

Registration Requirements: Authorising Engineer Medical Devices (MD)

Introduction

1.1 Medicines and Healthcare products Regulatory Agency (MHRA) Managing Medical Devices (2021) - Guidance for health and social care organisations, outlines a systematic approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices. Monitoring the organisation's performance on medical device management is important to minimise or eliminate risks to patients and staff. The CQC will inspect against their Essential standards of quality and safety. Healthcare organisations should consider benchmarking their management of medical devices with other healthcare organisations. An audit report should be submitted to the board.

1.2 Chapter 2 (MHRA 2021) - Systems of Management - Healthcare organisations should appoint a director or board member with overall responsibility for medical device management. Healthcare organisations should set out a long-term approach and objectives for the management of their medical devices, including strategic replacement and development equipment procurement planning. This should include an overarching medical devices management strategy setting out medium to long term organisational requirements of assets taking account of cost, performance and risk across the entire equipment lifecycle. This strategic approach should also align with the responsible organisations overarching business / strategic plan. Accurate and complete copies of records in paper or electronic form are required to be made available for future inspection, review and copying e.g. for CQC, internal audits, traceability, investigations.

1.3 IHEEM maintains a register of Authorising Engineers (MD). The responsibility for maintaining the register within IHEEM is through the AE (MD) Registration Board, which is described in the Terms of Reference for that Group, held by the Institute. The Registration Board is also responsible for the publication of an AE (MD) Code of Conduct, the investigation of complaints, the endorsement of appropriate training courses, registration of new AE (MD), periodic re-registration of AE (MD) and general management of the register.

1.4 This document outlines the registration matters of AE (MD), new entrants to the scheme and re-registration procedures for those already registered. The registration procedure will be transparent and controlled.

1.5 Acceptance onto the register will be undertaken by successful completion of an application form together with a Practice Report, and a Professional Review, whereby a satisfactory level of professional competence including work experience and CPD will be assessed.

AE (MD) Registration

2.1 The following criteria will apply for registration as an AE (MD):

The applicant must be either:

- i) Member of IHEEM at Fellow or Member level
- ii) Chartered Engineer, or an Incorporated Engineer, or equivalent professional experience with a minimum of 10 years with practical and relevant technical engineering knowledge and experience in MD systems to current standards (supported by a relevant CPD Log or suitable documented evidence).

- a) Have a minimum of 10 years relevant MD systems engineering experience in one or more of the following areas:
- i. Operational Management
 - ii. Auditing management systems
 - iii. Risk Assessment
 - iv. Design of MD Systems
 - v. Project Management
 - vi. Statutory Enforcement
 - vii. Other related MD Health and Safety experience.
- b) Have completed an appropriate AP (MD) course and passed the Authorised Persons training courses within 3 years prior to application.
- c) Have completed an AE Course (CPD Certified) within the previous three years or six months for first registration.
- d) Have completed health and safety, and fire safety training.
- e) Have completed a recognised emergency first aid training course within the last three years.
- f) Undergo a professional interview by the AE (MD) Panel.
- g) Submit a Practice Report of approximately 2000 words + appendices outlining the experience and type of work carried out.
- h) Submit a separate CPD log.
- i) Agree by signature to adhere to AE (MD) Code of Conduct

2.2 The Registration Panel of the AE (MD) Registration Board can recommend further actions regarding education and training as deemed necessary before the applicant is accepted onto the register. These recommendations could be in the form of mentoring by an existing AE(MD), or gaining further experience at management level in the MD field.

Re-registration of AE (MD)s

3.1 All registrants will be reviewed by the Registration Board every 3 years.

3.2 The registrar will inform each registrant at least 4 months prior to the review date to request the re-registration documentation.

3.3 Each registrant must submit to the AE (MD) Registration Panel sub-group the following:

- a) Documentary evidence or a CPD log showing a minimum of 30 hours of CPD annually
- b) A written professional review of the registrant's activity summarising the period since last registration; the review should be on one side of A4.
- c) Collectively, these documents should adequately demonstrate:
 - i. Awareness and application of current MD systems standards and practices and related health and safety issues.
 - ii. On-going development of knowledge and skills.
 - iii. Routine decision-making and accountability criteria associated with MD systems under the registrant's control.

3.4 It will be at the discretion of the registration panel to call the registrant to an interview if the documents submitted for re-registration do not meet the criteria outlined above.

4. CPD objectives for AE (MD)

4.1 All AE (MD)s should have a clear understanding of current strategies and techniques in MD systems and an appreciation of how and when to apply them in practice. This will include the ability to make judgements about the areas of MD systems in their designated field and take responsibility for their decisions and actions.

4.2 A yearly IHEEM AE (MD) Panel endorsed seminar session will be available, together with a range of regional presentations, where it is expected that all those on the AE (MD) register will participate and/or attend in order to be kept up to date with the latest procedures, health sector policies (UK wide), new technologies and any new or proposed standards and guidance.

4.3 Documentary evidence or a CPD log showing a minimum of 30 hours of CPD annually.

4.4 CPD may consist of the following categories:

- a) Monitoring and coaching of individuals working with MD Systems.
- b) Knowledge of current legislation, practices and technology associated with MD systems
- c) Attendance at a technical seminar as described above.
- d) Management and Communication, personal skill development, including soft skills.
- e) Keeping updated on knowledge and skills through Seminars and appropriate courses.
- f) Supplementary work and duties, private study, reading and committee work.
- g) Health and safety legislation.

Further guidance for Registration and Subsequent Reviews

The details given in the review process should highlight the activities in areas such as those listed below:

- a) Management of MD Systems.
- b) Reporting and auditing.
- c) Provision of advice to department design/to technical guidance.
- d) Departmental auditing and site assessments.
- e) Appointments of staff or consultants in the process such as AP(MD)
- f) Invitations to join and work on documentation policy/document review groups.
- g) Membership of MD groups or committees.
- h) Attendance of relevant educational or technical seminars.
- i) Setting up and running or presenting at technical seminars.
- j) Managing technical groups of personnel in the MD field.
- k) Educational – presentations on MD policies or procedures, Attendance at technical seminars.
- l) Attendance of technical courses of various disciplines.
- m) Management development courses.
- n) Specialist work, research work or papers written.
- o) Papers published in technical journals.