



Developments at the U.S. Food and Drug Administration

Aftin Ross, MSE, PhD
Senior Project Manager/Senior Science Health Advisor
Emergency Preparedness/Operations and Medical Countermeasures
Center for Devices & Radiological Health
US FDA

IVD Round Table: Medical Device Cybersecurity Updates

Aftin Ross, MSE, PhD

**Senior Project Manager/Senior Science Health Advisor
Emergency Preparedness/Operations and Medical Countermeasures
Center for Devices & Radiological Health
US FDA**

FDA Update – *Recent & Hot off The Press*

- Medical Device Safety Action Plan (April 2018)
- Perspective piece in American Heart Association Journal ‘Circulation’ (Sept 2018)
- Report on Advancing Coordinated Vulnerability Disclosure – MDIC publication (Oct 2018)
- FDA Commissioner’s Statement (Oct 2018):
 - Strong commitment to efforts that bolster medical device cybersecurity
 - Regional Incident Preparedness & Response Playbook – MITRE publication (Oct 2018)
 - New FDA Draft Premarket Cybersecurity Guidance & Announcement of FDA convened Public Workshop (Oct 2018)
 - Execution of MOA with Department of Homeland Security (Oct 2018)
 - Execution of 3-way MOUs with H-ISAC for 2 newly stood up ISAOs for medical device vulnerability reporting (Oct 2018):
 - MedISAO
 - Sensato

FDA Update - *Forward Looking* FY '19

- FDA Commissioner's Statement:
 - FY 19 budget proposal includes Digital Health Center of Excellence
- Complete CVSS clinical rubric & submit for MDDT qualification (MITRE-led WG)
- Further enhance public-private partnership collaborations to collectively address Imperative 2 of 2017 Task Force Report:
 - HSCC Task Group 1B *soon to be released* Joint Security Plan
 - MDIC Webinar on Advancing Coordinated Disclosure; future projects TBA
 - CYMSAB Pilot currently under development (with MITRE support)
 - Additional ISAOs in formation for device vulnerability info-sharing
 - Dedicated effort on defining and operationalizing Software Bill of Materials

FDA Update - *Forward Looking* FY '19

- International Medical Device Regulators Forum (IMDRF) new medical device cybersecurity work item:
 - FDA and Health Canada co-leads
- Expand x-stakeholder participation in DefCon Biohacking Village Device Hacking Lab, with the following goals:
 - Increase medical device manufacturer (MDM) presence
 - Introduce to clinical community
 - Engage HDOs
- Leverage cross-agency / multi-stakeholder collaborative efforts:
 - NTIA (Dept of Commerce) Multi-stakeholder engagement on software component transparency includes representation on WGs from: HDOs, MDMs, device trade organizations and FDA
 - NCCoE (NIST/Dept of Commerce) working with industry to develop use cases for medical device security

Medical device cybersecurity is a shared responsibility
Your input is important to us!

FDA contacts:

Suzanne.Schwartz@fda.hhs.gov

Seth.Carmody@fda.hhs.gov

Aftin.Ross@fda.hhs.gov

Or email the team:

CyberMed@fda.hhs.gov

<https://www.fda.gov/medicaldevices/digitalhealth/ucm373213.htm>