Welcome to today's
FDA/CDRH Webinar

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POSTMARKET MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES – FINAL GUIDANCE

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January 12, 2017 CDRH Webinar

Bottom Line Up Front

- Implement a proactive, comprehensive risk management program
  - Apply the National Institute of Standards and Technology (NIST) Framework to Strengthen Critical Infrastructure Cybersecurity
  - Establish and communicate processes for vulnerability intake and handling
  - Adopt a coordinated disclosure policy and practice
  - Deploy mitigations that address cybersecurity risk early and prior to exploitation
- Engage in collaborative information sharing for cyber vulnerabilities and threats

Agenda

- Background
- Total Product Life Cycle (TPLC) Framework
  - Premarket & Postmarket Cybersecurity Approach
- What's Changed
- Key Terms
- Cybersecurity Risk Assessment
- Information Sharing and Analysis Organization (ISAO)
- Controlled and Uncontrolled Vulnerabilities + Examples
- Information Sharing Example
- Key Messages

Framing The Issue: Environment

- The health care and public health (HPH) critical infrastructure sector represents a significantly large attack surface for national security today
  - Intrusions and breaches occur through weaknesses in the system architecture
- Connected medical devices, like all other computer systems, incorporate software that are vulnerable to threats
- We are aware of cybersecurity vulnerabilities and incidents that could directly impact medical devices or hospital network operations
- When medical device vulnerabilities are not addressed and remediated, they can serve as access points for entry into hospital/health care facility networks
  - May lead to compromise of data confidentiality, integrity, and availability

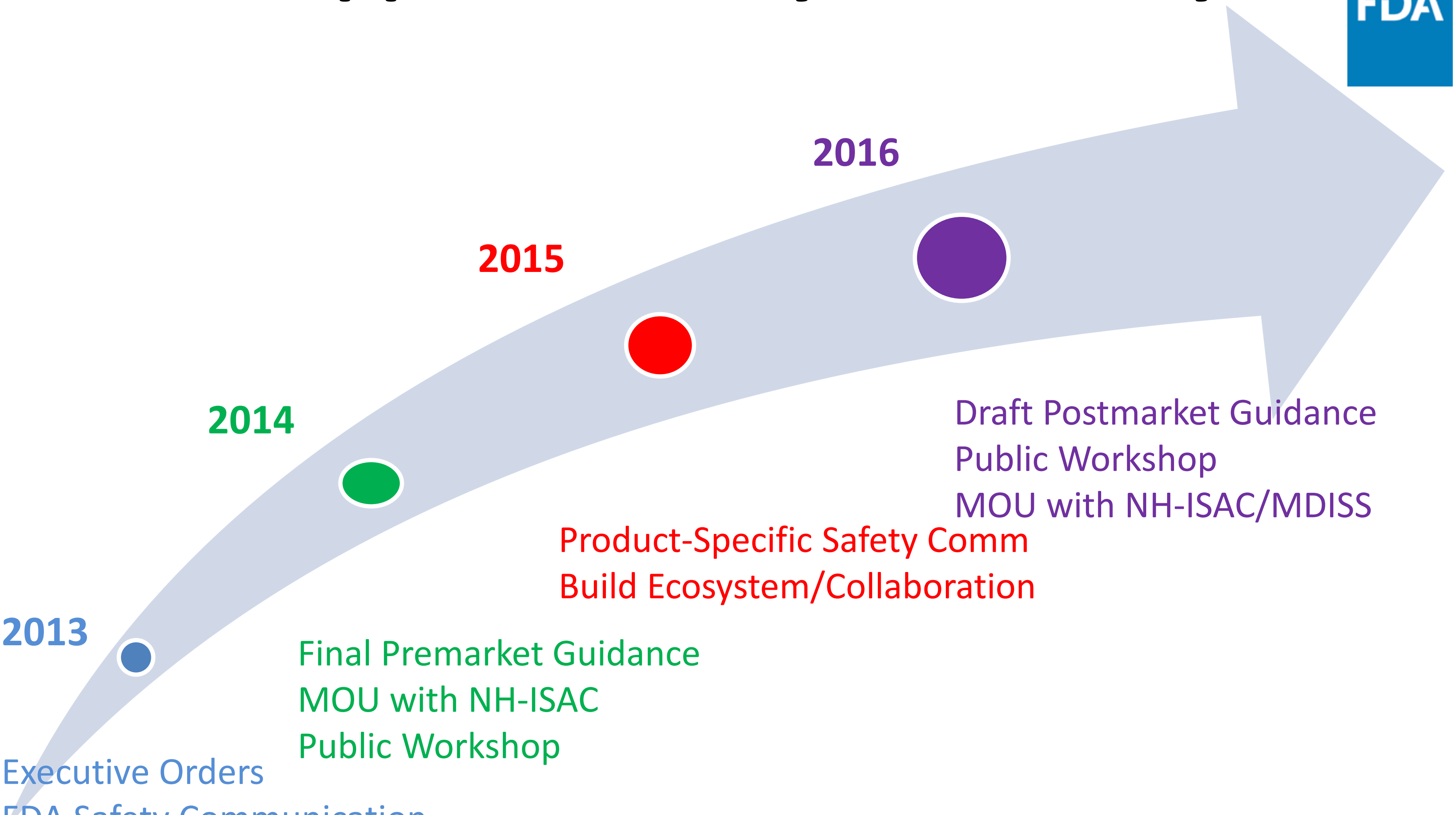
Executive Orders (EO), Presidential Policy Directives (PPD), and NIST Framework to Strengthen Critical Infrastructure Cybersecurity

- EO 13636 (Feb 2013)

"We can achieve these goals through a partnership with the owners and operators of critical infrastructure to improve cybersecurity information sharing and collaboratively develop and implement risk-based standards."

- PPD 21 (Feb 2013)
- NIST Framework to Strengthen Critical Infrastructure Cybersecurity (Feb 2014)
- EO 13691 (Feb 2015) – establishment of Information Sharing and Analysis Organizations (ISAO)

FDA’s Approach to Cybersecurity



2013

Executive Orders
FDA Safety Communication
Draft Premarket Guidance
Begin Coordination with DHS
Recognize Standards
Establish Incident Response Team

2014

Final Premarket Guidance
MOU with NH-ISAC
Public Workshop

2015

Product-Specific Safety Comm
Build Ecosystem/Collaboration

2016

Draft Postmarket Guidance
Public Workshop
MOU with NH-ISAC/MDISS

Premarket Cybersecurity Guidance

- Draft June 2013
- Final October 2014
- Key Principles:
  - #1 Shared responsibility between stakeholders, including health care facilities, patients, providers, and manufacturers of medical devices
  - #2 Address cybersecurity during the design and development of the medical device
  - #3 Establish design inputs for device related to cybersecurity, and establish a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g)

Key Principles of FDA Postmarket Management of Cybersecurity in Medical Devices

- Use a risk-based framework to assure risks to public health are addressed in a continual and timely fashion
- Articulate manufacturer responsibilities by leveraging existing Quality System Regulation and postmarket authorities
- Foster a collaborative and coordinated approach to information sharing and risk assessment
- Align with Presidential EOs and NIST Framework
- Incentivize the “right” behavior

What's Changed From Draft to Final Guidance

- 30 day remediation timeframe has been expanded to include a 60 day tier
- In alignment with current FDA-recognized standards, essential clinical performance is now safety and essential performance scoped to patient harm
- With respect to ISAOs, we clarified the definition of active participation by providing specific criteria
- The scope has been clarified with respect to privacy and confidentiality harms

Cybersecurity – Assessing Risk

Assessment of impact of vulnerability on safety and essential performance of the medical device based on:

- Severity of Patient Harm (if the vulnerability were to be exploited)
- Exploitability

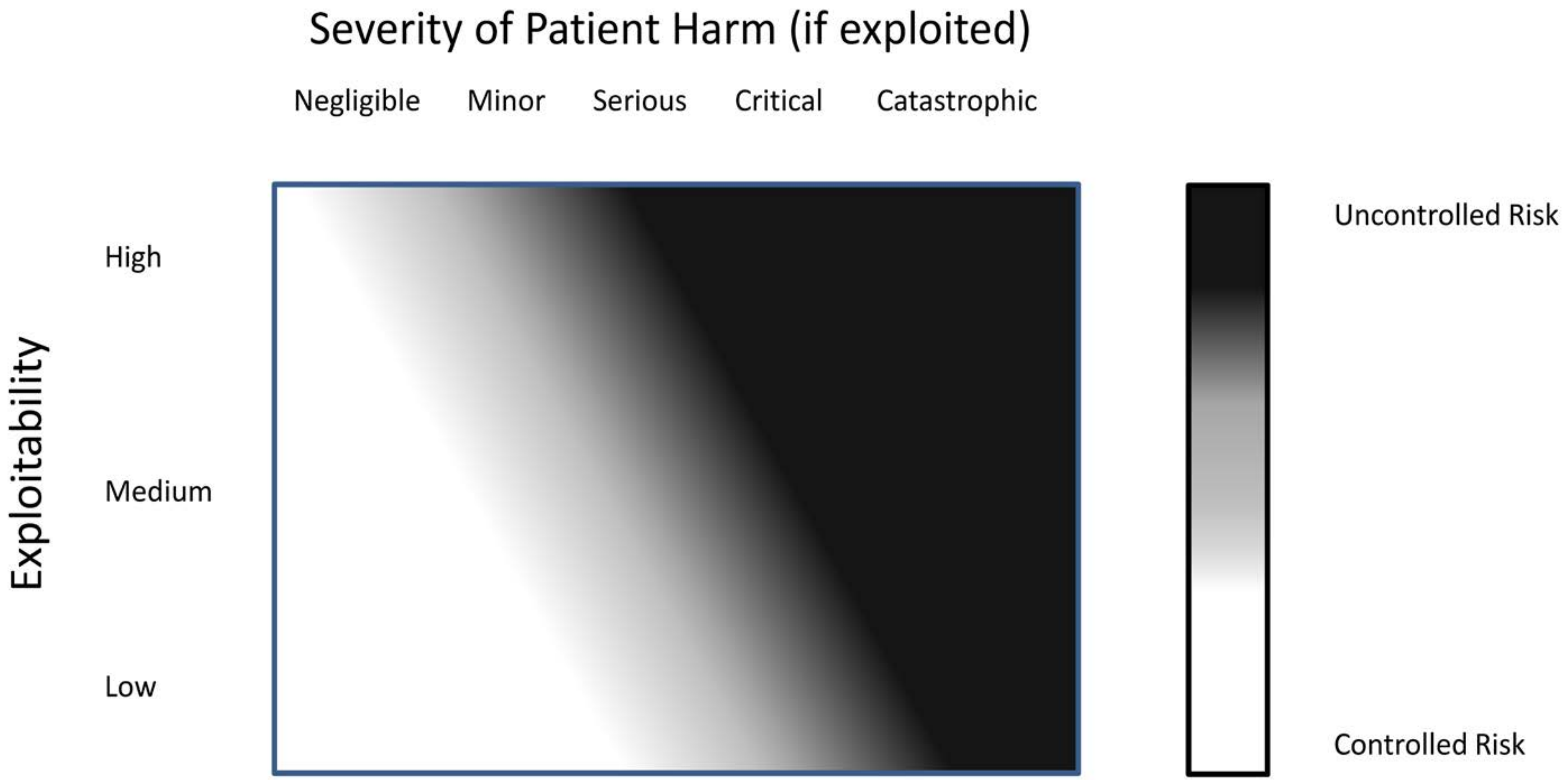
Key Terms: Safety and Essential Performance

- Derived from American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) ES60601-1:Medical electrical equipment— Part 1: General requirements for basic safety and essential performance
- Functions of a device which must remain operational in order to fulfill the intended use and that can be disrupted by exploit

Key Term: Patient Harm

- Derived from ANSI/AAMI/ISO 14971: Medical Devices – Application of Risk Management to Medical Devices
- Limited scope to physical harm to patients
  - Changes to devices to address uncontrolled risk of patient harm are called remediations
- Changes to devices to address controlled risk of patient harm and/or other harms would be categorized as cybersecurity routine updates and patches

Postmarket Cybersecurity Risk Assessment



Assessing Exploitability with Common Vulnerability Scoring System (CVSS)

- **Establish a repeatable process by leveraging existing frameworks (e.g. CVSS)**

Base Scoring (risk factors of the vulnerability)
Attack Vector (physical, local, adjacent, network)
Attack Complexity (high, low)
Privileges Required (none, low, high)
User Interaction (none, required)
Scope (changed, unchanged)

Confidentiality Impact (high, low, none)
Integrity Impact (none, low, high)
Availability Impact (high, low, none)

Temporal Scoring (risk factors that change over time)
Exploit Code Maturity (high, functional, proof-of-concept, unproven)
Remediation Level (unavailable, work-around, temporary fix, official fix, not defined)
Report Confidence (confirmed, reasonable, unknown, not defined)

CVSS – Common Vulnerability Scoring System https://www.first.org/cvss

Assessing Severity

Common Term	Possible Description
Negligible	Inconvenience or temporary discomfort
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Serious	Results in injury or impairment requiring professional medical intervention
Critical	Results in permanent impairment or life-threatening injury
Catastrophic	Results in patient death

ANSI/AAMI/ISO 14971: 2007/(R)2010: Medical Devices – 441Application of Risk Management to Medical Devices:

Information Sharing and Analysis Organizations (ISAO) – What are they?

The ISAO best practice models are intended to be:

Inclusive - groups from any and all sectors, both non-profit and for-profit, expert or novice, should be able to participate in an ISAO;

Actionable - groups will receive useful and practical cybersecurity risk, threat indicator, and incident information via automated, real-time mechanisms if they choose to participate in an ISAO;

Transparent - groups interested in an ISAO model will have adequate understanding of how that model operates and if it meets their needs; and

Trusted - participants in an ISAO can request that their information be treated as Protected Critical Infrastructure Information. Such information is shielded from any release otherwise required by the Freedom of Information Act or State Sunshine Laws and is exempt from regulatory use and civil litigation.

An example of an ISAO is the National Health Information Sharing & Analysis Center (NH-ISAC)

DHS: http://www.dhs.gov/isao

NH-ISAC: https://nhisac.org/announcements/nh-isac-and-mdiss-partner-to-form-medical-device-security-information-sharing-initiative/

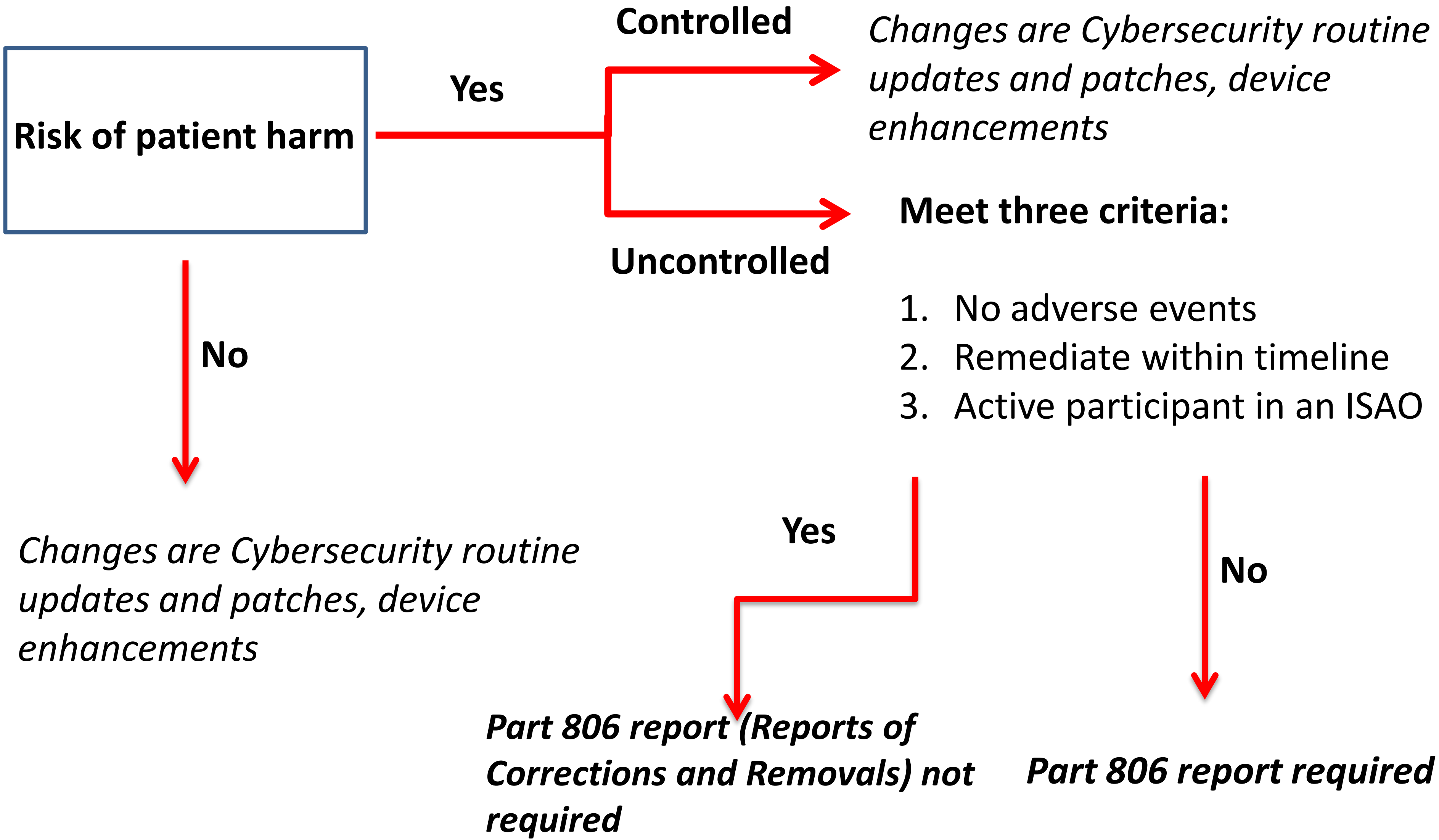
Criteria for Defining Active Participation by a Manufacturer in an ISAO

Active participation by a manufacturer in an ISAO can assist the company, the medical device community and the HPH Sector by proactively addressing cybersecurity vulnerabilities and minimizing exploits through the timely deployment of risk control measures including communication and coordination with patients and users.

FDA will consider a manufacturer to be an active participant in an ISAO if:

- The manufacturer is a member of an ISAO that shares vulnerabilities and threats that impact medical devices;
- The ISAO has documented policies pertaining to participant agreements, business processes, operating procedures, and privacy protections;
- The manufacturer shares vulnerability information with the ISAO, including any customer communications pertaining to cybersecurity vulnerabilities;
- The manufacturer has documented processes for assessing and responding to vulnerability information, threat intelligence, medical device risk assessments, countermeasure solutions, cyber incident response approaches, and best practices received from the ISAO that impacts their medical device product portfolio.

Changes to a Device for Controlled vs. Uncontrolled Risk



Risk of patient harm

Yes

Controlled

Changes are Cybersecurity routine updates and patches, device enhancements

Uncontrolled

Meet three criteria:

1. No adverse events
2. Remediate within timeline
3. Active participant in an ISAO

No

Changes are Cybersecurity routine updates and patches, device enhancements

Yes

Part 806 report (Reports of Corrections and Removals) not required

No

Part 806 report required

[Distinguishing Medical Device Recalls from Medical Device Enhancements]()

ISAO (Information Sharing and Analysis Organization)

Controlled Vulnerabilities

“Acceptable Residual Risk”

- Promote good cyber hygiene and reduce cybersecurity risks even when residual risk is acceptable
- Changes to a device solely to strengthen the cybersecurity associated with vulnerability with controlled risk are referred to as cybersecurity routine updates and patches and are typically considered to be device enhancements and are not required to be reported
- Annual reporting requirements for premarket approval (PMA) devices

Uncontrolled Vulnerabilities

“Unacceptable Residual Risk”

Guidance Addresses:

- Reporting Requirements
- Time Frame for Mitigating Risks
- Public Disclosure
- Information Sharing and Stakeholder Collaboration

Uncontrolled Vulnerabilities Approach

- Manufacturers are expected to report these vulnerabilities to the FDA according to 21 CFR 806 (Reports of Corrections and Removals)
- FDA does not intend to enforce reporting requirements under CFR 806 if all of the following circumstances are met:
  - No known serious adverse events or deaths associated with the vulnerability
  - Remediate within a tiered 30 and 60 day timeline
  - The manufacturer actively participates as a member of an ISAO that shares vulnerabilities and threats that impact medical devices, such as NH-ISAC (see section IX) and provides the ISAO with any customer communications upon notification of its customers.
- The manufacturer should evaluate the device changes to assess the need to submit a premarket submission (e.g., PMA, 510(k), etc.) to the FDA
- Remediation of devices with annual reporting requirements (e.g., class III devices) should be included in the PMA annual report, as indicated for controlled vulnerabilities

Guidance Example: Controlled Risk

- Vulnerability Identification: a researcher publicly discloses exploit code for a four year old vulnerability in commercial off-the-shelf database software.
  - The vulnerable version of the software is in a percentage of the manufacturer's installed base and in two separate product lines including a multi-analyte chemistry analyzer.
- Vulnerability Assessment and Validation: The manufacturer determines that the vulnerability is the result of a misconfigured database setting and could allow an unauthorized user to view patient health information in the database.
- Vulnerability Impact Analysis: The vulnerability does not permit the unauthorized user the ability to edit/manipulate data in the database.
- Vulnerability Risk Determination (controlled VS uncontrolled): Thus, the manufacturer determines the vulnerability has acceptable and ***controlled*** risk of patient harm.
- Manufacturer's Actions include Communication and Appropriate Mitigation: The manufacturer notifies its customers and the user community of the issue, details the secure configuration setting, and documents the effectiveness of the cybersecurity routine update for the configuration setting.

Guidance Example: Uncontrolled Risk

A vulnerability known to the security community, yet unknown to a medical device manufacturer, is incorporated into a Class II device during development.

- Vulnerability Identification, Assessment and Validation: During postmarket, the manufacturer becomes aware of the vulnerability and determines that the device continues to meet its specifications, and that no device malfunctions or patient injuries have been reported. There is no evidence that the identified vulnerability has been exploited.
- Vulnerability Impact Analysis: However, it was determined that the vulnerability introduced a new failure mode to the device that impacts its essential performance.
- Vulnerability Risk Determination (controlled VS uncontrolled): The manufacturer determines that the device's design controls do not adequately reduce the risk to an acceptable level. Without additional mitigations, the risk of patient harm is ***uncontrolled***.

Guidance Example: Uncontrolled Risk *continued*

- Manufacturer's Actions including Communications and Appropriate Mitigations: manufacturer does not have a fix immediately available to mitigate vulnerability impact on the device's essential performance. Therefore-
  - Within 30 days of learning of the vulnerability the manufacturer notifies its customers, the ISAO, and user community of the cybersecurity risk and instructs them to disconnect the device from the hospital network to prevent unauthorized access to the device. The company's risk assessment concludes that the risk of patient harm is now controlled with this additional mitigation.
  - Disconnection of the device from the network is only a temporizing measure, not a viable long-term solution. Manufacturer distributes a patch within 60 days of learning of the vulnerability.
  - If the firm is an active participating member of an ISAO, FDA does not intend to enforce compliance with the reporting requirement under 21 CFR part 806.

Vulnerability Information Sharing* in Support of FDA Guidance

System Description

- Medical device vulnerability information sharing system
- Based on 21 CFR 806 reporting
- Web-based system available at: MDVIS.NHISAC.ORG
- Current submission of vulnerability information is via secure unloadable PDF file
- Vulnerability information will be shared by manufacturer with MDVIS after it has evaluated the vulnerability
  - *MDVIS may assist in connecting third parties with manufacturers, if needed, to help ensure vulnerabilities are evaluated appropriately before sharing.*
- All vulnerability information shared with MDVIS will be embargoed until coordinated disclosure is executed by manufacturer, ICS-CERT and FDA

*This work is executed under Memorandum of Understanding (MOU) 225-16-024 between FDA, NHISAC and MDISS; Published October 06, 2016

Vulnerability Information Sharing* in Support of FDA Guidance

Key Attributes

- Collaboratively developed service
- Introduces new type of initiative
  - Cybersecurity-related content
  - Reporting guidance
- Familiar process and format for reporting
- Coordinate processes, e.g. ICS-CERT and coordinated disclosure
- Public health best practices
- Service driven
- Scientific foundation
- Safety and privacy impact

NH-ISAC
NATIONAL HEALTH - ISAC

MDISS
MEDICAL DEVICE INNOVATION, SAFETY & SECURITY CONSORTIUM

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Vulnerability Information Sharing* in Support of FDA Guidance

Key Outcomes

- Improve understanding of vulnerabilities in medical devices
- Improve stakeholder community's solution development work
- Harmonize best practices for device security information sharing
- Improve efficiency to market while improving security, safety and privacy profiles for devices and associated networks

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Vulnerability Information Sharing* in Support of FDA Guidance

Learn More

Join us for a Webinar

Tentative Date: January 19th

Overview:
Medical Device Vulnerability
Information Sharing System

Information at either:
NHISAC.ORG
MDISS.ORG

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Key Messages

- Implement a proactive, comprehensive risk management program
  - Apply the NIST Framework to Strengthen Critical Infrastructure Cybersecurity
  - Establish and communicate processes for vulnerability intake and handling
  - Adopt a coordinated disclosure policy and practice
  - Deploy mitigations that address cybersecurity risk early and prior to exploitation
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Questions

For Specific Questions Related to the Cybersecurity Final Guidance: AskMedCyberWorkshop@fda.hhs.gov

For Questions related to the Cybersecurity Webinar: Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:
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Under Heading: Specialty Technical Topics; Sub-heading: IT and Software