

SL Power 3rd edition Presentation

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Overview of 3rd edition

- > System risk management needs to be managed by the customer.
- Most applications are categorized as:
 - MOOP: Means of Operator Protection
 - MOPP: Means of Patient Protection
- > SL Power provides a COMPONENT risk management at component level is not required
- After June 2012 all Europe medical Safety submissions must be to 3rd edition
- After June 2013 all UL medical Safety submissions must be to 3rd edition
- Products approved to prior editions are still allowed by UL
- > So far, very few power supplies are approved to 3rd edition
- > SL Power has started the 3rd edition upgrade



IEC/EN 60601-1 2nd Ed. and IEC/EN 60601-1 3rd Ed. DIFFERENCES

DESCRIPTION	2 ND EDITION	3 RD EDITION
Earth Leakage Current:	300/500 uA NC, 500/1000 uA SFC	5 mA NC, 10 mA SFC
Temperatures determined using operating ambient:	Components in Table XA at highest ambient and components in Table XB corrected for 25 C ambient.	All components tested for highest ambient.
Temperature for accessible surfaces:	Less stringent	More stringent
Dielectric test voltage determined using :	Vrms: Less stringent.	Vpk or Vdc: More stringent with switch-mode power supplies.
Creepage and clearance	More stringent and no interpolation allowed.	Same for MOPP, but MOOP is less stringent (based on 60950-1 requirements). Interpolation is permitted for creepage requirements for MOOP and MOPP.
Clearance for operating altitude:	Clearance table for up to 3000 m.	Clearance table for MOOP for up to 2000 m, and 3000 m for MOPP. Multiplication factors added for higher altitudes up to 5000 m using Table 8.



IEC/EN 60601-1 2nd Ed. and IEC/EN 60601-1 3rd Ed. DIFFERENCES Continued

DESCRIPTION	2 ND EDITION	3 RD EDITION
Enamel coating on magnet wire in transformers:	Considered as providing 1 mm creepage.	Insulation not considered.
240 VA Limit for Accessible Part (Output):	Not applicable.	Added requirement.
Y1 & Y2 type capacitors:	1-Y2 considered as Basic insulation from Primary to Ground; 2-Y2s in series or 1-Y1 considered as Double/Reinforced insulation.	MOOP: 1-Y2 considered as 1-MOOP (Basic insulation); 2-Y2s in series or 1-Y1 considered as 2-MOOPs (Double/Reinforced insulation). MOPP: 1-Y1 considered as 1-MOPP (Basic insulation); 2-Y1s in series considered as 2-MOPPs (Double/Reinforced insulation). NOTE: Use of Y2 type is not acceptable for MOPP.
Attention, consult Accompanying Documents Symbol		i



SL Power Timeline

- > SLPE will have all standard products developed in the last 2 years validated to 3rd edition MOOP by end Q4. (90% should qualify)
 - MINT1065 received approval expected
 - Priority list for 3rd edition upgrade has been generated and estimated approval dates are slated accordingly
- > If the SYSTEM requires MOPP a redesign may be necessary with the attendant testing. This is due to constructional / isolation requirements.
- **Legacy products need to be analyzed to match customer application and requirements.**



EN60601-1 3rd Edition Summary

- > EN60601-1 3rd edition is a <u>system</u> specification
- > Four questions We need to know details about the customer's application:
 - AC Grounding class I or class II
 - MOOP or MOPP
 - If MOPP isolation "B", "BF" or "CF"
 - Touch temperature in customer's system



Thank you!

