Chief Medical Officer for Scotland

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

MEDICAL DEVICE REGULATION (MDR) PREPAREDNESS AND NHS BOARD MEDICAL DEVICES POLICIES GUIDANCE

Purpose

1. **To remind all NHS Boards of their requirement to have a Board Medical Device Policy by 31 March 2025.**

2. This guidance has been developed to support NHS Boards in their existing requirement to have in place a Board Medical Device Policy as instructed in CEL35(2010). This guidance provides a checklist, a template, and an example Terms of Reference (ToR) for a local Medical Device Committee to assist in this development.

Context

3. All NHS Boards are required to have a Board Medical Device Policy as described in CEL35(2010). This should provide an organisational wide policy on the safety and governance of medical devices and include the management of medical devices and the Board system in place to ensure that all risks associated are minimised.

4. As outlined in CMO Letter 2024(1) "MDR Preparedness and Medical Devices Policy Framework and Action Plan 2024-26", key to Board preparedness for the current and future MDR requirements is an effective Board Medical Device Policy that will provide assurance for Boards of implementation of the new regulations.

5. The Scottish Government Medical Devices and Legislation Unit (MDLU) has worked with NHS Boards and key stakeholders to develop a checklist and guidance to support Boards to develop their local medical devices policies. These should provide a foundation for assurance of their management of medical devices, compliance with regulatory requirements and integrate with other Board safety and governance structures, as they form part of a wider governance system.

From the Chief Medical Officer for Scotland
Professor Sir Gregor Smith

30 September 2024

SGHD/CMO(2024)17

Addresses

For action
NHS Board Chief Executives
NHS Board Chairs

For information
NHS Board Executive Directors responsible for medical device policies
NHS Boards, Chairs, Medical Device Committees
NHS Board Medical Directors
NHS Board Directors of Estates and Facilities
NHS Board Nurse Directors
NHS Board AHP Directors
NHS Board Healthcare Science Leads
NHS Board Clinical Engineering Leads
NHS Board Digital Leads
Scottish Technical Managers Group
National Medical Devices Committee

Enquiries to:

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6. The Board Medical Device Policy and its governance structure is vital in providing Boards with assurance that they are able to comply with changing regulation and provides the mechanism for local risks to be identified and managed.

7. Specific areas within Board Medical Device Policies may require a longer period to complete implementation but a start to this improvement journey will be to have a policy and a system of management to provide assurance to their Board by 31 March 2025.

Summary

8. The Board Medical Device Policy should provide a high-level framework of how governance, systems of management and Board policies and procedures will work together to deliver safe and effective management of medical devices.

9. The Board Medical Device Policy checklist (Annex A) has been developed to provide a clear statement of key areas to be considered in the development of an effective Medical Device Policy.

10. The Board Medical Device Policy Template and Guidance (Annex B) has been developed as a guide on how to structure a Medical Devices Policy. Local variations are anticipated as each health board will be structured slightly differently and the policy must be crafted to meet the assurance requirements of the Board. An example of a Board Medical Devices Committee Terms of Reference is provided in Annex C.

Board Chairs of Medical Devices Committee Group

11. An NHS Board Chairs of local Medical Devices Committee Group is being established. The intention is that this Group will meet regularly to share learning in relation to Medical Devices Policy developments at national and local level, including MDR. This Group will also help to better understand local challenges and opportunities that can be considered by the national Medical Devices Committee which is co-chaired by the Chief Medical Officer and Gordon James, on behalf of NHS Board Chief Executives.

Education and Training Resources available

12. National education and training learning modules to support the safe use of medical devices by all health and social care staff, have been developed in partnership with NHS Boards, social care colleagues and IRIC. These are available on the Turas Platform. NHS Boards are encouraged to use these and also to share on this platform, any resources they are able to share to support other Boards.

Monitoring and Evaluation

13. A baseline review on the current position of Board Medical Device policies was undertaken by the SG MDLU. This was reported on and discussed by the national Medical Devices Committee who made the recommendation that guidance, now included in this letter, be produced. The baseline position provides a key measurement indicator and will inform further work being planned on the development of a monitoring and measurement framework, for Boards to assess their own progress as outlined in CMO Letter 2024(1) "MDR Preparedness and Medical Devices Policy Framework and Action Plan 2024-26".

Action Required

14. NHS Boards are required to have their Board Medical Device Policy in place by 31 March 2025. Specific areas within Board Medical Device Policies may require a longer period to complete implementation but a start to this improvement journey will be for NHS Boards to have a policy and a system of management to provide assurance to their Board by 31 March 2025.

15. The Board Medical Device Policy should be published within the organisation and on a publicly accessible website.

Yours sincerely

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer for Scotland

Annex A

Medical Device Policy Checklist

The checklist below has been developed to provide a clear statement of key areas to be considered in the development of an effective Medical Device Policy. Further details on individual areas are available within the NHS Scotland Medical Device Policy template (Annex B).

The checklist is based on key areas within existing guidance including MHRA Managing Medical Devices, SHTN 00-04 Safe Management of Medical Devices, CEL 35(2010) and CEL 43(2009).

1. The Board should have published a Medical Devices Policy within the organisation and on a publicly accessible website by 31 March 2025.

2. Boards are encouraged to consider this Medical Device Policy guidance and template when developing or reviewing their Medical Device Policy.

3. All Boards are required to have a designated Executive Director with responsibility for medical devices.

The Board Medical Device Policy should:

4. Clearly define the scope of the policy which should encompass the management of all medical devices including the use of Software as a Medical Device and In-Vitro Diagnostic (IVD) Medical Devices.

5. Clearly describe roles and responsibilities and the system of management that links these roles into a safe and effective solution.

6. Have a governance framework that ensures regular reporting and risk management.

7. Where alternative operational management responsibilities exist for specific medical device categories, these should be clearly detailed.

8. Include a system to train staff to understand and undertake their responsibilities described within the Medical Device Policy.

9. Include a system to monitor and review the application of the Medical Device Policy and associated procedures.

10. Include a regular structured policy review and a process to communicate future changes to the policy.

Annex B

Medical Devices Policy Guidance and Template

Introduction

1. All NHS Scotland Health Boards are required to have a Medical Devices Policy as instructed in CEL 35 (2010).

2. This template has been developed as a guide on how to structure a Medical Devices Policy. It is not definitive - local variations are anticipated as each Health Board will be structured slightly differently and the policy must be crafted to suit. It does, however, suggest some core aspects that should be considered for inclusion in order to form the basis of a good Medical Device Policy. Responsibility for the development, structure and application of the Board Medical Device Policy remains with local Boards governance structures.

3. The Medical Device Policy provides a high level framework of how governance, systems of management and Board policies and procedures will work together to deliver safe and effective management of medical devices. Each organisation will have detailed policies and procedures in related areas such as procurement, infection control etc. There is no requirement to include the detail of these policies within the main Medical Device Policy though it will be valuable to reference them where applicable.

4. In developing the Medical Device Policy, it would be of particular value to refer to SHTN 00-04 "Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Care System" which provides detailed material drawn from key regulation, legal and best practice guidance. Any Medical Device Policy should ensure it covers all stages of the life cycle of a medical device.

5. For the safe management of software as a medical device further guidance is provided in the Management of Software as a Medical Device Guidance – Summary Report, which is published on Turas.

6. Use should be made of diagrams, flow-charts etc where this would aid the understanding of the section being described. Consider using hyper-links when referring to other policies, procedures or organisation web pages and any source material, where it would make it easier for staff to access these items.

Medical Devices Policy Structure

7. **Front Page and Title** –the title should incorporate the term "medical devices". The front page should incorporate the review date of the policy and the appropriate controlled document management information. The review period of this document should not ordinarily exceed 2 years.

8. **Introduction** – here you should state the purpose of the policy, what the policy is, why it is needed, why staff should be aware of it and its relevance to their roles.

9. **Scope** – this section should lay out the breadth of the policy and the services it covers (e.g community services, HSCPs or IJBs) along with any exceptions**.** The policy should describe the management of medical devices throughout the entire medical device lifecycle (Figure 1) and include all medical devices and equipment including digital products that will fall under the definition of Software as a Medical Device (SAMD) or

Artificial Intelligence as a Medical Device (AIaMD). The scope of the intended staff groups for whom this policy is applicable should be documented. In particular, whether this policy applies to health and social care staff who use, provide and/or loan medical devices in a community or care setting.

10. **Definitions** – this section should include definitions for the following;

    Medical Devices
    In Vitro Diagnostic Devices
    Software as a Medical Device and Artificial Intelligence as a Medical Device (AIMD)
    Medical Equipment
    Single Use Devices
    Re-usable Devices

Further information can be found here: SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services (nhs.scot)

11. **Governance and Systems of Management –** the policy should describe how the roles, structures, processes and procedures work across the organisation to deliver safe and effective medical device management. In addition to describing responsibility and accountability it is important to describe how information will flow between respective groups and individuals and how risk is managed. Diagrams will be particularly helpful in this section.

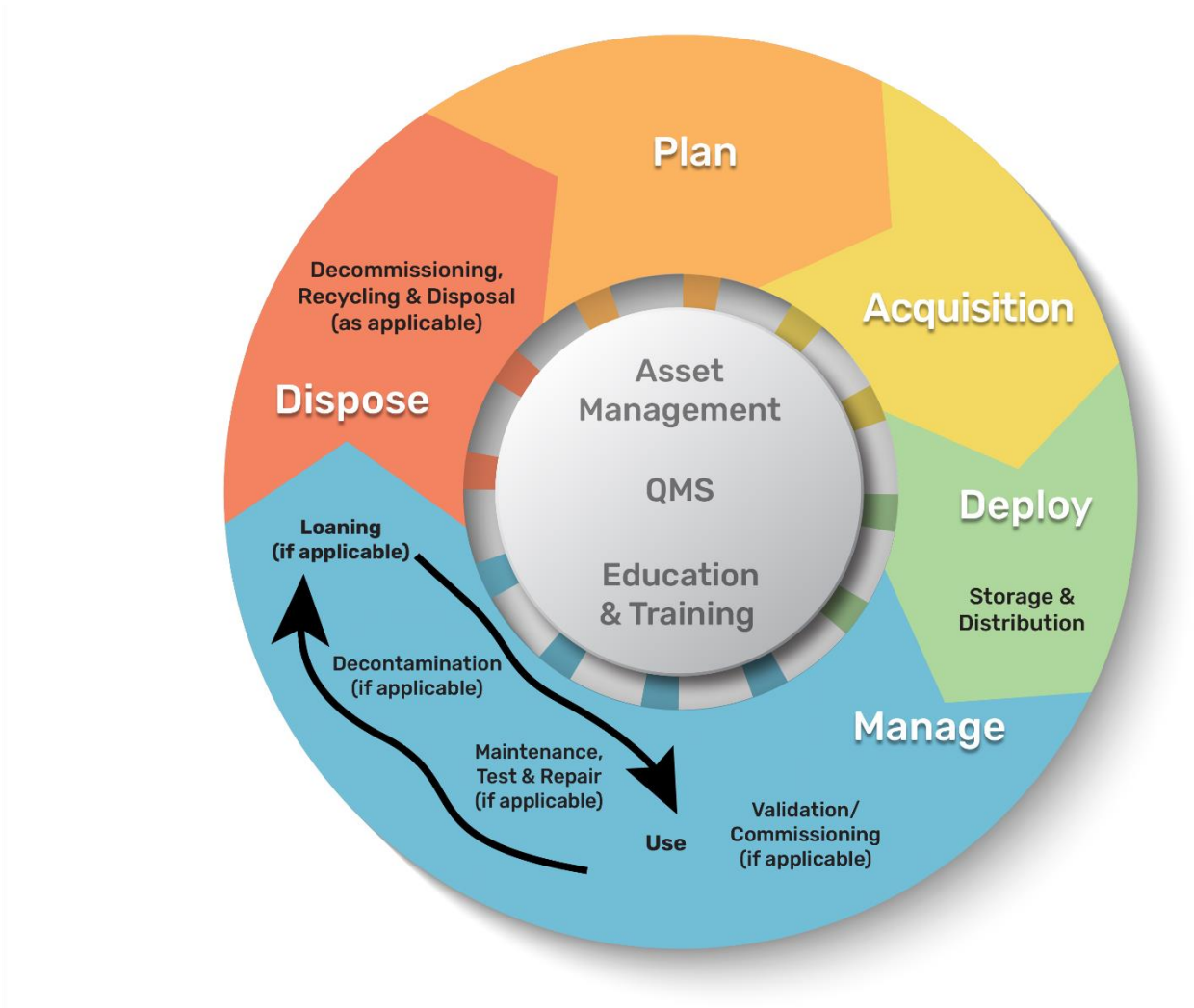
12. **Roles and Responsibilities**: in this section, you should consider the roles that require to be defined within the policy. Depending on your local Health Board structures, these may include;

    • Medical Device and/or Equipment Users
    • Chief Executive
    • Medical Director / person with organisational oversight of clinical care
    • Responsible Executive Director
    • Medical Device and Equipment Risk Managers
    • Incidents and Alerts Safety Officers (previously known as Equipment Coordinator)
    • Departmental Managers
    • Technical Specialists or persons responsible for Devices and Equipment
    • Specialist Multi-disciplinary and Professional Expert Groups
    • Staff who procure medical devices or equipment

    You should also describe the remit, role and responsibility of any committees included in the governance structures.

13. **Equality Impact Assessment (EQIA)** - the policy should undergo an EQIA, and this should be documented within the policy.

The Medical Device Lifecycle



Life Cycle Stage - Plan / Acquire (Figure 1)

14. **Procurement/ Production / Acquisition** – in this section, you should define what is meant by procurement, the procurement process within your own Health Board, including tender exercises, sourcing consumables, planned equipment replacement programmes, revenue purchases and standardisation. You should also describe the processes for equipment procured via other routes e.g. on loan, equipment supplied through consumables contracts and donated equipment. As part of this process, where devices require decontamination, cognisance should be taken of the ability to decontaminate the device using the organisation's existing system, process and equipment in their own facilities. Where innovative technology is being considered you may wish to include how this will be assessed, referencing any external bodies e.g. Scottish Health Technologies Group. The policy should reference Board procedures for the introduction of interventions that are either completely novel or new to the organisation.

Alternative routes:

14. The process for appropriate risk assessment and approval for medical devices that are manufactured, modified or custom made within the Board should be included.

15. For Boards who manufacture devices: Boards who carry out the manufacture of devices should include a section describing the associated controls and processes including the anticipated regulatory requirement for a formal Quality Management System (QMS).

16. For Boards who make custom made devices: Boards who supply patients/clients with custom made devices should include a section describing the associated controls and processes.

17. Modifying or Off-Label use: Modifying or using Medical Devices for purposes not intended by the manufacturer ("off label use") has serious safety implications, and liability may be partly or wholly transferred to the person or organisation making the modifications if the device is implicated in an incident. The processes required for off-label use in exceptional circumstances should be included and aligned to current MHRA guidance. This should detail the requirement for risk assessment, consideration of ethical and legal implications, and approval at an appropriate organisational level.

18. Research and Development Clinical Trials/Investigations: The Board process for the use of medical devices in clinical trials/investigations should be outlined.

Life Cycle Stage – Deploy

19. **Commissioning** – this section should state why there is a commissioning procedure, outline your own local procedure and what devices to which it is applicable**.** It should also state how re-usable medical equipment must be registered on a medical equipment database, how records are maintained and reference any legal requirements relating to the retention of such records. It should also detail how staff may access the acceptance/ commissioning procedure. The policy should include arrangements for medical devices that are used as part of clinical trials or on loan within the organisation as well as equipment that is loaned to patients.

Life Cycle Stage – Manage

20. **Use of medical devices –** Mechanisms for traceability of medical devices particularly re-usable and implantable devices should be documented**.** The appropriate use and importance of Instructions for Use (IFU) and how staff will have access to IFU's should be documented.

Life Cycle Stage – Manage

21. **Training** – The policy should include a description of how training for use of devices is assessed, delivered, and documented where appropriate. The policy should outline requirements for staff to only use devices that they have been trained to use.

Life Cycle Stage – Manage

22. **Repair and Maintenance**– this section should include how re-usable medical devices and equipment will be maintained, including responsibilities of all those involved in the process. It should include reference to any end-user routine maintenance, planned preventive maintenance, calibration and also refer to the systems in place to deal with faulty or damaged equipment. The storage of medical devices should be in accordance with manufacturer's instructions.

Life Cycle Stage – Manage

23. **Incidents and Safety Alerts -** this section should set out the local process for reporting incidents or near misses, including electronic reporting tools, how to escalate serious incidents and reporting to the Incident Reporting and Investigation Centre (IRIC).This section should also describe the process for dissemination of Safety Alerts, including the responsibilities for action and closure.

Life Cycle Stage – Manage

24. **Infection Control, Single Use and Decontamination** – this section should reference any local Infection Control and Decontamination policies, including those on single use devices. It should comply with the relevant Standards, national guidance (SHTN 01 series), National Infection Prevention Control Manual, etc) and manufacturer's recommendations and individuals duty of care to others. It should be clear where advice can be sought.

Life Cycle Stage – Dispose

25. **Decommissioning, Recycling and Disposal** – this section should contain the criteria for de-commissioning, re-cycling or disposal of medical equipment. It should describe the system and also reference any policy on charitable donation. It should also describe the procedure for dealing with equipment that may contain patient identifiable data.

Life Cycle Stage – Monitoring & Compliance

26. **Monitoring of Implementation** – Roles, responsibilities and mechanisms for monitoring the implementation of the processes described in this policy should be outlined. This will include a number of different groups and the use of a table or diagram would be helpful.

Other Inclusions

27. **Appendices** – as required. These may include links to related policies, procedures, guidance and regulation.

28. **References** – Source information should be recorded in this section and where possible, should contain hyperlinks to those documents.

Annex C

EXAMPLE OF BOARD MEDICAL DEVICES COMMITTEE (MDC) – TERMS OF REFERENCE

Aims/Purpose of Medical Devices Committee

- Provide assurance to the Board that there are systems in place to meet its responsibility to minimise the risks associated with the safe and effective acquisition and use of Medical Devices.
- Ensure that Medical Devices management in the Board complies with relevant regulation, legislation, and guidance.

Accountable to:

The Medical Device Committee (MDC) reports for assurance to ….

Accountability and Delegation

The Medical Devices Committee is chaired by x

It is likely that the Medical Devices Committee (MDC) will delegate responsibility for some aspects of management to appropriate Groups such as:

Examples

- Procurement Prioritisation Group
- Point of Care Testing Committee
- Decontamination Committee
- Medical Devices Training Group
- Scan for Safety Implementation Group
- Net Zero/Circular Economy Group
- Sustainability Group

Where delegation occurs, it should be clear how information will flow between Groups and the MDC and the overall safety governance structure.

Frequency of Meetings

How often the Committee will meet during the year. Include provision there is for extraordinary meetings.

Responsibilities

- Promote the safe use of Medical Devices throughout the Board, providing assurance for the life cycle of all Medical Devices which includes procurement, use, maintenance and disposal by the organisation.
- Implementation and monitoring of the Board Medical Devices Policy and supporting procedures.
- Ensuring Medical Device management in the Board complies with relevant regulation, legislation, standards and guidelines.

- Receive regular reports regarding events (near misses and incidents) involving Medical Devices, working with the Quality Improvement Team to sure that lessons are learned from and avoid recurrences of events.
- Receive regular reports on the decontamination of Medical Devices, through the Decontamination Committee.
- Ensure and monitor training needs of all staff in the safe use of medical devices through the Medical Device Training Group.
- Ensure there are procedures in place to monitor the quality and safety of Point of Care Testing equipment used in the Board through the Point of Care Testing Management Group (sub-committee).
- To define the scope of Point of Care Testing (POCT) provided in the Board taking into account; the clinical need, its financial implications, technical feasibility and the resources available.

Activities of the Medical Devices Committee

- Receive, comment and make recommendations on risk management reports involving Medical Devices;
- Provide expert advice and leadership on serious incidents involving medical devices;
- The activities of the MDC will vary depending on existing safety and governance structures. Boards should consider how they will receive and monitor compliance of Board status with Safety Alerts;
- Review the implementation of national guidance and agree and monitor an annual Medical Devices plan in line with Board strategy;
- Approval of the Board Annual Medical Devices Report;
- Develop and monitor performance indicators to ensure Medical Device activities are effective and progress in a timely manner;
- Provide product selection input for Medical Device procurement, as necessary.

The Medical Devices Committee will oversee and monitor a programme of risk management activities in relation to its specialist responsibilities. This will include a risk identification, review, management and progress/action monitoring of Medical Devices use in the Board.

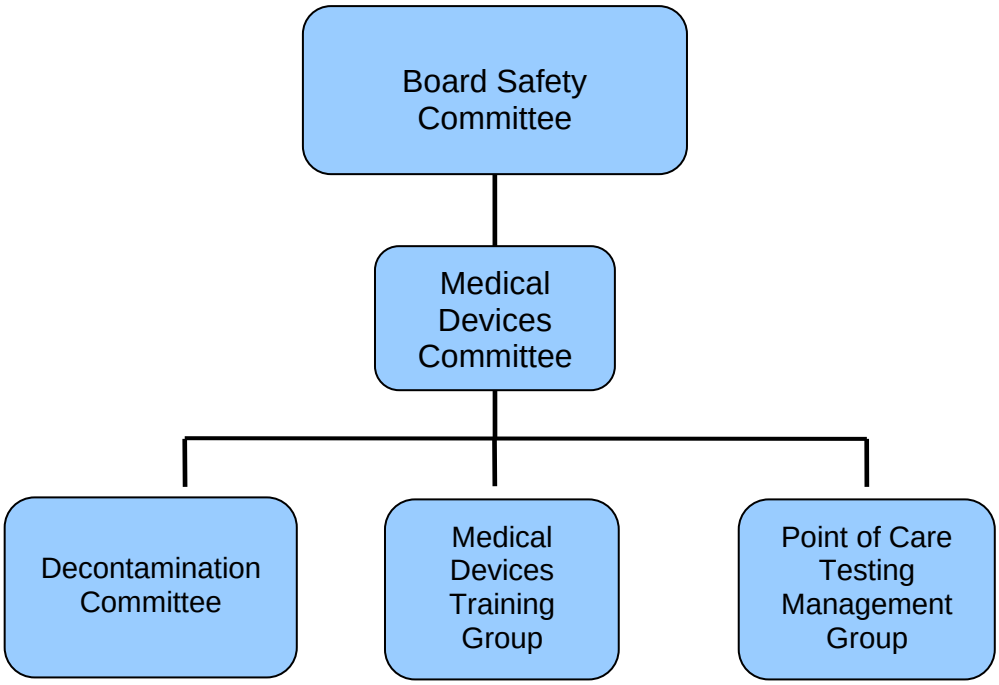
The Medical Devices Committee should work with the Board Safety Committee.

Reporting

The reporting structure for the Medical Devices Committee (MDC) and assurance reporting should be agreed. For example, it could report into the Board Safety Committee, and provide an assurance report twice a year to the Board Safety Committee, or more frequently as requested to do so.

Reporting to the MDC from the sub-committees will also need to be agreed. Each Group should have their own terms of reference.

Example:



The MDC should produce an annual report of activity including its sub-committees.

Membership

Chairperson
Medical Devices & Decontamination Manager and/or Infection Control Manager
Incident and Alerts Safety Officer
Clinical Engineering
eHealth
Director of Procurement
EBME Manager
Health & Safety Manager
Medical representation
Nursing representation
Medical Devices Training Lead
Point of Care Testing Lead
Renal Services Manager
Head of Estates
Community Services Representative
Governance Officer, Medical Devices

Patient/ Public Participation

Boards should consider patient/public representation within their local Board MDC or how alternative mechanisms ensure they have access to patient input for medical device safety.

Declaration of Interests

All Committee members should complete a Declarations of Interest form and the outcome noted and kept updated.

Secretariat Function

Secretariat for the Medical Devices Committee will be provided by x.

Minutes of meetings and an Action Log should be produced.

- The minutes should be concise and include all decisions made by the Committee and at least a concise summary of all discussions,
- The minute should refer to the papers as appropriate, the meeting papers will not be summarised / reproduced in the minutes.

Quorum

The Committee should be quorate when a minimum of 60% of the membership is present. Deputies can attend on behalf of members and count towards the quorum.

All papers submitted to the Committee must be presented by a member of the Committee or a speaker invited by the Committee.

Review of Medical Devices Committee and membership

Date of last review and next planned review.