

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

**Draft Guidance on Cybersecurity in Medical Devices: Quality System
Considerations and Content of Premarket Submissions**

June 14, 2022

Draft Guidance:

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

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Draft Guidance

- **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**
 - www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions

A Note about Draft Guidance

- You may comment on any guidance at any time
 - see 21 CFR 10.115(g)(5)
- Please submit comments on draft guidance before closure date
 - to ensure that FDA considers your comment on the draft guidance before we work on final guidance
- This is a draft guidance. The recommendations discussed today are proposals and may change based on public comment.

Learning Objectives

- Describe the updates from the 2018 draft
- Describe the general principles proposed in the guidance
- Describe the proposed design and documentation recommendations
- Describe the proposed transparency recommendations

Updates From the 2018 Draft

Guidance Title Change

- Reflects expanded scope of guidance and the increased focus on how cybersecurity fits into Quality System (QS) Regulation
- Provides greater detail from [2014 Final Premarket Guidance](#) on how FDA recommends cybersecurity be incorporated in device design and Total Product Lifecycle (TPLC) maintenance
- Outlines how QS Regulation aligns with the Secure Product Development Framework (SPDF)
- Highlights importance of QS Regulation integration as some medical device manufacturers (MDMs) have not fully incorporated cybersecurity into their quality systems

Content Differences

- **Expanded scope**
 - Provides more detail how cybersecurity aligns with the QS Regulation
 - Recommends assessment of system, not just end device in isolation to ensure all the relevant cybersecurity risks are appropriately addressed by the end-device design
- **Alignment with SPDF**
 - SPDFs exist as best practices within medical device sector and other sectors
- **Removed risk tiers for devices**
 - Based on public comments and to encourage all manufacturers to appropriately consider cybersecurity risks

Content Differences (cont.)

- **Changed Cybersecurity Bill of Materials (CBOM) to Software Bill of Materials (SBOM)**
 - Alignment with industry/sector efforts
 - Alignment with Presidential Executive Order 14028
- **More detailed recommendations for premarket submission documentation**
 - Increase clarity on documentation recommendations to help improve review process
- **Added Investigation Device Exemptions (IDEs) to scope with a subset of documentation recommendations**
 - Both to ensure cybersecurity is designed into the device and ensure patients are informed of cybersecurity risks for the devices

Proposed Scope

- **This guidance document is applicable to devices that contain software (including firmware) or programmable logic, as well as software as a medical device (SaMD).**
 - Devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) whether or not they require a premarket submission.
 - The guidance is not limited to devices that are network-enabled or contain other connected capabilities.

Proposed Scope (cont.)

- **Applicable Submission Types:**
 - Premarket Notification (510(k)) submissions
 - De Novo requests
 - Premarket Approval Applications (PMAs) and PMA supplements
 - Product Development Protocols (PDPs)
 - Investigational Device Exemption (IDE) submissions
 - Humanitarian Device Exemption (HDE) submissions

Proposed General Principles

Proposed General Principles A&B

A. Cybersecurity is Part of Device Safety and the QS Regulation

- Cybersecurity is a part of safety and effectiveness
- Cybersecurity aligns with the QS Regulation
- A SPDF can be used to fulfill aspects of QS Regulation

B. Designing for Security

- “Design in” rather than “bolt on” cybersecurity controls
- Outlines key security objectives medical devices should achieve

Proposed General Principles C&D

C. Transparency

- Importance of end user having cybersecurity information to ensure continued safe use of the device

D. Submission Documentation

- Recommendations complement and are in addition to the [software premarket guidance](#)
- Documentation expected to scale with cybersecurity risk of device

Proposed Design and Documentation Recommendations

Proposed Design Recommendations

- **Security Objectives for Design:**
 - Authenticity, which includes integrity
 - Authorization
 - Availability
 - Confidentiality
 - Secure and timely updateability and patchability

Proposed Design Recommendations

- 8 Security Control Categories to help in meeting the Security Objectives
- Appendix 1 provides specific control recommendations and implementation guidance for consideration to avoid common pitfalls
- Appendices are part of the document recommendations

Proposed Documentation Recommendations

- **Section V. Using an SPDF to Manage Cybersecurity Risks**
 - A. Security Risk Management
 - B. Security Architecture
 - C. Cybersecurity Testing
- **Section VI. Cybersecurity Transparency**
 - A. Labeling Recommendations
 - B. Vulnerability Management Plans

Proposed Security Risk Management

- System-level assessment
- Security risk management distinct from safety risk management but the two processes should feed into and out of one another
- Use of exploitability assessment for security risks
 - Premarket exploitability assessment may differ from postmarket assessments
- Known vulnerabilities should be assessed as reasonably foreseeable
- Risk transfer should only occur if all relevant information is known, assessed, and communicated to users

Proposed Security Risk Management (cont.)

1. Threat Modeling

- Includes full system and lifecycle of the device

2. Third Party Software Components

- SBOM and vulnerability assessment

3. Security Assessment of Unresolved Anomalies

- Anomalies can present a different vector to safety risks through cybersecurity

4. Security Risk Management Documentation

- Security Risk Management Plan and Report

5. TPLC Security Risk Management

- Maintain resources and documentation
- Track and monitor cybersecurity measures and metrics

Proposed Software Bill of Materials (SBOM)

- **Recommended Elements:**
 - A. The asset(s) where the software component resides
 - B. The software component name
 - C. The software component version
 - D. The software component manufacturer
 - E. The software level of support provided through monitoring and maintenance from the software component manufacturer
 - F. The software component's end-of-support date
 - G. Any known vulnerabilities

Proposed SBOM (cont.)

- Industry-accepted formats of SBOMs can be used to provide this information to FDA; however, if any of the [above] elements are not captured in such an SBOM, we recommend that those items also be provided, typically as an addendum, to FDA for the purposes of supporting premarket submission review.
- SBOMs provided to users in labeling can conform with industry-accepted formats

Proposed Architecture Views

- Can be part of Threat Modeling Documentation
- 4 View Categories
 - a) Global System View
 - b) Multi-Patient Harm View
 - c) Updateability/Patchability View
 - d) Security Use Case View(s)
 - Operational states and different clinical use cases

Proposed Architecture Views

- These security architecture views should:
 - Identify security-relevant system elements and their interfaces;
 - Define security context, domains, boundaries, and external interfaces of the system;
 - Align the architecture with (a) the system security objectives and requirements, (b) security design characteristics; and
 - Establish traceability of architecture elements to user and system security requirements.
- Level of recommended detail for the architecture views captured in Appendix 2 including:
 - Call-Flow Diagrams
 - Information Details for an Architecture View

Proposed Testing

- Recommendations on Types of Testing:
 - Security Requirement Testing
 - Threat Mitigation
 - Vulnerability Testing
 - Penetration Testing
- Section also makes recommendations on:
 - Independence and technical expertise of testers
 - Scope of testing (i.e., system-level)
 - Third-Party Testing recommendations
 - Submission documentation

Proposed Transparency: Labeling and Vulnerability Management Recommendations

Proposed Labeling Recommendations

- Largely similar to recommendations provided in 2018 Draft with some changes and reordering
- Can be provided in different locations depending on appropriate users for the information (manual vs. security implementation guide)
- Labeling mitigations and risk transfer items may need to be included as part of Human Factors Testing tasks
- Focus on ensuring users have sufficient information on device to integrate it and have sufficient information to manage security risks and updates

Proposed Vulnerability Management Plans

- Recommendations expand on the plan for providing validated software updates and patches described in the [2014 Premarket Guidance](#)
- Plans should include Coordinated Vulnerability Disclosure process as described in the [2016 Postmarket Guidance](#)
- Also includes items like:
 - Periodic security testing to test identified vulnerability impact
 - Timeline to develop and release patches
 - Patching capability (i.e., rate at which updates can be delivered to devices)

Resources

| Slide Number | Cited Resource | URL |
|--------------|--|--|
| 6, 27 | 2014 Premarket Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices | www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices |
| 13 | Premarket Software Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices | www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices |
| 27 | 2016 Postmarket Guidance: Postmarket Management of Cybersecurity in Medical Devices | www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices |

Submit Comments to Docket by: July 7, 2022

- **Draft Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**
 - Docket: [FDA-2021-D-1158](https://www.fda.gov/oc/foia/FDA-2021-D-1158)
(www.regulations.gov/document/FDA-2021-D-1158-0001)
 - [Guidance](#)

Summary

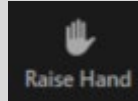
- This draft is more detailed than the 2018 Draft
- The general principles proposed in Section IV outline the core concepts in the guidance
- The proposed design recommendations focus on security objectives and that documentation will scale with cybersecurity risk
- Transparency of device cybersecurity recommendations include proposals for proactive labeling and plans to respond to emerging issues throughout the TPLC



Let's Take Your Questions

- **To Ask a Question:**

1. Please "Raise Your Hand"
2. Moderator will Announce Your Name to Invite You to Ask Your Question
3. Unmute yourself when called



- **When Asking a Question:**

- Ask 1 question only
- Keep question short
- No questions about individual submissions

- **After Question is Answered:**

- Please mute yourself again
- If you have more questions - raise your hand again



Thanks for Joining Today!

- Presentation and Transcript will be available at CDRH Learn


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- Additional questions about today's presentation

- Email: DICE@fda.hhs.gov

- Upcoming Webinars

- www.fda.gov/CDRHWebinar



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| Start Here/The Basics! - (Updated module 5/13/22) <i>MDUFA Small Business Program, Registration and Listing</i> | ▼ |
| How to Study and Market Your Device - (New module 12/23/21) <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i> | ▼ |
| Postmarket Activities - (New modules 9/22/21) <i>Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization</i> | ▼ |
| Unique Device Identification (UDI) System | ▼ |
| Specialty Technical Topics - (New module 3/22/22) | ▼ |
| Radiation-Emitting Products | ▼ |
| 510(k) Third Party Review Program (for Third Party Review Organizations) | ▼ |
| Industry Basics Workshop Series | ▼ |

