

Who is IEC?

- International Electrotechnical Commission
- Not-for-profit, non-governmental
- Established in 1906
- Global standardization for **electrical equipment**
- Other topics are developed by ISO



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IEC/TC 62

Electrical equipment and software in medical practice

- Established in 1967
- Provides advisory role for all standards work dealing with electrical equipment in medical practice
- has four sub-committees (SC)



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IEC/SC 62A

Common aspects of electrical equipment used in medical practice

- Develops all the general/collateral standards within the IEC 60601 family of standards



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IEC/SC 62B

Diagnostic imaging equipment

- Develops documents related to imaging



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IEC/SC 62C

Equipment for radiotherapy, nuclear medicine and radiation dosimetry

- Develops documents related to radiation



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IEC/SC 62D

Electromedical equipment

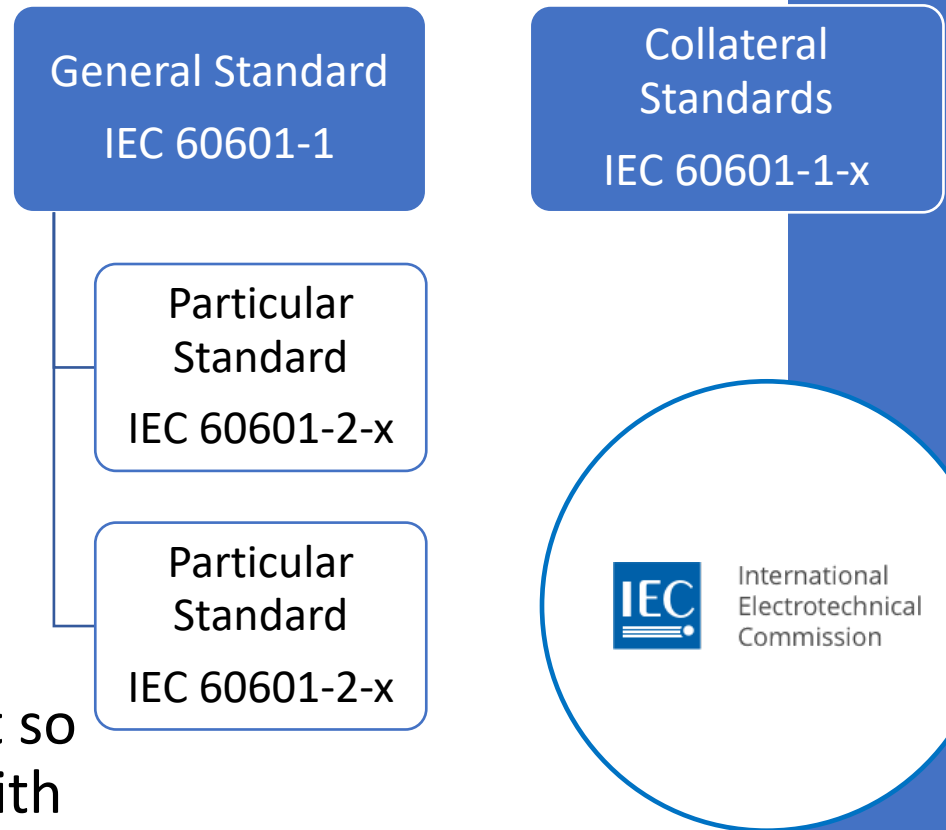
- Develops particular or device specific standards within the IEC 60601 family
- Has the biggest work program since this SC covers all electromedical standards that are not in the imaging or radiation space



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60601 relationships

- Particular device standards can override general/collateral standards requirements.
- 60601 was constructed to be a cohesive unit so that particular standards should be in line with horizontal, but if there are deviations, particulars can site them
- This makes particular standards the determining document for a particular device or method



Interesting facts

- “Collateral standards” is a unique term to IEC 60601-1 series
- Within IEC, TC 62 set up first Joint Working Group – IEC/SC 62D with ISO/TC 121/SC 3/JWG 1 on critical care ventilators
- 60601 series is not limited to TC 62 family but to the subject matter



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Current work program

- Many of the Particular standards are being updated to align with the 2020 Amendment of the IEC 60601-1 series.
- Design specification is being finalized for the 4th edition of the IEC 60601-1 series and revision work can begin as early as 2023.
- Common base standard for „refurbishment“ of medical (imaging) devices (IEC 63077) – to protect resources and provide more access to safe devices for people



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How to get involved

- Work with your National Committee to be appointed to the working groups/maintenance teams/joint working groups in TC 62 and subcommittees.
- Link to TC62 website. See the subcommittees under structure:

https://www.iec.ch/dyn/www/f?p=103:7:702000852280007::::FSP_ORG_ID,FSP_LANG_ID:1245,25



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Questions?

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