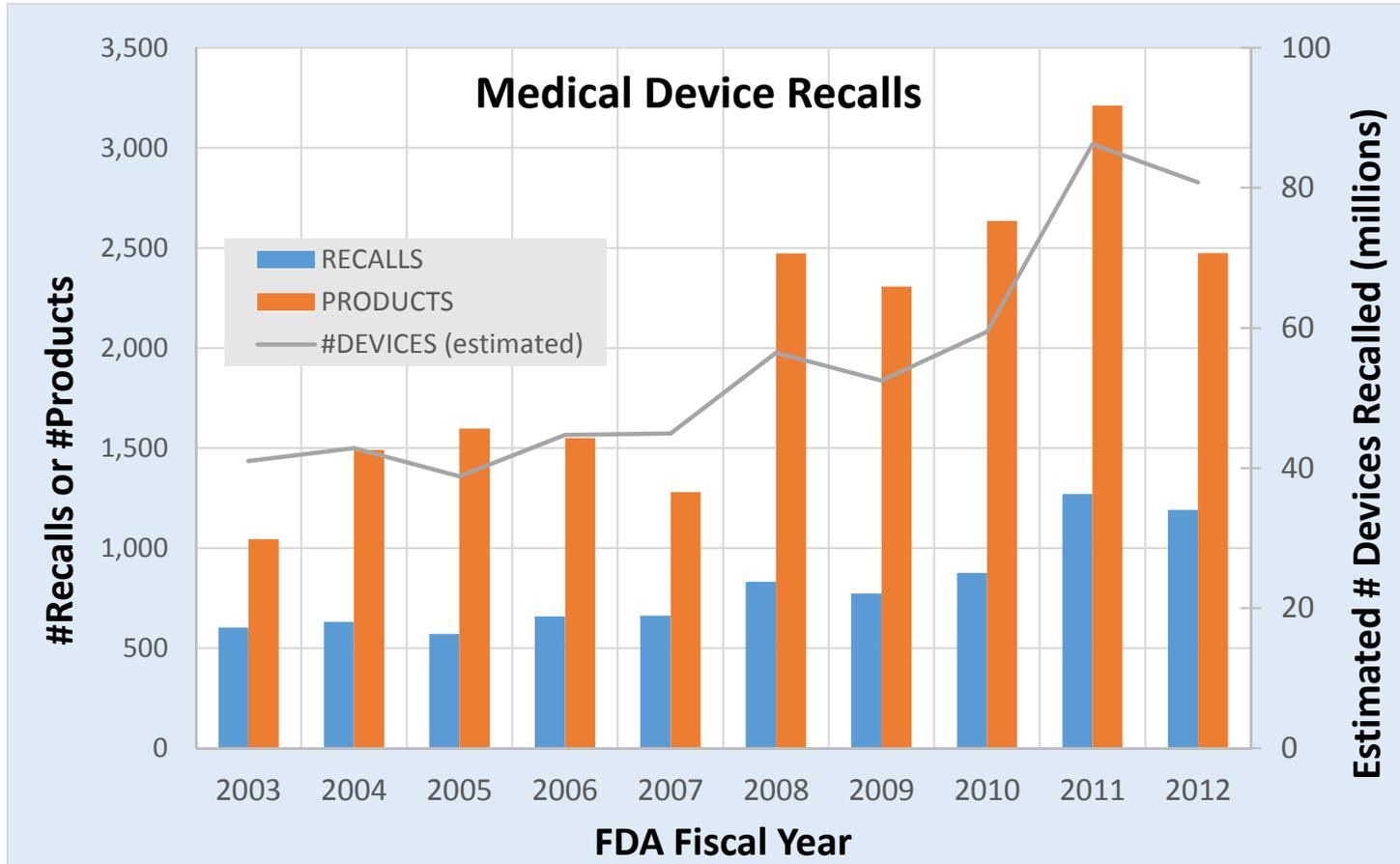
Data Type	YEAR										Decade Total	%
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013		
# incidents reports received	31	28	47	46	48	49	62	88	58	61	518	NA
# incidents investigated	28	26	39	36	41	48	61	84	53	60	476	91.9%
# investigated incidents with harm, including deaths (to patient or user)	12	11	16	21	11	21	23	38	17	27	197	41.4%
# investigated incidents with deaths	6	5	4	8	7	9	9	12	7	7	74	15.5%
# investigated incidents with deaths but no equipment or accessory failures	5	4	2	4	4	7	9	8	3	5	51	10.7%
# investigated incidents traced to equipment or accessory failures	14	8	14	19	19	24	22	31	21	30	202	42.4%
# investigated incidents potentially related to maintenance omission	1	0	0	1	0	2	0	0	1	1	6	1.3%
# equipment managed	694,148	827,503	944,449	942,006	920,109	895,064	905,747	1,195,054	1,176,401	1,182,936	9,683,417	
# SM performed	555,318	662,002	755,559	753,605	744,209	726,933	768,669	935,020	885,629	905,955	7,692,900	
# repairs performed	277,659	331,001	377,780	376,802	358,546	359,177	364,629	455,046	474,211	473,016	3,847,868	

Conclusion: 0.6/y caused by maintenance omission

2) What evidence exists regarding actual problems? (cont.)

- ▶ Senate committee reported “at least 250 patients who underwent procedures involving duodenoscopes were infected with antibiotic-resistant bacteria between 2012 and the spring of 2015.” (AAMI News, March 2016)
 - ▶ FDA issued a document entitled “**Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning**” (2/19/2015, updated 3/4/2015)
- ▶ **QUESTIONS FOR REFLECTION & FURTHER STUDIES:**
 - ▶ **Do you have anecdotal cases or statistical analyses to share?**
 - ▶ Are there other evidence (from OEMs, safety organizations, etc.) that you are aware of?
 - ▶ **How maintenance incidents compare to those caused by poor human-factor engineering (HFE)/use errors in your organization?**
 - ▶ **How maintenance incidents compare to OEM recalls?**

For Example: Device Recalls



Sources: FDA 2014, GAO 2011

3) What are the potential risks (patients/users) and failure modes (devices)?

- ▶ Risk = probability & severity (ISO 14971)
 - ▶ Severity = **#patients potential affected** & degree of hazard on each individual
 - ▶ Probability = $\sum P_j$ where P_j represents the probabilities of **independent failure causes**, which in turn is composed of **failure probabilities of multiple activities** (i.e., $P_j = \prod P_i$)
- ▶ In essence, actions should
 - ▶ Focus on highest severity cases, i.e., **highest #patients subject to serious injuries and/or deaths**
 - ▶ Focus on highest P_i , i.e., **highest organizational failures (latent conditions)** and less on individuals (unsafe acts)

3) What are the potential risks (patients/users) and failure modes (devices)?

- ▶ Unfortunately, **software** makes detailed failure mode & effects analysis very difficult if not impossible
- ▶ “Black-box” failure modes
 - ▶ **Evident failures**: known to users/patients (e.g., alarms)
 - ▶ **Safe failures**: default to safe mode (e.g., ventilator in “safety valve open” mode)
 - ▶ **Potential failures**: failure in progress and detectable through software or safety & performance inspection
 - ▶ **Hidden failures**: unknown to users/patients (out of calibration without any indication)

4) Are the risks different depending on who performs the previously mentioned activities?

- ▶ Aside from the distinction between individuals (unsafe acts) and organizations (latent conditions), risks are **not** dependent on
 - ▶ Type of organization (OEM, third-party, profit nature, etc.)
 - ▶ Size or total revenue
 - ▶ Geographic location
 - ▶ Longevity
- ▶ IDEALLY: **ethical behavior & culture** (and selfish interest: **we all are going to be patients**)
- ▶ PRACTICALLY, some **deterrents** may be necessary when risk severity (scope) and probability are high.

Examples of Deterrents

(for HC organizations & their vendors)

- ▶ For healthcare providers accredited for Medicare & Medicaid: CMS S&C14-07 (2013) and its accreditation organizations' (TJC, DNV, etc.) standards, including but not limited to:
 - ▶ Adhere to OEM maintenance recommendations on lasers, imaging & "new" equipment
 - ▶ Evaluate safety & effectiveness of AEM
 - ▶ Safety & Performance Inspections after "major" service
 - ▶ Sterilization process recordkeeping
- ▶ State licensing regulations, typically NFPA 99
- ▶ FDA regulations: recalls, MedWatch, (X-ray) **certified component**, **adulteration**, etc.
- ▶ **Malpractice liability insurance and lawsuits**

5) Are these activities more difficult or riskier to perform on certain devices versus others?

- ▶ **Software**-driven devices are more challenging than those without it
- ▶ **Networked devices** are more challenging than stand-alone devices
- ▶ **Integrated systems** of devices are more challenging than stand-alone devices

6) What information do third-party entities need?

- ▶ Clear and concise device safety & performance specifications including how to verify them without proprietary tools or software (i.e., **safety & performance inspection instructions**).
- ▶ User (operator) maintenance and pre-use checks
- ▶ **Validated** service instructions with principle of operation, cleaning & decontamination procedure, preventive and corrective maintenance procedures, calibration, parts lists and diagrams, and cautions.
- ▶ Precedent: service information for lasers (21 CFR 1040(h)(2)(ii))

How servicers have dealt with the lack of service information so far?

- ▶ Adherence to **OEM recommendations** is mandated by CMS through its accreditation organizations, unless the healthcare organization is adopting an Alternative Equipment Management program (except lasers, imaging and “new” equipment).
- ▶ When OEMs (only some) refuse to provide those recommendations or software keys, servicers rely on generic procedures issued by ASHE, ECRI Institute, and their own experience
- ▶ To ensure safety & performance, **a Safety & Performance Inspection (SPI) is performed before first use and after each service to verify original specifications** (required by CMS).
- ▶ **Ultimately, the extremely low rate of maintenance-omission related patient injuries and deaths (> 6.5 Sigma) validates this approach.**
- ▶ Nonetheless, this approach is far from ideal and is becoming increasingly more challenging due to the progressive incorporation of software in medical devices. **Without collaboration of all stakeholders, safety risks are inevitable.**

7) What **additional** challenges do stakeholders encounter with devices that result from these activities? (some possible starting points)

- ▶ Challenges already mentioned by FDA in RfC
 - ▶ Ineffective recalls
 - ▶ Disabled device safety features
 - ▶ Improper or unexpected device operation
 - ▶ Service information (in Question #6)
- ▶ OEMs
 - ▶ Lack of information about user qualifications and training
 - ▶ Lack of information about alternative parts & services used
- ▶ Healthcare Organizations
 - ▶ Lack of information about R4S, including OEM, staff qualifications and training
 - ▶ OEMs cannot cover extensive territory in timely manner
 - ▶ Cost of OEM services, training, parts, etc. often inaccessible
 - ▶ Lack of support for orphan (“obsolete”) products from OEMs
- ▶ Third-Party Servicers
 - ▶ Access to cost-effective parts and training from OEMs
 - ▶ Cost pressure from device owners => alternative sources of parts, including used
- ▶ Alternate Sources of (New & Used) Parts
 - ▶ Why original sources to OEM are not deemed acceptable?
 - ▶ How to test parts for safety and performance?

Potential Impacts of Regulating R⁴S

Refurbish + Recondition + Remarket + Repair + Service = R⁴S

- ▶ **DISCLAIMER:** The potential effects presented below are possibilities that have not been verified and the presenters are, therefore, not responsible for possible mistakes, misunderstandings, or negative consequences to those who accept these potential effects. In addition, these potential effects are not intended to disparage any person, company, or organization. Comments and corrections are always welcome.
- ▶ **EXCLUSION:** Remanufacturers (those that modify device specifications) are already and should remain regulated as a manufacturer through QS.
- ▶ **POSITIVE**
 - ▶ Higher service quality => safer devices
 - ▶ Higher quality of used equipment, both within USA and for export
- ▶ **NEUTRAL**
 - ▶ **Patient safety** (due to lack of statistical evidence of problems)

Potential Impacts of Regulating R⁴S (cont.)

Refurbish + Recondition + Remarket + Repair + Service = R⁴S

▶ NEGATIVE

- ▶ Excessive broad scope (including clinical, lab, EMT staff, etc.) => unnecessary burden with **risks of delayed or denial of patient care**
- ▶ Service delay due to lack of local OEM support => **device shortage & reduction of capacity for patient care & possible additional capital investment**
- ▶ Reduced competition => **higher costs** and **shortage & reduction of capacity for patient care**
- ▶ Reduced sources for replacement parts, accessories, and batteries (only new, “genuine” OEM parts) => **higher costs** and **shortage & reduction of capacity for patient care**

Potential Impacts of Regulating R⁴S (cont.)

Refurbish + Recondition + Remarket + Repair + Service = R⁴S

▶ NEGATIVE (cont.)

- ▶ Required training and certification of service personnel (may even include clinical users, lab personnel, EMT staff, etc.) => **higher costs** & higher turnaround time, thus **reduced availability of devices and increased safety risks to patients**
- ▶ More attention on service (scheduled maintenance, documentation, etc.) => less time and resources for equipment management (planning, acquisition, user training, alarm mgmt, device integration, etc.) thus **reducing patient safety & reduced care capacity**
- ▶ Stricter requirements on used equipment => reduced transfer, sale & donation of equipment, thus **higher costs** & **reduced care capacity**
- ▶ Submission of service documentation to OEM (and/or government) => **increased liability exposure** if documentation has deficiencies & risks of HIPAA violations
- ▶ **BOTTOM LINE: reduce care capacity due to reduced device availability => increase patient safety risks**

Potential Impacts of QS/cGMP Compliance

- ▶ **For Third-Parties (& their vendors)**
 - ▶ Annual registration fees (\$3,845 for 2016)
 - ▶ Potential audits (already happening to blood banks) leading to fines, recalls and closures with negative publicity
 - ▶ Software validation (21 CFR Part 11) for CMMS (>\$100k for new software & >\$10k for annual update)
 - ▶ Complaint management & recordkeeping, eMDR reporting (in addition to MedWatch for healthcare organizations)
 - ▶ Metrology (calibration of test & measurement equipment) (>\$5k/year)
 - ▶ Staff competency & training (not only for service but also for QS)
 - ▶ Service documentation (the “**exception reporting**” allowed by NFPA 99 is not allowed by QS) => additional FTEs needed
 - ▶ Process validation (especially critical for endoscope processing) => **risks of delayed or denial of care due to capacity reduction**

Potential Impacts of QS/cGMP Compliance (cont.)

▶ For OEMs

- ▶ Increase staffing for field service
- ▶ Establish additional service depots
- ▶ **Validate maintenance recommendations and service documents**
- ▶ Disclose procedures for reconditioning/refurbishing
- ▶ Assume responsibility for “out of support” devices
- ▶ Distinguish new parts from repaired exchanged parts
- ▶ Train and certify third-parties and alternate part sources
- ▶ Audit third-parties and alternate part sources trained and certified by them
- ▶ **Collect and review of all service records provided by third-parties for eMDR**
- ▶ **Share liability with the third-parties and alternate part sources trained and certified by them**

Potential Financial Impact

(for HC organizations & their multi-service vendors)

▶ Estimated cost increase for a 400-bed hospital

- ▶ Without including endoscope processing, “genuine” supplies, FDA registration, software validation & QMS implementation & upkeep
- ▶ Increases mostly due to “genuine” parts & supplies, training & certification, higher service prices, etc.

Service Cost Component	CURRENT		IF REGULATED	
	% of Total	value	% increase	value
labor	15%	\$600,000	0%	\$600,000
parts	10%	\$400,000	200%	\$1,200,000
svc contracts	40%	\$1,600,000	35%	\$2,160,000
training & certification	1.5%	\$60,000	400%	\$300,000
3rd party repairs	10%	\$400,000	-100%	\$0
OEM repairs	10%	\$400,000	200%	\$1,200,000
miscellaneous	14%	\$540,000	0%	\$540,000
TOTAL		\$4,000,000		\$6,000,000
Estimated Increase			50%	\$2,000,000

Also device shortage & reduction of capacity for patient care

Suggested Actions

- ▶ Search and analyze **your own service and incident data** for root causes and origin (OEM, hospital, and 3rd-party) and submit them to your senior executives and FDA
- ▶ Inform your **senior executives** about possible impacts & suggest them to
 - ▶ Contact AHA, AMA, Nursing Associations, etc. for their awareness and response
 - ▶ Contact their congressional liaisons for extending the comment period in order to **gather & analyze more data**
- ▶ Alert your **Central/Sterile Processing** about possible impacts on processing of endoscopes & surgical instruments and **Material Mgmt/Supply Chain** about possible challenges in purchasing accessories & consumable
- ▶ Discuss with 3rd-party parts, service, and training providers **that you depend on for device support**

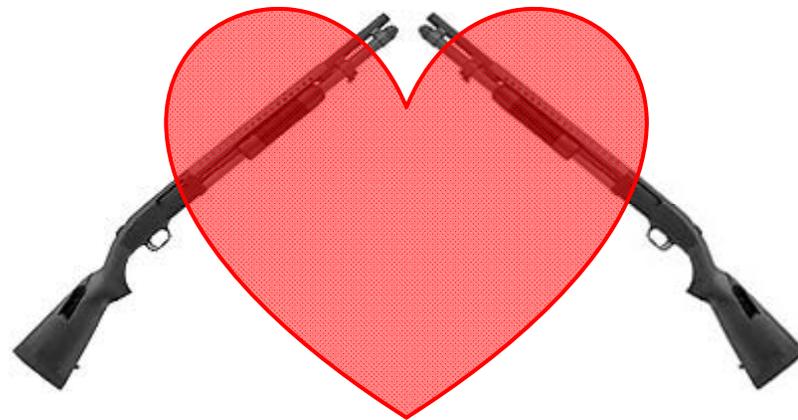
Suggested **Actions** (cont.)

- ▶ Discuss with your colleagues from your state and regional professional associations
- ▶ Prepare your individual or department comments, and assist your organization in providing the organizational response **with emphasis on objective evidence**
- ▶ Above all, brainstorm on

How can we collaborate with other stakeholders to make devices safer & continue to be effective?

An Example of Disruptive Idea

- ▶ Lock up leaders of all stakeholder segments, **with the FDA Commissioner as the facilitator**, on the Alcatraz island and feed them only bread and water until they come up with a consensual, win-win solution for the post-market support of medical devices.
- ▶ **Hope you have better ideas!**



THANK YOU!

- ▶ Please contact us if you have any questions, comments or suggestions
 - ▶ Binseng Wang, binseng@alum.mit.edu
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- ▶ Corrections and additional data are always welcome.

Questions and Discussion

