IEC 81001-5-1 Ed.1

Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle

＜Overview＞

IEC 81001-5-1 Ed.1 is a process standard for healthcare software, including software incorporated in medical devices, that specifies activities that manufacturers perform as part of their development and maintenance life cycle.

＜Technical Committee＞

Joint Working Group 7 (JWG7) of IEC SC62A (Medical electrical equipment) and ISO/TC215 (Health informatics)

＜Main Points＞

- The scope covers all health software, including SaMD (Software as a Medical Device) and software incorporated in a medical device.
- It specifies the life cycle requirements for the development and maintenance of health software that are necessary to support conformity to IEC 62443-4-1 (Security for industrial automation and control systems - Part 4-1: Secure product development life-cycle requirements), which is considered state of the art.
- The requirements are structured in accordance with the sequence of IEC 62304 (JIS T 2304). They are intended to extend the framework of existing software life cycle process and risk management process to address cybersecurity.
- The requirements specify activities for each of the following processes: general requirements (including QMS and risk management), the software development process, the software maintenance process, the security-related risk management process, the software configuration management process, and the software problem resolution process.
- Consideration is also given to the conformity of health software released before the publication of this standard, which may not fully comply with all the requirements of the standard (transitional health software).

＜Publication History＞

- Recognizing the need for a cybersecurity standard for all health software, including medical device software, the development project was approved on September 13, 2018.
- Subsequently, a Project Team (PT) was organized within JWG7 to conduct deliberations, a

CDV (Committee Draft for Vote) was created on December 9, 2020 (approved March 4, 2021), and an FDIS (Final Draft International Standard) was created on September 15, 2021 (approved November 6, 2021), with the international standard being published on December 16, 2021.

- The corresponding JIS was established as JIS T 81001-5-1 on February 25, 2023.

＜PMDA Involvement＞

Attendance at international conferences, teleconferences, and domestic committees.