



# **SL Power 3<sup>rd</sup> edition Presentation**

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# Overview of 3<sup>rd</sup> 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 3<sup>rd</sup> edition**
- **After June 2013 all UL medical Safety submissions must be to 3<sup>rd</sup> edition**
- **Products approved to prior editions are still allowed by UL**
- **So far, very few power supplies are approved to 3<sup>rd</sup> edition**
- **SL Power has started the 3<sup>rd</sup> edition upgrade**

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

DESCRIPTION	2 <sup>ND</sup> EDITION	3 <sup>RD</sup> EDITION
<b>Earth Leakage Current:</b>	300/500 uA NC, 500/1000 uA SFC	5 mA NC, 10 mA SFC
<b>Temperatures determined using operating ambient:</b>	Components in Table XA at highest ambient and components in Table XB corrected for 25 C ambient.	All components tested for highest ambient.
<b>Temperature for accessible surfaces:</b>	Less stringent	More stringent
<b>Dielectric test voltage determined using :</b>	Vrms: Less stringent.	Vpk or Vdc: More stringent with switch-mode power supplies.
<b>Creepage and clearance</b>	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.
<b>Clearance for operating altitude:</b>	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 <sup>ND</sup> EDITION	3 <sup>RD</sup> EDITION
<b>Enamel coating on magnet wire in transformers:</b>	Considered as providing 1 mm creepage.	Insulation not considered.
<b>240 VA Limit for Accessible Part (Output):</b>	Not applicable.	Added requirement.
<b>Y1 &amp; Y2 type capacitors:</b>	1-Y2 considered as Basic insulation from Primary to Ground; 2-Y2s in series or 1-Y1 considered as Double/Reinforced insulation.	<p>MOOP: 1-Y2 considered as 1-MOOP (Basic insulation); 2-Y2s in series or 1-Y1 considered as 2-MOOPs (Double/Reinforced insulation).</p> <p>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.</p>
<b>Attention, consult Accompanying Documents Symbol</b>		

# SL Power Timeline

- **SLPE will have all standard products developed in the last 2 years validated to 3<sup>rd</sup> edition MOOP by end Q4. (90% should qualify)**
  - MINT1065 received approval expected
  - Priority list for 3<sup>rd</sup> 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 3<sup>rd</sup> Edition Summary

- EN60601-1 3<sup>rd</sup> edition is a system 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!**