

## Role and Responsibilities of the Authorising Engineer for Medical Devices AE (MD)

### 1.0 Role of the Authorising Engineer MD

The Authorising Engineer MD / AE (MD) will act as an independent professional adviser to the healthcare organisation. The AE (MD) should be appointed by the organisation with a brief to provide services in accordance with the relevant legislation and guidance in accordance with the Medicines and Healthcare Products Regulatory Agency and other statutory requirements.

The AE (MD) will act as an assessor and make recommendations for the appointment of Authorised Persons, monitor the performance of service to which the AE (MD) is appointed and provide an annual report to the Designated Person.

Effectively carry out this role, particularly with regard to audit, the AE (MD) should remain independent of the operational structure of the healthcare organisation. The roles and responsibilities are set out in more detail below.

Healthcare organisations should ensure that where facilities are provided under a PFI (Private Finance Initiative) or other similar provision models, a clear understanding exists on the role and duties to be carried out by each party

The Authorising Engineer should be qualified to meet the membership requirements of Member or Fellow grade of the Institute of Healthcare Engineering and Estate Management (IHEEM) and have at least 10 years' experience in at least one of the following areas:

- Operational Management
- Auditing management systems
- Risk Assessment
- Design of MD Systems
- Project Management
- Statutory Enforcement
- Other related MD Health and Safety experience
- Auditing

The AE (MD) should be registered on the Register of Authorising Engineers AE (MD) maintained by the Institute of Healthcare Engineering and Estate Management (IHEEM), and will be bound by its Code of Conduct.

## **2.0 The Responsibilities of the Authorising Engineer AE(MD)**

- a) The AE (MD) will be required to advise healthcare organisations of the relevant standards relating to the safe management of MD systems.
- b) Providing advice and support to the Healthcare Organisation to ensure:
  - Full risk assessments and procedures on all MD systems have been carried out and are documented.
  - Healthcare Organisation has in place a suitable and sufficient MD safety policy.
  - Contingency plans are in place to manage any MD incidents.
  - Healthcare Organisation has in place an MD Safety Group with representation from the relevant departments including Estates, Facilities. The AE (MD) should be a member of this Group.
- c) Assess and make recommendations to the Designated Person of the healthcare organisation to appoint sufficient Authorised Persons (MD) to provide the necessary arrangements for the safe management of MD systems installed in that organisation.
- d) Define the exact extent of the systems and installations for which each Authorised Person AP (MD) has responsibility for and where appropriate any part of the system which is excluded from the Authorised Persons' responsibility.
- e) Maintain a register of all Authorised Persons - AP (MD).
- f) Ensure the candidates for appointment as Authorised Person – AP (MD)
  - i) Satisfy the qualification requirements.
  - ii) Satisfy the training and familiarisation requirements
  - iii) Can demonstrate adequate knowledge of each system installation and type of equipment for which authorisation is sought.
  - iv) Has satisfied the AE (MD) as to their competence and ability.
- g) The AE (MD) makes the necessary recommendations for the appointment of the AP (MD) to the Designated Person. The Designated Person issues a letter of appointment on behalf of the Healthcare Organisation to appoint the AP(MD). The Authorising Engineer AE (MD) on appointment of the AP (MD) issues a certificate valid for a period not exceeding three years.
- h) At the request of the Designated Person initiate and co-ordinate the investigations of reported injuries and dangerous occurrences involving MD Systems within the remit of the AE (MD) responsibility. The AE (MD) working with the organisation's risk management team and other statutory bodies shall make a report together with recommendations to the Designated Person of the organisation.
- i) Advise the Designated Person of any amendments to Legislation and Guidance and the implications of the changes.
- j) Ensure there is a system in place to notify and circulate relevant information which will include the notification of any defects or operational restrictions issued by a manufacturer, supplier or distributor, the statutory agencies and the NHS reporting agencies.

- k) Obtain written approval from the responsible person for any exceptions or deviations from the general rules or requirements applicable to specific items, systems, or locations.
- l) At random intervals not exceeding twelve months, the AE (MD) is to carry out an audit of the healthcare organisations' MD management systems. The audit should pay particular attention to:
  - Operating records of the MD systems under their management including permit to works / contractors, management databases, operational policies and procedures, equipment maintenance, MD testing results and subsequent action plans, incident records, back up systems, UPS and IPs systems and test equipment.
  - Identification of any training and development needs.

The reviews shall include a one to one meeting with the Organisation's Authorised Person(s) AP (MD). The outcome of the reviews to be formally documented and a copy held by the AE (MD) and copies provided to the Designated Person and the AP (MD).