

# Postmarket Management of Cybersecurity in Medical Devices

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## Draft Guidance for Industry and Food and Drug Administration Staff

### *DRAFT GUIDANCE*

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For questions regarding this document, contact Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5418, Silver Spring, MD 20993-0002, 301-796-6937. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-8010 or [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov).



**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
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# **Preface**

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# Postmarket Management of Cybersecurity in Medical Devices

## Draft Guidance for Industry and Food and Drug Administration Staff

*This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.*

### I. Introduction

FDA is issuing this guidance to inform industry and FDA staff of the Agency's recommendations for managing postmarket cybersecurity vulnerabilities for marketed medical devices. In addition to the specific recommendations contained in this guidance, manufacturers are encouraged to address cybersecurity throughout the product lifecycle, including during the design, development, production, distribution, deployment and maintenance of the device. A growing number of medical devices are designed to be networked to facilitate patient care. Networked medical devices, like other networked computer systems, incorporate software that may be vulnerable to cybersecurity threats. The exploitation of vulnerabilities may represent a risk to the safety and effectiveness of medical devices and typically requires continual maintenance throughout the product life cycle to assure an adequate degree of protection against such exploits. Proactively addressing cybersecurity risks in medical devices reduces the patient safety impact and the overall risk to public health.

This guidance clarifies FDA's postmarket recommendations and emphasizes that manufacturers should monitor, identify and address cybersecurity vulnerabilities and exploits as part of their postmarket management of medical devices. For the majority of cases, actions taken by manufacturers to address cybersecurity vulnerabilities and exploits are considered "cybersecurity routine updates or patches," for which the FDA does not require advance notification or reporting under 21 CFR part 806. For a small subset of cybersecurity vulnerabilities and exploits that may compromise the essential clinical performance of a device and present a reasonable probability of serious adverse health consequences or death, the FDA would require medical device manufacturers to notify the Agency.<sup>1</sup>

<sup>1</sup> See 21 CFR 806.10.

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37 For the current edition of the FDA-recognized standard(s) referenced in this document, see the  
38 FDA Recognized Consensus Standards Database Web site at  
39 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

40  
41 FDA's guidance documents, including this draft guidance, do not establish legally enforceable  
42 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should  
43 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
44 cited. The use of the word *should* in Agency guidance means that something is suggested or  
45 recommended, but not required.

46

## 47 **II. Background**

48

49 On February 19, 2013, the President issued Executive Order 13636 – Improving Critical  
50 Infrastructure Cybersecurity (EO 13636), which recognized that resilient infrastructure is  
51 essential to preserving national security, economic stability, and public health and safety in the  
52 United States. EO 13636 states that cyber threats to national security are among the most serious,  
53 and that stakeholders must enhance the cybersecurity and resilience of critical infrastructure. This  
54 includes the Healthcare and Public Health Critical Infrastructure Sector (HPH Sector).  
55 Furthermore, Presidential Policy Directive 21 – Critical Infrastructure Security and Resilience  
56 (PPD-21) issued on February 12, 2013 tasks Federal Government entities to strengthen the  
57 security and resilience of critical infrastructure against physical and cyber threats such that these  
58 efforts reduce vulnerabilities, minimize consequences, and identify and disrupt threats. PPD-21  
59 encourages all public and private stakeholders to share responsibility in achieving these outcomes.

60

61 In recognition of the shared responsibility for cybersecurity, the security industry has established  
62 resources including standards, guidelines, best practices and frameworks for stakeholders to adopt  
63 a culture of cybersecurity risk management. Best practices include collaboratively assessing  
64 cybersecurity intelligence information for risks to device functionality and clinical risk. FDA  
65 believes that, in alignment with EO 13636 and PPD-21, public and private stakeholders should  
66 collaborate to leverage available resources and tools to establish a common understanding that  
67 assesses risks for identified vulnerabilities in medical devices among the information technology  
68 community, healthcare delivery organizations (HDOs), the clinical user community, and the  
69 medical device community. These collaborations can lead to the consistent assessment and  
70 mitigation of cybersecurity threats, and their impact on medical device safety and effectiveness.

71

72 Cybersecurity risk management is a shared responsibility among stakeholders including, the  
73 medical device manufacturer, the user, the Information Technology (IT) system integrator, Health  
74 IT developers, and an array of IT vendors that provide products that are not regulated by the FDA.  
75 FDA seeks to encourage collaboration among stakeholders by clarifying, for those stakeholders it  
76 regulates, recommendations associated with mitigating cybersecurity threats to device  
77 functionality and device users.

78

79 As stated in the FDA guidance document titled “Content of Premarket Submissions for  
80 Management of Cybersecurity in Medical Devices,” when manufacturers consider cybersecurity  
81 during the design phases of the medical device lifecycle, the resulting impact is a more proactive

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82 and robust mitigation of cybersecurity risks. Similarly, a proactive and risk based approach to the  
83 postmarket phase for medical devices, through engaging in cybersecurity information sharing and  
84 monitoring, promoting “good cyber hygiene” through routine device cyber maintenance,  
85 assessing postmarket information, employing a risk-based approach to characterizing  
86 vulnerabilities, and timely implementation of necessary actions can further mitigate emerging  
87 cybersecurity risks and reduce the impact to patients.

88  
89 To further aid manufacturers in managing their cybersecurity risk, the Agency encourages the use  
90 and adoption of the voluntary “Framework for Improving Critical Infrastructure Cybersecurity”  
91 that has been developed by the National Institute of Standards and Technology (NIST) with  
92 collective input from other government agencies and the private sector.

93  
94 Critical to the adoption of a proactive, rather than reactive, postmarket cybersecurity approach, is  
95 the sharing of cyber risk information and intelligence within the medical device community. This  
96 information sharing can enhance management of individual cybersecurity vulnerabilities and  
97 provide advance cyber threat information to additional relevant stakeholders to manage and  
98 enhance cybersecurity in the medical device community and HPH Sector.

99 Executive Order 13691 – Promoting Private Sector Cybersecurity Information Sharing (EO  
100 13691), released on February 13, 2015, encourages the development of Information Sharing  
101 Analysis Organizations (ISAOs), to serve as focal points for cybersecurity information sharing  
102 and collaboration within the private sector as well as between the private sector and government.  
103 EO 13691 also mandates that the ISAO “...protects the privacy and civil liberties of individuals,  
104 that preserves business confidentiality, [and] that safeguards the information being shared...”  
105 ISAOs gather and analyze critical infrastructure information in order to better understand  
106 cybersecurity problems and interdependencies, communicate or disclose critical infrastructure  
107 information to help prevent, detect, mitigate, or recover from the effects of cyber threats, or  
108 voluntarily disseminate critical infrastructure information to its members or others involved in the  
109 detection and response to cybersecurity issues.<sup>2</sup>

110 The ISAOs are intended to be: Inclusive (groups from any and all sectors, both non-profit and for-  
111 profit, expert or novice, should be able to participate in an ISAO); Actionable (groups will receive  
112 useful and practical cybersecurity risk, threat indicator, and incident information via automated,  
113 real-time mechanisms if they choose to participate in an ISAO); Transparent (groups interested in  
114 an ISAO model will have adequate understanding of how that model operates and if it meets their  
115 needs); and Trusted (participants in an ISAO can request that their information be treated as  
116 Protected Critical Infrastructure Information. Such information is shielded from any release  
117 otherwise required by the Freedom of Information Act or State Sunshine Laws and is exempt  
118 from regulatory use and civil litigation if the information satisfies the requirements of the Critical  
119 Infrastructure Information Act of 2002 (6 U.S.C. §§ 131 et seq.)).

120 The FDA Center for Devices and Radiological Health has entered into a Memorandum of  
121 Understanding with one such ISAO, the National Health Information Sharing & Analysis Center,

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<sup>2</sup> See Homeland Security Act, 6 U.S.C. § 212 (2002).

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122 (NH-ISAC)<sup>3</sup> in order to assist in the creation of an environment that fosters stakeholder  
123 collaboration and communication, and encourages the sharing of information about cybersecurity  
124 threats and vulnerabilities that may affect the safety, effectiveness, integrity, and security of the  
125 medical devices and the surrounding Health IT infrastructure.

126  
127 The Agency wishes to promote collaboration among the medical device and Health IT community  
128 to develop a shared understanding of the risks posed by cybersecurity vulnerabilities to medical  
129 devices and foster the development of a shared understanding of risk assessment to enable  
130 stakeholders to consistently and efficiently assess patient safety and public health risks associated  
131 with identified cybersecurity vulnerabilities and take timely, appropriate action to mitigate the  
132 risks. This approach will also enable stakeholders to provide timely situational awareness to the  
133 HPH community and take efforts to preemptively address the cybersecurity vulnerability through  
134 appropriate mitigation and/or remediation before it impacts the safety, effectiveness, integrity or  
135 security of medical devices and the Health IT infrastructure.

136  
137 The Agency considers voluntary participation in an ISAO a critical component of a medical  
138 device manufacturer's comprehensive proactive approach to management of postmarket  
139 cybersecurity threats and vulnerabilities and a significant step towards assuring the ongoing safety  
140 and effectiveness of marketed medical devices. For companies that voluntarily participate in such  
141 a program, and follow other recommendations in this guidance, the Agency does not intend to  
142 enforce certain reporting requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act)  
143 (see Section VIII).

144

### **III. Scope**

145  
146 This guidance applies to: 1) medical devices that contain software (including firmware) or  
147 programmable logic, and 2) software that is a medical device. This guidance supplements the  
148 information addressed in the FDA guidance document titled "Cybersecurity for Networked  
149 Medical Devices Containing Off-the-Shelf (OTS) Software." This guidance does not apply to  
150 experimental or investigational medical devices.

151  
152

### **IV. Definitions**

153

154 For the purposes of this guidance, the following definitions are used:

155  
156

#### **A. Compensating Controls**

157

158 A cybersecurity compensating control is a safeguard or countermeasure, external to the device,  
159 employed by a user in lieu of, or in the absence of sufficient controls that were designed in by a  
160 device manufacturer, and that provides supplementary or comparable cyber protection for a  
161

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<sup>3</sup> See Memorandum of Understanding between the National Health Information Sharing & Analysis Center, Inc. (NH-ISAC) and the U.S. Food and Drug Administration Center for Devices and Radiological Health.

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162 medical device.<sup>4</sup> For example, a manufacturer’s assessment of a cybersecurity vulnerability  
163 determines that unauthorized access to a networked medical device will most likely impact the  
164 device’s essential clinical performance. However, the manufacturer determines that the device  
165 can safely and effectively operate without access to the host network, in this case the hospital  
166 network. The manufacturer instructs users to configure the network to remove the ability of  
167 unauthorized/unintended access to the device from the hospital network. This type of counter  
168 measure is an example of a compensating control.  
169

### **B. Controlled Risk**

170  
171  
172 Controlled risk is present when there is sufficiently low (acceptable) residual risk that the device’s  
173 essential clinical performance could be compromised by a cybersecurity vulnerability.  
174

### **C. Cybersecurity Routine Updates and Patches**

175  
176  
177 Cybersecurity “routine updates and patches” are updates or patches to a device to increase device  
178 security and/or remediate vulnerabilities associated with controlled risk and not to reduce a risk to  
179 health or correct a violation of the FD&C Act. They include any regularly scheduled security  
180 updates or patches to a device, including upgrades to the software, firmware, programmable logic,  
181 hardware, or security of a device to increase device security as well as updates or patches to  
182 address vulnerabilities associated with controlled risk performed earlier than their regularly  
183 scheduled deployment cycle even if they are distributed to multiple units. Cybersecurity routine  
184 updates and patches are generally considered to be a type of device enhancement that may be  
185 applied to vulnerabilities associated with controlled risk and is not considered a repair.  
186 Cybersecurity routine updates and patches may also include changes to product labeling,  
187 including the instructions for use, to strengthen cybersecurity through increased end-user  
188 education and use of best practices. The concept “cybersecurity routine updates and patches” has  
189 been developed for the purpose of this guidance and are generally not required to be reported  
190 under 21 CFR part 806. See Section VII for more details on reporting requirements for  
191 vulnerabilities with controlled risk. Security updates made to remediate vulnerabilities associated  
192 with a reasonable probability that use of, or exposure to, the product will cause serious adverse  
193 health consequences or death are not considered to be cybersecurity routine updates or patches.  
194

### **D. Cybersecurity Signal**

195  
196  
197 A cybersecurity signal is any information which indicates the potential for, or confirmation of, a  
198 cybersecurity vulnerability or exploit that affects, or could affect a medical device. A  
199 cybersecurity signal could originate from traditional information sources such as internal  
200 investigations, postmarket surveillance, or complaints, and/or security-centric sources such as  
201 CERTS (Computer/Cyber, Emergency Response/Readiness Teams), ISAOs<sup>5</sup> and security

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<sup>4</sup> This definition is adapted from NIST Special Publication “[Assessing Security and Privacy Controls in Federal Information Systems and Organizations](#),” NIST SP 800-53A Rev. 4.

<sup>5</sup> See Department of Homeland Security, “[Frequently Asked Questions about Information Sharing and Analysis Organizations \(ISAOs\)](#).”



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202 researchers. Signals may be identified within the HPH Sector. They may also originate in  
203 another critical infrastructure sector (e.g., defense, financial) but have the potential to impact  
204 medical device cybersecurity.  
205

### **E. Essential Clinical Performance**

206  
207  
208 Essential clinical performance means performance that is necessary to achieve freedom from  
209 unacceptable clinical risk<sup>6</sup>, as defined by the manufacturer. Compromise of the essential clinical  
210 performance can produce a hazardous situation that results in harm and/or may require  
211 intervention to prevent harm. The concept “essential clinical performance” has been developed  
212 for the purpose of this guidance.  
213

### **F. Exploit**

214  
215  
216 An exploit is an instance where a vulnerability or vulnerabilities have been exercised (accidentally  
217 or intentionally) and could impact the essential clinical performance of a medical device or use a  
218 medical device as a vector to compromise the performance of a connected device or system.  
219

### **G. Remediation**

220  
221  
222 Remediation is any action(s) taken to reduce the risk to the medical device’s essential clinical  
223 performance to an acceptable level. Remediation actions may include complete solutions to  
224 remove a cybersecurity vulnerability from a medical device (sometimes known as official fix<sup>7</sup>) or  
225 compensating controls that adequately mitigate the risk (e.g., notification to customer base and  
226 user community identifying a temporary fix, or work-around). An example of remediation is a  
227 notification to the customer base and user community that discloses the vulnerability and potential  
228 impact to essential clinical performance and provides a strategy to reduce the risk to the marketed  
229 device’s essential clinical performance to an acceptable level. If the customer notification does  
230 not provide a strategy to reduce the risk to the marketed device’s essential clinical performance to  
231 an acceptable level, then the remediation is considered *incomplete*.  
232

### **H. Threat**

233  
234  
235 Threat is any circumstance or event with the potential to adversely impact the essential clinical  
236 performance of the device, organizational operations (including mission, functions, image, or  
237 reputation), organizational assets, individuals, or other organizations through an information  
238 system via unauthorized access, destruction, disclosure, modification of information, and/or

---

<sup>6</sup> IEC 60601-1:2005, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*, Section 3.27 defines “Essential Performance” as “performance necessary to achieve freedom from unacceptable risk.” This draft guidance adapts this definition to explain “Essential Clinical Performance.”

<sup>7</sup> “Common Vulnerability Scoring System, Version 3.0,” defines “Official Fix” as “A complete vendor solution is available. Either the vendor has issued an official patch, or an upgrade is available.”

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239 denial of service.<sup>8</sup> Threats exercise vulnerabilities, which may impact the essential clinical  
240 performance of the device.

241

### 242 **I. Threat modeling**

243

244 Threat modeling is a methodology for optimizing Network/Application/Internet Security by  
245 identifying objectives and vulnerabilities, and then defining countermeasures to prevent, or  
246 mitigate the effects of, threats to the system.<sup>9</sup> For medical devices, threat modeling can be used to  
247 optimize mitigations by identifying vulnerabilities and threats to a particular product, products in  
248 a product line, or from the organization's supply chain that can adversely affect patient safety.

249

### 250 **J. Uncontrolled Risk**

251

252 Uncontrolled risk is present when there is unacceptable residual risk that the device's essential  
253 clinical performance could be compromised due to insufficient compensating controls and risk  
254 mitigations.

255

### 256 **K. Vulnerability**

257

258 A vulnerability is a weakness in an information system, system security procedures, internal  
259 controls, or implementation that could be exploited by a threat.<sup>10</sup>

260

## 261 **V. General Principles**

262

263 FDA recognizes that medical device cybersecurity is a shared responsibility between stakeholders  
264 including health care facilities, patients, providers, and manufacturers of medical devices. Failure  
265 to maintain cybersecurity can result in compromised device functionality, loss of data (medical or  
266 personal) availability or integrity, or exposure of other connected devices or networks to security  
267 threats. This in turn may have the potential to result in patient illness, injury or death.

268

269 Effective cybersecurity risk management is intended to reduce the risk to patients by decreasing  
270 the likelihood that device functionality is intentionally or unintentionally compromised by  
271 inadequate cybersecurity. An effective cybersecurity risk management program should  
272 incorporate both premarket and postmarket lifecycle phases and address cybersecurity from  
273 medical device conception to obsolescence. It is recommended that manufacturers apply the  
274 NIST Framework for Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect,  
275 Detect, Respond and Recover) in the development and implementation of their comprehensive  
276 cybersecurity programs. Alignment of the NIST Framework for Improving Critical Infrastructure

---

<sup>8</sup> NIST SP 800-53; SP 800-53A; SP 800-27; SP 800-60; SP 800-37; CNSSI-4009. Note: Adapted from NIST definition (SP 800-53).

<sup>9</sup> See "Threat Modeling" as defined in the Open Web Application Security Project (OWASP).

<sup>10</sup> National Institute of Standards and Technology, "Guide for Conducting Risk Assessments," NIST Special Publication 800-30, Revision 1.

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277 Cybersecurity five core functions to management of cybersecurity in medical devices is discussed  
278 in the Appendix in greater detail.  
279

### **A. Premarket Considerations**

280  
281  
282 The FDA guidance document titled “Content of Premarket Submissions for Management of  
283 Cybersecurity in Medical Devices” clarifies recommendations for manufacturers to address  
284 cybersecurity during the design and development of the medical device, as this can result in more  
285 robust and efficient mitigation of patient risks. Manufacturers should establish design inputs for  
286 their device related to cybersecurity, and establish a cybersecurity vulnerability and management  
287 approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g).  
288 The approach should appropriately address the following elements:  
289

- 290 • Identification of assets, threats, and vulnerabilities;
- 291 • Assessment of the impact of threats and vulnerabilities on device functionality and end  
292 users/patients;
- 293 • Assessment of the likelihood of a threat and of a vulnerability being exploited;
- 294 • Determination of risk levels and suitable mitigation strategies;
- 295 • Assessment of residual risk and risk acceptance criteria.

296  
297 For additional information see FDA guidance titled “Content of Premarket Submissions for  
298 Management of Cybersecurity in Medical Devices.”  
299

### **B. Postmarket Considerations**

300  
301  
302 Because cybersecurity risks to medical devices are continually evolving, it is not possible to  
303 completely mitigate risks through premarket controls alone. Therefore, it is essential that  
304 manufacturers implement comprehensive cybersecurity risk management programs and  
305 documentation consistent with the Quality System Regulation (21 CFR part 820), including but  
306 not limited to complaint handling (21 CFR 820.198), quality audit (21 CFR 820.22), corrective  
307 and preventive action (21 CFR 820.100), software validation and risk analysis (21 CFR  
308 820.30(g)) and servicing (21 CFR 820.200).  
309

310 These programs should emphasize addressing vulnerabilities which may permit the unauthorized  
311 access, modification, misuse or denial of use, or the unauthorized use of information that is  
312 stored, accessed, or transferred from a medical device to an external recipient, and may impact  
313 patient safety. Manufacturers should respond in a timely fashion to address identified  
314 vulnerabilities. Critical components of such a program include:  
315

- 316 • Monitoring cybersecurity information sources for identification and detection of  
317 cybersecurity vulnerabilities and risk;
- 318 • Understanding, assessing and detecting presence and impact of a vulnerability;
- 319 • Establishing and communicating processes for vulnerability intake and handling;
- 320 • Clearly defining essential clinical performance to develop mitigations that protect, respond  
321 and recover from the cybersecurity risk;

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- 322       • Adopting a coordinated vulnerability disclosure policy and practice; and  
323       • Deploying mitigations that address cybersecurity risk early and prior to exploitation.  
324 Postmarket cybersecurity information may originate from an array of sources including  
325 independent security researchers, in-house testing, suppliers of software or hardware technology,  
326 health care facilities, and information sharing and analysis organizations. It is strongly  
327 recommended that manufacturers participate in a cybersecurity ISAO as sharing and  
328 dissemination of cybersecurity information and intelligence pertaining to vulnerabilities and  
329 threats across multiple sectors is integral to a successful postmarket cybersecurity surveillance  
330 program.

331  
332 To manage postmarket cybersecurity risks for medical devices, a company should have a  
333 structured and systematic approach to risk management and quality management systems  
334 consistent with 21 CFR part 820. For example, such a program should include:

- 335  
336       • Methods to identify, characterize, and assess a cybersecurity vulnerability.  
337       • Methods to analyze, detect, and assess threat sources. For example:  
338           ○ A cybersecurity vulnerability might impact all of the medical devices in a  
339           manufacturer's portfolio based on how their products are developed; or  
340           ○ A cybersecurity vulnerability could exist vertically (i.e., within the  
341           components of a device) which can be introduced at any point in the supply  
342           chain for a medical device manufacturing process.  
343

344 It is recommended as part of a manufacturer's cybersecurity risk management program  
345 that the manufacturer incorporates elements consistent with the NIST Framework for  
346 Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond,  
347 and Recover).  
348

349 FDA recognizes that medical devices and the surrounding network infrastructure cannot be  
350 completely secured. Design, architecture, technology, and software development environment  
351 choices may result in the inadvertent incorporation of vulnerabilities. The presence of a  
352 vulnerability does not necessarily trigger patient safety concerns. Rather it is the impact of the  
353 vulnerability on the essential clinical performance of the device which may trigger patient safety  
354 concerns. Vulnerabilities that do not appear to currently impact essential clinical performance  
355 should be assessed by the manufacturer for future impact.  
356

### **C. Defining Essential Clinical Performance**

357  
358  
359 Essential clinical performance means performance that is necessary to achieve freedom from  
360 unacceptable clinical risk, as defined by the manufacturer. Compromise of the essential clinical  
361 performance can produce a hazardous situation that results in harm and/or may require  
362 intervention to prevent harm.  
363

364 Manufacturers should define, as part of risk management, the essential clinical performance of  
365 their device, the resulting severity outcomes if compromised, and the risk acceptance criteria.  
366 Defining essential clinical performance requirements, severity outcomes, and mapping

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367 requirements allows manufacturers to triage vulnerabilities for remediation (see Section VI for  
368 additional information on risk assessments).

369  
370 When defining essential clinical performance, manufacturers should consider the requirements  
371 necessary to achieve device safety and effectiveness. Understanding and defining essential  
372 clinical performance is of importance in assessing a vulnerability's impact on device  
373 performance, and in determining whether proposed or implemented remediation can provide  
374 assurance that the cybersecurity risk to the essential clinical performance is reasonably controlled.  
375 Importantly, acceptable mitigations will vary according to the device's essential clinical  
376 performance. For example, a cybersecurity vulnerability affecting the essential clinical  
377 performance of a thermometer may be quite different than a cybersecurity vulnerability affecting  
378 the essential clinical performance of an insulin infusion pump.

379

## **VI. Medical Device Cybersecurity Risk Management**

381

382 As part of their risk management process consistent with 21 CFR part 820, a manufacturer should  
383 establish, document, and maintain throughout the medical device lifecycle an ongoing process for  
384 identifying hazards associated with the cybersecurity of a medical device, estimating and  
385 evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the  
386 controls. This process should include risk analysis, risk evaluation, risk control, and  
387 incorporation of production and post-production information. Elements identified in the Appendix  
388 of this guidance should be included as part of the manufacturer's cybersecurity risk management  
389 program to support an effective risk management process. Manufacturers should have a defined  
390 process to systematically conduct a risk evaluation and determine whether a cybersecurity  
391 vulnerability affecting a medical device presents an acceptable or unacceptable risk. It is not  
392 possible to describe all hazards, associated risks, and/or controls associated with medical device  
393 cybersecurity vulnerabilities in this guidance. It is also not possible to describe all scenarios  
394 where risk is controlled or uncontrolled. Rather, FDA recommends manufacturers to define and  
395 document their process for objectively assessing the cybersecurity risk for their device(s).

396

397 As outlined below, it is recommended that such a process focus on assessing the *risk to the*  
398 *device's essential clinical performance* by considering:

399

- 400 1) The exploitability of the cybersecurity vulnerability, and  
401 2) The severity of the health impact to patients if the vulnerability were to be exploited.

402

403 Such analysis should also incorporate consideration of compensating controls and risk  
404 mitigations.

405

### **A. Assessing Exploitability of the Cybersecurity Vulnerability**

407

408  
409 Manufacturers should have a process for assessing the exploitability of a cybersecurity  
410 vulnerability. In many cases, estimating the probability of a cybersecurity exploit is very difficult

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411 and in the absence of data on the probability of the occurrence of harm, conventional medical  
412 device risk management approaches suggest using a “reasonable worst-case estimate” or setting  
413 the default value of the probability to one. While these approaches are acceptable, FDA suggests  
414 that manufacturers instead consider using a cybersecurity vulnerability assessment tool or similar  
415 scoring system for rating vulnerabilities and determining the need for and urgency of the  
416 response.

417  
418 One such tool, the “Common Vulnerability Scoring System,” Version 3.0, for example, provides  
419 numerical ratings corresponding to high, medium and low by incorporating a number of factors in  
420 assessing exploitability including<sup>11</sup>:

- 421 • Attack Vector (physical, local, adjacent, network)
- 422 • Attack Complexity (high, low)
- 423 • Privileges Required (none, low, high)
- 424 • User Interaction (none, required)
- 425 • Scope (changed, unchanged)
- 426 • Confidentiality Impact (high, low, none)
- 427 • Integrity Impact (none, low, high)
- 428 • Availability Impact (high, low, none)
- 429 • Exploit Code Maturity (high, functional, proof-of-concept, unproven)
- 430 • Remediation Level (unavailable, work-around, temporary fix, official fix, not defined)
- 431 • Report Confidence (confirmed, reasonable, unknown, not defined)

432  
433 Other vulnerability scoring systems may also be adapted for assessing the exploitability of  
434 medical device cybersecurity vulnerabilities.

### 436 **B. Assessing Severity Impact to Health**

437  
438 Manufacturers should also have a process for assessing the severity impact to health, if the  
439 cybersecurity vulnerability were to be exploited. While there are many potentially acceptable  
440 approaches for conducting this type of analysis, one such approach may be based on qualitative  
441 severity levels as described in ANSI/AAMI/ISO 14971: 2007/(R)2010: Medical Devices –  
442 Application of Risk Management to Medical Devices:

444 <u>Common Term</u>	<u>Possible Description</u>
446 Negligible:	Inconvenience or temporary discomfort
447 Minor:	Results in temporary injury or impairment not requiring professional 448 medical intervention
449 Serious:	Results in injury or impairment requiring professional medical intervention
450 Critical:	Results in permanent impairment or life-threatening injury
451 Catastrophic:	Results in patient death

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<sup>11</sup> For a full description of each factor, see “Common Vulnerability Scoring System,” Version 3.0: Specification Document.

### C. Evaluation of Risk to Essential Clinical Performance

A key purpose of conducting the cyber-vulnerability risk assessment is to evaluate whether the risk to essential clinical performance of the device is controlled (acceptable) or uncontrolled (unacceptable). One method of assessing the acceptability of risk to essential clinical performance is by indicating in a matrix in which combinations of “exploitability” and “severity impact to health” represent risks that are controlled or uncontrolled. A manufacturer can then conduct assessments of the exploitability and severity impact to health and then use such a matrix to assess the risk to essential clinical performance for the identified cybersecurity vulnerabilities.

For risks that remain uncontrolled, additional remediation should be implemented.

The following figure shows a possible evaluation approach and the relationship between exploitability and impact to health. It can be used to assess the risk to the device’s essential clinical performance from a cybersecurity vulnerability as controlled or uncontrolled. While in some cases the evaluation will yield a definite determination that the situation is controlled or uncontrolled, it is possible that in other situations this determination may not be as distinct. Nevertheless, in all cases, FDA recommends that manufacturers make a binary determination that a vulnerability is either controlled or uncontrolled using an established process that is tailored to the product, its essential clinical performance, and the situation. Risk mitigations, including compensating controls, should be implemented when necessary to bring the residual risk to an acceptable level.



Figure – Evaluation of Risk to Essential Clinical Performance. The figure shows the relationship between exploitability and risk to health, and can be used to assess the risk to the device’s essential clinical performance from a cybersecurity vulnerability. The figure can be used to categorize the risk to essential clinical performance as controlled or uncontrolled.

480 **VII. Remediating and Reporting Cybersecurity**  
481 **Vulnerabilities**

482

483 Based on the vulnerability assessment described in the previous section, the exploitability of an  
484 identified vulnerability and its severity impact to health can help determine the extent of the  
485 compromise to the essential clinical performance of a device and can be categorized as either  
486 “controlled” (acceptable residual risk) or “uncontrolled” (unacceptable residual risk). When  
487 determining how to manage a cybersecurity vulnerability, manufacturers should incorporate  
488 already implemented compensating controls and risk mitigations into their risk assessment.

489

490 FDA encourages efficient, timely and ongoing cybersecurity risk management for marketed  
491 devices by manufacturers. For cybersecurity routine updates and patches, the FDA will, typically,  
492 not need to conduct premarket review to clear or approve the medical device software changes.  
493 In addition, manufacturers should:

494

- 495 • Proactively practice good cyber hygiene, and reduce cybersecurity risks even when  
496 residual risk is acceptable;
- 497 • Remediate cybersecurity vulnerabilities to reduce the risk of compromise to essential  
498 clinical performance to an acceptable level;
- 499 • Conduct appropriate software validation under 21 CFR 820.30(g) to assure that any  
500 implemented remediation effectively mitigates the target vulnerability without  
501 unintentionally creating exposure to other risks;
- 502 • Properly document the methods and controls used in the design, manufacture, packaging,  
503 labeling, storage, installation and servicing of all finished devices as required by 21 CFR  
504 part 820.
- 505 • Identify and implement compensating controls, such as a work-around or temporary fix,  
506 to adequately mitigate the cybersecurity vulnerability risk, especially when an “official  
507 fix” may not be feasible or immediately practicable. In addition, manufacturers should  
508 consider the level of knowledge and expertise needed to properly implement the  
509 recommended fix;
- 510 • Provide users with relevant information on recommended work-arounds, temporary fixes  
511 and residual cybersecurity risks so that they can take appropriate steps to mitigate the risk  
512 and make informed decisions regarding device use.

513

514 In addition to the general recommendations described above, Sections VII.A. and VII.B. below  
515 clarify specific recommendations for managing controlled and uncontrolled risks to essential  
516 clinical performance.<sup>12</sup>

517

518

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<sup>12</sup> Please note that manufacturers and user facilities may have additional reporting requirements from sources other than FDA.



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### 519 **A. Controlled Risk to Essential Clinical Performance**

520  
521 Controlled risk is present when there is sufficiently low (acceptable) residual risk that the device's  
522 essential clinical performance could be compromised by the vulnerability.  
523

524  
525 Manufacturers are encouraged to promote good cyber hygiene and reduce cybersecurity risks  
526 even when residual risk is acceptable. The following are recommendations for changes or  
527 compensating control actions taken to address vulnerabilities associated with controlled risk:  
528

- 529 • Changes to a device that are made solely to strengthen cybersecurity are typically  
530 considered device enhancements<sup>13</sup>, which may include cybersecurity routine updates and  
531 patches, and are generally not required to be reported, under 21 CFR 806.10;
- 532 • For premarket approval (PMA) devices with periodic reporting requirements under 21  
533 CFR 814.84, newly acquired information concerning cybersecurity vulnerabilities and  
534 device changes made as part of cybersecurity routine updates and patches should be  
535 reported to FDA in a periodic (annual) report. See Section VIII for recommended content  
536 to include in the periodic report.

537  
538 *Examples of Vulnerabilities Associated with Controlled Risk and their Management:*  
539

- 540 • A device manufacturer is notified of an open, unused communication port by the U.S.  
541 Department of Homeland Security Industrial Control Systems-Cyber Emergency  
542 Response Team (ICS-CERT). Subsequent analyses show that a design feature of the  
543 device prevents unauthorized remote firmware download onto the device. The threat is  
544 mitigated substantially by the need for physical access due to this device feature and the  
545 residual risk is considered "acceptable." The manufacturer takes steps to further enhance  
546 the device's security by taking steps to close the unused communication port(s) and  
547 provide adequate communication to device users (e.g., user facilities) to facilitate the  
548 patch. If the manufacturer closes the open communication ports, the change would be  
549 considered a cybersecurity routine update or patch, a type of device enhancement. The  
550 change may not require reporting under 21 CFR part 806.
- 551  
552 • A device manufacturer receives a user complaint that a recent security software scan of the  
553 PC component of a Class III medical device has indicated that the PC is infected with  
554 malware. The outcome of a manufacturer investigation and impact assessment confirms  
555 the presence of malware and that the primary purpose of the malware is to collect internet  
556 browsing information. The manufacturer also determined that the malware has actively  
557 collected browsing information, but that the device's essential clinical performance is not  
558 impacted by such collection. The manufacturer's risk assessment determines that the risk  
559 due to the vulnerability is controlled. Since essential clinical performance was not  
560 impacted, the manufacturer can update the product and it will be considered a

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<sup>13</sup> See FDA guidance titled "[Distinguishing Medical Device Recalls from Medical Device Enhancements](#)."

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561 cybersecurity routine update or patch. In this case, the manufacturer does not need to  
562 report this software update to the FDA in accordance with 21 CFR 806.10. Because the  
563 device is a Class III device, the manufacturer should report the changes to the FDA in its  
564 periodic (annual) report required for holders of an approved PMA under 21 CFR 814.84.  
565

### **B. Uncontrolled Risk to Essential Clinical Performance**

566  
567  
568 Uncontrolled risk is present when there is unacceptable residual risk that the device's essential  
569 clinical performance could be compromised due to insufficient risk mitigations and compensating  
570 controls. If the risk to essential clinical performance is assessed as uncontrolled, additional risk  
571 control measures should be applied.  
572

573 The following are recommendations for changes or compensating control actions to address  
574 vulnerabilities associated with uncontrolled risk:  
575

- 576 • Manufacturers should remediate the vulnerabilities to reduce the risk of compromise to  
577 essential clinical performance to an acceptable level;
- 578 • While an official fix may not be feasible or immediately practicable, manufacturers should  
579 identify and implement risk mitigations and compensating controls, such as a work-around  
580 or temporary fix, to adequately mitigate the risk;
- 581 • Manufacturers should report these vulnerabilities to the FDA according to 21 CFR part  
582 806, unless reported under 21 CFR parts 803 or 1004. However, the FDA does not intend  
583 to enforce reporting requirements under 21 CFR part 806 if all of the following  
584 circumstances are met:
  - 585 1) There are no known serious adverse events or deaths associated with the  
586 vulnerability,
  - 587 2) Within 30 days of learning of the vulnerability, the manufacturer identifies and  
588 implements device changes and/or compensating controls to bring the residual risk  
589 to an acceptable level and notifies users, and
  - 590 3) The manufacturer is a participating member of an ISAO, such as NH-ISAC;
- 591 • Remediation of devices with annual reporting requirements (e.g., Class III devices) should  
592 be included in the annual report;
- 593 • The manufacturer should evaluate the device changes to assess the need to submit a  
594 premarket submission (e.g., PMA supplement, 510(k), etc.) to the FDA;
- 595 • The customer base and user community should be provided with relevant information on  
596 recommended work-arounds, temporary fixes and residual cybersecurity risks so that they  
597 can take appropriate steps to mitigate the risk and make informed decisions regarding  
598 device use;
- 599 • For PMA devices with periodic reporting requirements under 21 CFR 814.84, information  
600 concerning cybersecurity vulnerabilities, and the device changes and compensating  
601 controls implemented in response to this information should be reported to FDA in a

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602 periodic (annual) report. See Section VIII for recommended content to include in the  
603 periodic report.

604 In the absence of remediation, a device with uncontrolled risk to its essential clinical performance  
605 may be considered to have a reasonable probability that use of, or exposure to, the product will  
606 cause serious adverse health consequences or death. The product may be considered in violation  
607 of the FD&C Act and subject to enforcement or other action.

608

609 *Examples of Vulnerabilities Associated with Uncontrolled Risk That Must Be Remediated and*  
610 *Response Actions:*

611

612 • A manufacturer is made aware of open, unused communication ports. Subsequent  
613 analysis determines that the device's designed-in features do not prevent a threat from  
614 downloading unauthorized firmware onto the device, which could be used to compromise  
615 the device's essential clinical performance. Although there are no reported serious  
616 adverse events or deaths associated with the vulnerability, the risk assessment concludes  
617 the risk to the device's essential clinical performance is uncontrolled. The manufacturer  
618 develops and implements a software update to close the unused communication port(s)  
619 and notifies device users (e.g., Healthcare Delivery Organizations (HDOs)) to facilitate the  
620 remediation. The manufacturer identifies and implements compensating controls to bring  
621 the residual risk to an acceptable level and notifies users within 30 days of becoming  
622 aware of the vulnerability. The manufacturer is also a participating member of an ISAO  
623 and the manufacturer did not submit an 806 report to the Agency. For Class III devices,  
624 the manufacturer does submit a summary of the remediation as part of their periodic  
625 (annual) report to FDA. Under these circumstances, FDA does not intend to enforce the  
626 reporting requirements under 21 CFR part 806.

627

628 • A manufacturer becomes aware of a vulnerability via a researcher that its Class III medical  
629 device (e.g., implantable defibrillator, pacemaker, etc.) can be reprogrammed by an  
630 unauthorized user. If exploited, this vulnerability could result in permanent impairment, a  
631 life-threatening injury, or death. The manufacturer is not aware that the vulnerability has  
632 been exploited and determines that the vulnerability is related to a hardcoded password,  
633 and cannot be mitigated by the device's design controls. The risk assessment concludes  
634 that the exploitability of the vulnerability is moderate and the risk to the device's essential  
635 clinical performance is uncontrolled. The manufacturer notifies appropriate stakeholders,  
636 and distributes a validated emergency patch. The manufacturer is not a participating  
637 member of an ISAO and reports this action to the FDA under 21 CFR 806.10.

638

639 • A vulnerability known to the security community, yet unknown to a medical device  
640 manufacturer, is incorporated into a Class II device during development. Following  
641 clearance, the manufacturer becomes aware of the vulnerability and determines that the  
642 device continues to meet its specifications, and that no device failures or patient injuries  
643 have been reported. There is no evidence that the identified vulnerability has been  
644 exploited. However, it was determined that the vulnerability introduced a new failure  
645 mode to the device that impacts essential clinical performance, and the device's design  
646 controls do not mitigate the risk. The manufacturer conducts a risk assessment and

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647 determines that without additional mitigations, the risk to essential clinical performance is  
648 uncontrolled. Although the manufacturer does not currently have a software update to  
649 mitigate the impact of this vulnerability on the device's essential clinical performance, the  
650 manufacturer notifies the customer base and user community of the cybersecurity risk and  
651 instructs them to disconnect the device from the hospital network to prevent unauthorized  
652 access to the device. The company's risk assessment concludes that the risk to essential  
653 clinical performance is controlled with this additional mitigation. If the company took this  
654 action to mitigate the risk within 30 days of learning of the vulnerability and is a  
655 participating member of an ISAO, FDA does not intend to enforce compliance with the  
656 reporting requirement under 21 CFR part 806.

657

- 658 • A hospital reports that a patient was harmed after a medical device failed to perform as  
659 intended. A manufacturer investigation determines that the medical device malfunctioned  
660 as a result of exploitation of a previously unknown vulnerability in its proprietary  
661 software. The outcome of the manufacturer's investigation and impact assessment  
662 determines that the exploit indirectly impacts the device's essential clinical performance  
663 and may have contributed to a patient death. The manufacturer notifies the customer base  
664 and user community, and develops a validated emergency patch within 30 days of learning  
665 of the vulnerability. The manufacturer is a participating member of an ISAO. Because  
666 there has been a serious adverse event or death associated with the vulnerability, the  
667 manufacturer files a report in accordance with 21 CFR 806.10 to notify FDA and complies  
668 with reporting requirements under 21 CFR part 803.

669

## 670 **VIII. Recommended Content to Include in PMA Periodic** 671 **Reports**

672

673 For PMA devices with periodic reporting requirements under 21 CFR 814.84, information  
674 concerning cybersecurity vulnerabilities, and device changes and compensating controls  
675 implemented in response to this information should be reported to FDA in a periodic (annual)  
676 report.

677

678 It is recommended that the following information be provided for changes and compensating  
679 controls implemented for the device:

- 680
- 681 • A brief description of the vulnerability prompting the change including how the  
682 firm became aware of the vulnerability;
  - 683 • A summary of the conclusions of the firm's risk assessment including whether the  
684 risk to essential clinical performance was controlled or uncontrolled;
  - 685 • A description of the change(s) made, including a comparison to the previously  
686 approved version of the device;
  - 687 • The rationale for making the change;
  - 688 • Reference to other submissions/devices that were modified in response to this  
689 same vulnerability;

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- Identification of event(s) related to the rationale/reason for the change (e.g., MDR number(s), recall number);
- Unique Device Identification (UDI) should be included, if available;
- A link to an ICS-CERT advisory, if applicable;
- The date and name of the ISAO to which the vulnerability was reported, if any; and
- Reference to other relevant submission (PMA Supplement<sup>14</sup>, 30-Day Notice, 806 report, etc.), if any, or the scientific and/or regulatory basis for concluding that the change did not require a submission/report.

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<sup>14</sup> See 21 CFR 814.39.

701 **IX. Appendix: Elements of an Effective Postmarket**  
702 **Cybersecurity Program**  
703

704 It is recommended that the following elements, consistent with the NIST Framework for  
705 Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond,  
706 and Recover), be included as part of a manufacturer’s cybersecurity risk management  
707 program.  
708

709 **A. Identify**  
710

711 **(1) Defining Essential Clinical Performance**  
712

713 Essential clinical performance means performance that is necessary to achieve freedom  
714 from unacceptable clinical risk, as defined by the manufacturer. Compromise of the  
715 essential clinical performance can produce a hazardous situation that results in harm  
716 and/or may require intervention to prevent harm.  
717

718 Manufacturers should define the essential clinical performance of their device, the  
719 resulting severity outcomes if compromised, and the risk acceptance criteria. Defining  
720 essential clinical performance requirements, severity outcomes, and mapping requirements  
721 allows manufacturers to triage vulnerabilities for remediation (see Section VI for  
722 additional information on risk assessments).  
723

724 When defining essential clinical performance, manufacturers should consider the  
725 requirements necessary to achieve device safety and effectiveness. Understanding and  
726 defining essential clinical performance is of importance in assessing vulnerability impact  
727 on device performance, and in determining whether proposed or implemented  
728 remediations can provide assurance that the cybersecurity risk to the essential clinical  
729 performance is reasonably controlled. Importantly, acceptable mitigations will vary  
730 according to the device’s essential clinical performance. For example, mitigation for a  
731 cybersecurity vulnerability affecting the essential clinical performance of a thermometer  
732 may be quite different than a mitigation considered for an insulin infusion pump.  
733

734 **(2) Identification of Cybersecurity Signals**  
735

736 Manufacturers are required to analyze complaints, returned product, service records, and  
737 other sources of quality data to identify existing and potential causes of nonconforming  
738 product or other quality problems (21 CFR 820.100). Manufacturers are encouraged to  
739 actively identify cybersecurity signals that might affect their product, and engage with the  
740 sources that report them. It is important to recognize that signals can originate from  
741 sources familiar to the medical device workspace such as internal investigations, post  
742 market surveillance and or/complaints. It is also important to recognize that cybersecurity  
743 signals may originate from cybersecurity-centric sources such as Cyber Emergency  
744 Response Teams (CERTS), ISAOs, security researchers, or from other critical

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745 infrastructure sectors such as the Defense or Financial Sectors. Irrespective of the  
746 originating source, a clear, consistent and reproducible process for intake and handling of  
747 vulnerability information should be established and implemented by the manufacturer.  
748 FDA has recognized ISO/IEC 30111:2013: *Information Technology – Security Techniques*  
749 *– Vulnerability Handling Processes* that may be a useful resource for manufacturers.  
750 Manufacturers should develop strategies to enhance their ability to detect signals (e.g.,  
751 participating in an ISAO). Manufacturers can also enhance their postmarket detection of  
752 cybersecurity risks by incorporating detection mechanisms into their device design and  
753 device features to increase the detectability of attacks and permit forensically sound  
754 evidence capture.  
755

### **B. Protect/Detect**

#### **(1) Vulnerability Characterization and Assessment**

760 FDA recommends that manufacturers characterize and assess identified vulnerabilities  
761 because it will provide information that will aid manufacturers to triage remediation  
762 activities. When characterizing the exploitability of a vulnerability, the manufacturer  
763 should consider factors such as remote exploitability, attack complexity, threat privileges,  
764 actions required by the user, exploit code maturity, and report confidence. Scoring  
765 systems such as the “Common Vulnerability Scoring System” (CVSS)<sup>15</sup> provide a  
766 consistent framework for assessing exploitability by quantifying the impact of the factors  
767 that influence exploitability. See Section VI for additional guidance on vulnerability risk  
768 assessment.  
769

#### **(2) Risk Analysis and Threat Modeling**

772 FDA recommends that manufacturers conduct cybersecurity risk analyses that include  
773 threat modeling for each of their devices and to update those analyses over time. Risk  
774 analyses and threat modeling should aim to triage vulnerabilities for timely remediation.  
775 Threat modeling is a procedure for optimizing Network/Application/Internet Security by  
776 identifying objectives and vulnerabilities, and then defining countermeasures to prevent,  
777 or mitigate the effects of, threats to the system.<sup>16</sup> Threat modeling provides traditional  
778 risk management and failure mode analysis paradigms, and a framework to assess threats  
779 from active adversaries/malicious use. For each vulnerability, a summary report should be  
780 produced that concisely summarizes the risk analysis and threat modeling information.  
781 Due to the cyclical nature of the analyses, the information should be traceable to related  
782 documentation.  
783

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<sup>15</sup> “Common Vulnerability Scoring System,” Version 3.0, Scoring Calculator.

<sup>16</sup> See “Threat Modeling” as defined in the [Open Web Application Security Project](#).

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### 784 **(3) Analysis of Threat Sources<sup>17</sup>**

785  
786 FDA recommends manufacturers to analyze possible threat sources. A threat source is  
787 defined as the intent and method targeted at the intentional exploitation of a vulnerability  
788 or a situation and method that may accidentally trigger a vulnerability<sup>18</sup>. Analysis of  
789 threat sources, as part of risk analysis and threat modeling provides a framework for risk  
790 introduced by an active adversary. Therefore, characterization of threat sources will be  
791 advantageous to manufacturers in accessing risks not covered by traditional failure mode  
792 analysis methods.

### 794 **(4) Incorporation of Threat Detection Capabilities**

795  
796 Medical devices may not be capable of detecting threat activity and may be reliant on  
797 network monitoring. Manufacturers should consider the incorporation of design features  
798 that establish or enhance the ability of the device to detect and produce forensically sound  
799 postmarket evidence capture in the event of an attack. This information may assist the  
800 manufacturer in assessing and remediating identified risks.

### 802 **(5) Impact Assessment on All Devices**

803  
804 FDA recommends manufacturers to have a process to assess the impact of a cybersecurity  
805 signal horizontally (i.e., across all medical devices within the manufacturer's product  
806 portfolio and sometimes referred to as variant analyses) and vertically (i.e., determine if  
807 there is an impact on specific components within the device). A signal may identify a  
808 vulnerability in one device, and that same vulnerability may impact other devices  
809 including those in development, or those not yet cleared, approved or marketed.  
810 Therefore, it will be advantageous to manufacturers to conduct analyses for cybersecurity  
811 signals such that expended detection resources have the widest impact.

## 813 **C. Protect/Respond/Recover**

### 814 815 **(1) Compensating Controls Assessment (Detect/Respond)**

816  
817 FDA recommends manufacturers to implement device-based features as a primary  
818 mechanism to mitigate the impact of a vulnerability to essential clinical performance.  
819 Manufacturers should assess and prescribe to users, compensating controls such that the  
820 risk to essential clinical performance is further mitigated by a defense-in-depth strategy.  
821 Section VII describes recommendations for remediating and reporting identified  
822 cybersecurity vulnerabilities, including the development, implementation and user  
823 notification concerning official fixes, temporary fixes, and work-arounds. Manufacturers

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<sup>17</sup> National Institute of Standards and Technology, "[Guide for Conducting Risk Assessments](#)," NIST Special Publication 800-30 Revision 1.

<sup>18</sup> National Institute of Standards and Technology, "[Security and Privacy Controls for Federal Information Systems and Organizations](#)," NIST Special Publication 800-53, Revision 4, Appendix B.



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824 should also adopt a coordinated vulnerability disclosure policy. FDA has recognized  
825 ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability  
826 Disclosure that may be a useful resource for manufacturers.  
827

### **(2) Risk Mitigation of Essential Clinical Performance**

828  
829  
830 Once the preceding information has been assessed and characterized, manufacturers  
831 should determine if the risk levels presented by the vulnerability to the essential clinical  
832 performance are adequately controlled by existing device features and/or manufacturer  
833 defined compensating controls (i.e., residual risk levels are acceptable). Actions taken  
834 should reflect the magnitude of the problem and align with the risks encountered.  
835 Manufacturers should also include an evaluation of residual risk, benefit/risk, and risk  
836 introduced by the remediation. Manufacturers should design their devices to ensure that  
837 risks inherent in remediation are properly mitigated including ensuring that the  
838 remediation is adequate and validated, that the device designs incorporate mechanisms for  
839 secure and timely updates.  
840

841 Changes made to improve the performance or quality of a device that do not impact the  
842 essential clinical performance of the device are considered device enhancements, not  
843 recalls. Cybersecurity routine updates and patches are generally considered a type of  
844 device enhancement. For further information on distinguishing between device  
845 enhancements and recalls, see FDA guidance titled Distinguishing Medical Device Recalls  
846 from Medical Device Enhancements.  
847