

# DECISION SHEET

<b>Standard(s)- (year and edition):</b> IEC 60601-1:1988 Ed.2 Am1+Am2	<b>Sub clause(s):</b>	<b>Sheet n°:</b> <b>DSH-412</b>
<b>Subject:</b> Detection of fault	<b>Key words:</b> SFC, detection, fault	<b>Confirmed by CTL at its 39<sup>th</sup> meeting, in Cologne</b>
<p><b>Question:</b></p> <p>Shall a fault which remains undetected be considered a NORMAL CONDITION (NC) or a SINGLE FAULT CONDITION (SFC)?</p> <p>If every fault is considered as SFC, regardless of whether it is detected or not, the consequence will be that there is no protection required against situations where an undetected first fault is followed by a second fault which may cause a SAFETY HAZARD.</p> <p><b>Decision:</b></p> <p>If a fault is not detected (for example by periodic inspection, maintenance, auto test, etc...), it shall not be considered as a SINGLE FAULT CONDITION.</p> <p>Time periodicity for the detection of fault depends on the risk analysis</p> <p><b>Explanatory notes:</b></p> <p>See Annex A 3.6 d), a single fault is discovered and remedied by periodic inspection and maintenance which is prescribed in the instructions for use.</p> <p>Also auto test when switching on can check the protective device.</p> <p>A faulty condition becomes a SFC when detected. Reaction time after a SFC (when detected) should also be taken into account</p>		