

## DECISION SHEET

<b>Standard(s)- (year and edition):</b> IEC 60601-1:1988 Ed.2 Am1+Am2	<b>Sub clause(s):</b> 10.1 10.2	<b>Sheet n°:</b> <b>DSH-413</b>
<b>Subject:</b> Environmental conditions specified by the manufacturer	<b>Key words:</b> Environmental conditions	<b>Confirmed by CTL at its 39<sup>th</sup> meeting, in Cologne</b>
<p><b>Question:</b></p> <p>Compliance with the conditions of 10.2 is checked by application of this standard. 10.1 is no longer included in Amendment 2 of 601-1 replaced by "EQUIPMENT shall be capable, while.....environmental conditions as stated by the manufacturer (see 6.8.3 d))".</p> <p><b>Decision:</b></p> <p>EQUIPMENT shall comply with the requirements of this Standard after being exposed to the environmental conditions specified by the manufacturer.</p> <p>Compliance may be checked by testing and/or inspection of documentary evidence.</p> <p><b>Explanatory notes:</b></p> <p>Instead of "EQUIPMENT shall be capable...", we should read something like: After packing, transport and storage, the EQUIPMENT shall be in compliance with the standard. Sub-clause 10.1 does not contain any therefore we recommend that a compliance paragraph should be added. Further work is needed.</p>		