

IEC 60601 Ed.4 Architecture Document

ARCHITECTURAL SPECIFICATION FOR SAFETY STANDARDS OF MEDICAL
ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS, AND SOFTWARE USED IN
HEALTHCARE

< Overview >

The IEC 60601-1 Ed.4 architectural specification is a document available on the IEC website, which establishes an architectural concept for IEC 60601 Ed.4 which to be published in 2029. In this document, eight goals are set up and the guidelines are showed for each goal.

< Technical Committee >

IEC/TC 62 ad-hoc group 2 (AG2)

< Main Points >

- The following eight goals to be achieved are presented.
- Details are provided on major comments from Japan, including "reducing risk management citations" and "enforcing a reasonable publication schedule".
- It indicates that the correspondence between the standard and requirements such as the IMDRF Essential Principles will be described in an annex.
 - Goal 1 – Sharpen the focus on basic safety and essential performance.
 - Goal 2 – Reconcile requirements to a single statement.
 - Goal 3 – Simplify the structure of the IEC 60601 series.
 - Goal 4 – Increase separation of type testing and process requirements.
 - Goal 5 – Clarification of scope of the IEC 60601 series.
 - Goal 6 – Establish a policy relating requirement of the IEC 60601 series to the IMDRF Essential Principles and labelling principles.
 - Goal 7 – Establish a policy for scheduled release and stability dates.
 - Goal 8 – Establish training for authors of documents developed by IEC/TC62.

< Publication History >

- The establishment of an ad-hoc group to develop the architecture document for IEC 60601 Ed.4 was approved at IEC TC 62 general meeting in 2015.
- A kick-off meeting was held in May 2019, and the first edition was circulated to national committees. After that, two international meetings were held for the purpose of circulation and comment resolution.

- At the IEC TC 62 plenary meeting in 2019, it was approved that this document would be published on the website as a Supporting Document of IEC TC 62, and it was subsequently published in May 2020.

<PMDA Involvement >

Attendance at international conferences, teleconferences, and domestic committees.