MHRA Electrical Guidance for Clinical Investigations

**Scope.** This document aims to provide basic supporting explanatory guidance for devices that are electrically powered but it is not prescriptive.

MHRA recommends that a Clinical Investigation application includes a separate document that is submitted for electrical safety and electromagnetic disturbances (EMC and EMI).

The document should include the following sections -

1. **Device Description**
   Electrical terms must be used for our assessors. Block diagrams are welcomed to save lengthy paragraphs.

   This should include electrical voltage and class (I, II, SELV or Battery).

   Applied Part details along with any patient isolation design methods.

   Details of protective or functional earth conductors. Circuit diagrams are always welcomed and should show how the functional earth connects to the protective earth.

   Any relevant mechanical build specifications should also be included.

2. **Device Specification**
   Electrical Ratings especially the technical details of any mains PSU that has been bought “off the shelf” and has a compliant Means of Patient and Operator Protection.
Standards Complied with – minimum of IEC 60601-1 and IEC 60601-2-10 (EMD). List any other relevant IEC standards.

3. **Foreseeable Risks and the mitigation methods.**
   a. One example is liquid ingress and how the device is sealed.
   b. EMI.
   c. Devices that use electrical energy as part of the actual treatment or have a connection to the patient that enters the vascular system, are deemed higher risk so a detailed application is required.

4. **Verification and Testing Methods and details of the test facility.**
   a. The tests should include the SELV power supply.
   b. Details of relevant leakage tests.
   c. The test plan for the EMD testing should include the environment the device will be used in.
   d. MHRA recognises that battery powered devices do not have as many compliance requirements with IEC60601 compared with mains powered devices. The battery charger needs to be explained along with any interlocks.
   e. Any battery powered device may have the inherent safety compromised with a data cable to a laptop so this should be considered.
   f. Ensure the UK mains lead and 13A plug is compliant. This is often overlooked with devices already submitted for trials in Europe or the USA.

5. **UK Mains Supply – Specific Requirements for Medical Devices**
   a. If the risk of mains disconnection means a risk to the patient, the instructions for use (IFU) must indicate that the device is used in a medical IT socket.
b. If the risk of mains failure means a risk to the patient, then the IFU shall indicate the requirement for an uninterruptable power supply.

c. If the device has a PE connection point, the device shall be supplied with a potential equalising conductor because it is part of the device and defined within IEC 60601-1.

   a. Ideally, the application should include a checklist of applicable clauses within IEC 60601-1 with an associated justification compliance column.