IEC 80601-2-77 Ed.1

Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

＜Overview＞

IEC 80601-2-77 Ed.1 is a particulars standard in the IEC 60601 SERIES for surgical robots. It covers robotically assisted surgical equipment for a wide range of applications such as endoscopic surgery and orthopedic surgery.

＜Technical Committee＞

Joint Working Group 35 (JWG35) of IEC/SC 62D and ISO/TC 299

＜Main Points＞

- Surgical robots are expected to encompass a wide variety of devices with different intended uses, mechanical structures, and control methods. However, the standard was developed based on the assumption that they share the following common characteristics:
  - Surgical robots perform precise positioning and manipulation.
  - They are used in combination with other ME (Medical Electrical) equipment such as laser devices and endoscopes.
- Based on these characteristics of surgical robots, requirements concerning motion control (e.g., position and speed of movement of surgical instruments) and requirements for addressing thermal, electrical, and mechanical risks arising from combination/concurrent use with other ME equipment have been added to the requirements of IEC 60601-1.

＜Publication History＞

- In 2015, Joint Working Group 35 (JWG35) of ISO and IEC was established, and the development of a safety standard for surgical robots was initiated.
- The Committee Draft (CD) document was completed at the 2017 meeting in Busan, and a call for comments was made.
- At the Augsburg meeting in April 2018, comments on the CDV (Committee Draft for Vote) document were addressed, and discussions for creating the FDIS (Final Draft International Standard) document were held at the Kyoto meeting in June.

＜PMDA Involvement ＞

Attendance at international conferences, teleconferences, and domestic committee meeting