Pre-Competitive Collaborations to Advance Regulatory Science

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Linda Ricci, MME, MPH

Deputy Office Director

Office of Strategic Priorities and Technology Innovation (OST)

Center for Devices and Radiological Health (CDRH)

Food and Drug Administration (FDA)

Silver Spring, MD

Center for Devices and Radiological Health

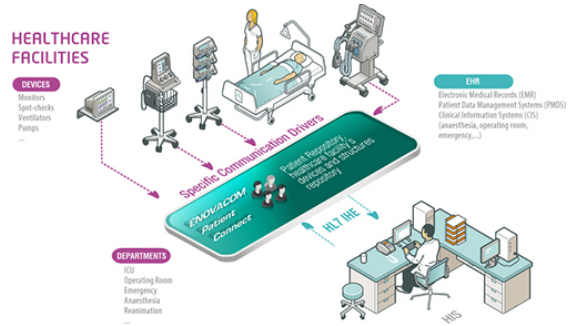
- **Vision**:
  - Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.
  - The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
  - U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.
  - Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

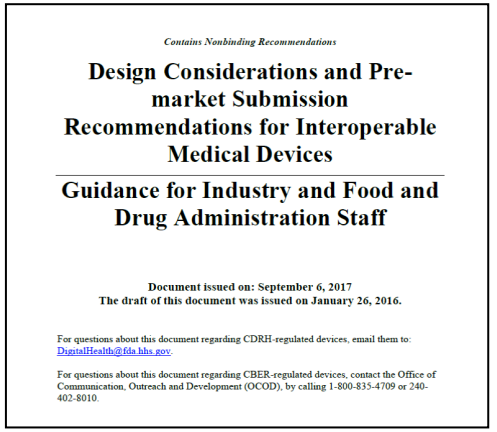
Ebola Response 2014

[Ebola Response – MD PnP (harvard.edu)]

Interoperability

- **FDA Workshop 2010**
  - The FDA (CDRH) Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness
- **Standards 2013**
  - Official recognitions
- **FDA Guidance 2017**
  - “Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices”





Contains Nonbinding Recommendations

Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

Guidance for Industry and Food and Drug Administration Staff

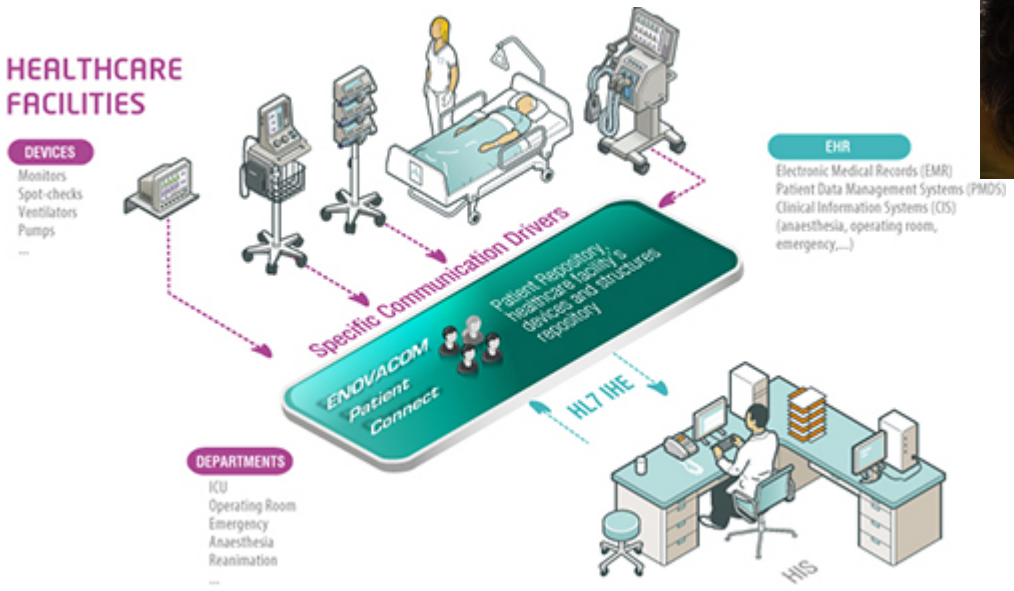
Document issued on: September 6, 2017
The draft of this document was issued on January 26, 2016.

For questions about this document regarding CDRH-regulated devices, email them to: DigitalHealth@fda.hhs.gov.

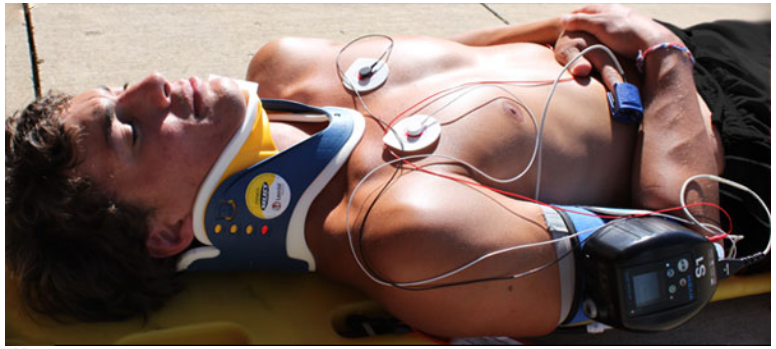
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010.

Balancing Innovation with Security

Telemedicine



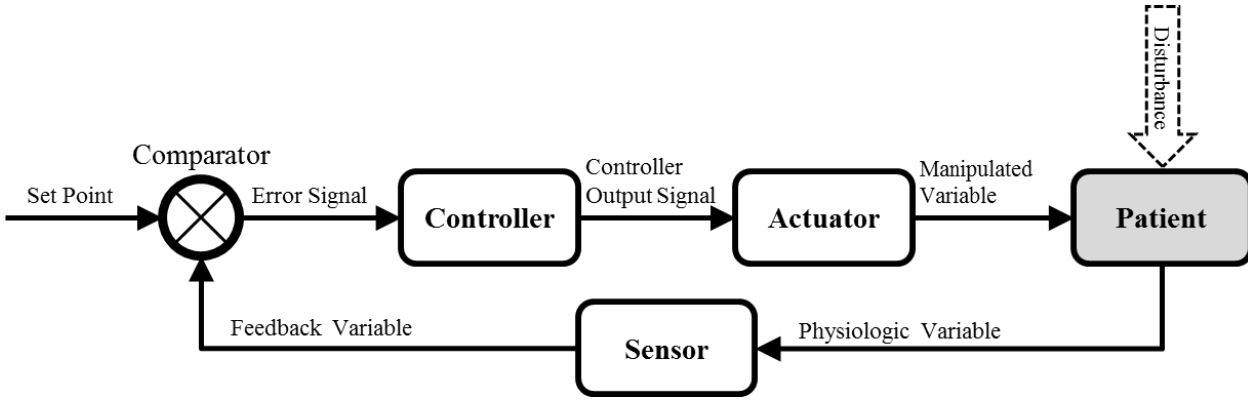
Interoperability



Wireless Monitoring

Remote Control of Medical Devices

Physiological Closed-loop Controlled Devices



Contains Nonbinding Recommendations

Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology[1]

Guidance for Industry and Food and Drug Administration Staff

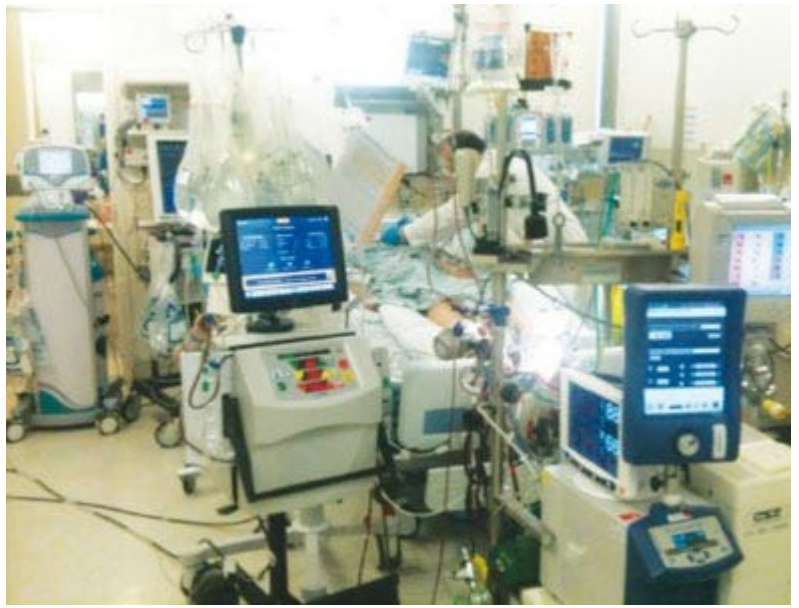
Document issued on September 29, 2023.

The draft of this document was issued on December 23, 2021.

Final Guidance released in 2023 outlines design, non-clinical testing, human factors, and labeling considerations

Next Steps

- Innovate
- Collaborate
- Move the Needle



www.mddionline.com/business/interoperability-in-healthcare-tech-could-save-30-billion

Thank you!