The microstim was originally designed in MRI by a team of Medical Physicist Technicians headed by Malcolm Purnell.

CE marking did not exist.

ISO 9000 (BS5750) was not in operation and it was not until the mid 1990's that MRI obtained ISO900 for design.

The current microstim file can therefore only be re-written as a product already designed & manufactured with a 10 year track record before the current legislation

I believe we can only update the file as long as we do not falsify information not originally existing.

1) We can update safety
   Essential requirements
   Change to design etc.

2) We can complete the risk assessment assessing we were starting now but still endeavour with the current design. Unless the current product is "unsafe"

3) EMC. We the product was designed pre EMC legislation but was tested clinically in severe EMC conditions i.e. Theatre. We need to confirm that the existing rationale is still holds

4) New information can be added to the file so long as it adds to its value and does not have the effect of reducing product credibility. This would ordinarily mean a product withdrawal & re-design. Probably not economic.

06/06/03