Project Number: P11073-40101
Type of Document: Standard
Life Cycle: Full Use

Title: Health informatics - Device interoperability - Part 40101: Cybersecurity - Processes for vulnerability assessment

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Projected Completion Date for Submittal to RevCom
  Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 10/2022

Approximate number of people expected to be actively involved in the development of this project: 10

Purpose: The purpose of this document is to define a common approach to cybersecurity assessment in Personal Health Devices (PHDs)/Point-of-Care Devices (PoCDs) and define an iterative, systematic, scalable, and auditable vulnerability assessment appropriate for use in the design of PHDs/PoCDs.

Need for the Project: Manufacturers of regulated personal health devices are required to address cybersecurity vulnerabilities through a detailed risk analysis of use cases specific to the device. Currently, there are various approaches to vulnerability assessment, some of which are not repeatable, scalable, systematic, and auditable. Both manufacturers and regulatory bodies could benefit from a common approach to vulnerability assessment based on threat modeling capable of analyzing all types of PHDs/PoCDs across domains and described in trusted open consensus recommendations. Likewise, patients, providers, and payers should benefit from consistent and sufficient information provided in
5.6 Stakeholders for the Standard: Medical and Health Device Manufacturers, System Integrators, Healthcare Facilitators, Researchers, and Software Developers

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Intellectual Property

6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No
6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

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7.1 Are there other standards or projects with a similar scope?: No
7.2 Joint Development

Is it the intent to develop this document jointly with another organization?: Yes
 Organization: IEEE Engineering in Medicine & Biology Society (EMBS)
 Technical Committee Name: 11073 Point-of-Care Device (PoCD) WG
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8.1 Additional Explanatory Notes: Within the context of secure Plug & Play interoperability, cybersecurity is the process and capability of preventing unauthorized access, modification, misuse, denial of use, or the unauthorized use of information that is stored on, accessed from, or transferred to and from a Personal Health Device (PHD) and/or Point-of-Care Devices (PoCD). The process part of cybersecurity is a detailed risk analysis of use cases specific to personal health devices.