

# Chapter 5: Approved Bodies

## Section 22 - General background

### Background

22.1 An Approved Body is an organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations).

22.2 Under the current regulations, when a manufacturer wishes to place a UKCA marked medical device on the market, that device is required to undergo an assessment (conformity assessment) to ensure it meets relevant regulatory requirements. Excluding class I medical devices without sterile/measuring functions and general IVDs, the conformity assessment must be undertaken by an Approved Body. The Approved Body will assess the medical device and the Quality Management System of the manufacturer (see Chapter 3, Section 11) to ensure they are meeting the requirements of the UK medical devices regulations. If they are satisfied that the manufacturer and the medical device meet the relevant requirements, the Approved Body will issue a 'Certificate of Conformity' which is required to place the medical device on the market. Once the certificate has been issued, the Approved Body monitors both the device and the manufacturer for the lifetime of the certificate to ensure they remain compliant with all regulatory requirements.

22.3 An organisation can apply to the MHRA to become an Approved Body. The MHRA assesses organisations to ensure they can meet the relevant requirements (see Section 21). Following an assessment of an organisation's application, a designation audit is undertaken, and completion of any corrective actions identified as a result of that audit are verified. When the MHRA is satisfied that the candidate Approved Body meets the requirements and has verified all associated actions taken by the Approved Body, the MHRA will designate that organisation as an 'Approved Body' for a maximum period of five years. The MHRA monitors Approved Bodies on an ongoing basis to ensure they can continue to meet these requirements.

## Section 23 - Requirements of Approved Bodies

### Background

23.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) set out the high-level criteria that Approved Bodies must meet to be designated by the MHRA. For example, Approved Bodies must demonstrate the

necessary competence, experience and facilities required to perform the assessment of medical devices. Further detail is provided for in Regulation 920/2013.

23.2 The UK medical devices regulations could set out more detailed requirements for Approved Bodies to drive improvements in their operation and ensure that they have the facilities, resources and procedures to effectively assess medical devices and the manufacturer's Quality Management System (QMS). This would also help to ensure harmonised standards across all Approved Bodies.

### **Possible Changes and Questions**

23.3 The MHRA considers that the UK medical devices regulations could place more stringent requirements on Approved Bodies to improve patient safety by improving the standards applied across all Approved Bodies. These requirements could cover:

- a. Organisational structure  
*for example, the Approved Body should document its organisational structure and the functions, responsibilities, and authority of its top-level management*
- b. Independence and impartiality  
*for example, the Approved Body should document and implement a structure and procedures for safeguarding impartiality. Such procedures shall provide for the identification, investigation, and resolution of any case in which a conflict of interest may arise, including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented*
- c. Liability  
*for example, the Approved Body should take out appropriate liability insurance for its conformity assessment activities, the scope and overall financial value of the liability insurance should correspond to the level and geographic scope of activities of the Approved Body and be commensurate with the risk profile of the medical devices certified by the Approved Body*
- d. Quality management  
*for example, the Approved Body should establish, document, implement, maintain and operate a Quality Management System that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of the UK medical devices regulations*
- e. Personnel (including requirements for personnel qualifications)  
*for example, the UK medical devices regulations could set out the minimum qualification requirements for personnel involved in medical device assessments and manufacturer QMS assessments*
- f. Process requirements

*for example, the Approved Bodies should have documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the medical devices.*

**Q23.1 Do you think the UK medical devices regulations should place more stringent requirements on Approved Bodies as set out in paragraph 23.3? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q23.2 Please outline any other requirements which should be introduced for Approved Bodies.**

23.4 The MHRA considers that the UK medical devices regulations could also be amended to define that Approved Bodies may conduct audits of their clients either partially or fully remotely. Fully remote audits could be used in specific circumstances - for example where there are restrictions to international travel / safety concerns due to a pandemic or civil unrest. 'Hybrid' audits, where some elements are completed onsite and others remotely, could potentially be allowed more generally. Hybrid audits, with appropriate technology, have the potential to maximise some of the benefits of remote working, whilst retaining onsite scrutiny where this is necessary.

**Q23.3 Do you think that Approved Bodies should be able to conduct fully remote or hybrid audits of their clients in specific circumstances, as outlined in paragraph 23.4? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q23.4 If you answered 'yes' to question 23.3 please outline any criteria you consider should apply to the use of remote and hybrid audits, and the expected impact of this change including any key implementation considerations that need to be considered.**

23.5 Currently, the UK medical devices regulations set out that the Secretary of State (the MHRA) may designate "any corporate or other body" to carry out the tasks of an Approved Body. This term is very broad and does not give meaning to the required location or legal status of the body. The MHRA considers that Approved Bodies should have a meaningful presence in the UK - for example with key roles physically based in the UK. Requiring a UK Approved Body to have a distinct legal presence in the UK would help to ensure that the legal liability rests with the UK entity as opposed to an overseas organisation, which would help to provide clearer lines of liability for both the manufacturer and from a patient safety perspective. There are a range of options for the legal status for an Approved Body including that the Approved Body is a distinct legal entity based in the UK e.g. a private limited company, or a UK establishment of an overseas company.

**Q23.5 Please select the option you agree with:**

**To become designated as an Approved Body the company/organisation:**

**a. should be a distinct legal entity based in the UK (the company as a whole)**

- b. should be a distinct legal entity based in the UK or have a branch in the UK
- c. other (please specify)
- d. don't know/no opinion

**Q23.6 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 23.1-23.5, including any impacts on you or other stakeholder groups.**

## Section 24 - Subsidiaries

### Background

- 24.1 Approved Bodies can have subsidiaries in place to fulfil tasks in relation to their conformity assessment activities. A subsidiary is a company controlled by a “parent” or “holding” company, in this case the Approved Body.
- 24.2 Currently, the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not set out specific requirements which must be met by subsidiaries.
- 24.3 The UK medical devices regulations could set out requirements for subsidiaries to ensure appropriate and transparent regulation of these organisations.

### Possible Changes and Questions

- 24.4 The MHRA considers that the UK medical devices regulations could be amended to incorporate more visibility of Approved Bodies using subsidiaries, including a list of the location of each subsidiary. This could also include the requirement for Approved Bodies to:
- a. publish high level monitoring activities undertaken relating to subsidiaries
  - b. publish a list of subsidiaries accompanying the designated scope of the Approved Body

**Q24.1 Do you think that Approved Bodies using subsidiaries should meet the requirements set out above? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q24.2 Please outline any other requirements which should be placed on Approved Bodies using subsidiaries.**

**Q24.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 24.1-24.2, including any impacts on you or other stakeholder groups.**

## Section 25 - Approved Body designation and monitoring

### Background

25.1 The relevant processes for designation and monitoring of Approved Bodies are set out in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) and Regulation 920/2013. MHRA currently uses this legislation to assess applicants and audit existing Approved Bodies.

25.2 The UK medical devices regulations could be amended to place additional requirements for the designation and monitoring of Approved Bodies to improve transparency of MHRA and Approved Body activity and to provide more clarity on MHRA procedures in the event that an Approved Body designation is withdrawn, restricted or suspended.

### Possible Changes and Questions

25.3 The MHRA considers that the UK medical devices regulations could be amended to require Approved Bodies, applying for designation to have United Kingdom Accreditation Service (UKAS) accreditation.

**Q25.1 Do you agree that the UK medical devices regulations should require Approved Bodies applying for designation to hold appropriate UKAS accreditation? ('Yes' / 'No' / 'Don't Know/No Opinion')**

25.4 The MHRA considers that the UK medical devices regulations could be amended to include new requirements for MHRA assessment of Approved Bodies. This could include a requirement for MHRA to perform a complete re-assessment of an Approved Body sooner than 5 years after designation (current requirement) where there is sufficient justification e.g. where concerns are raised regarding that Approved Body.

**Q25.2 Do you think the UK medical devices regulations should include the requirements set out in paragraph 25.4 for MHRA assessment of Approved Bodies? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q25.3 Please outline any other requirements which should be introduced for MHRA assessment of Approved Bodies.**

25.5 The MHRA considers that the UK medical devices regulations could also be amended to provide that the MHRA's audit of an Approved Body or their subsidiaries, may be conducted partially or fully remotely, in specific circumstances for example where there are restrictions to international travel / safety concerns due to a pandemic or civil unrest.

**Q25.4 Do you think that the MHRA should be able to perform remote audits of Approved Bodies or their subsidiaries in specific circumstances? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q25.5 If you answered 'yes' to question 25.4, please outline any criteria you consider should apply to the use of remote audits, and the expected impact of this change including any key implementation considerations that need to be taken into account.**

25.6 The MHRA considers that the UK medical devices regulations could set out that Medical Device and Active Implantable Medical Device Approved Body designations issued prior to July 2023 could be 'rolled over' until expiry of the designation. In this event, Approved Bodies would be expected to be in compliance 6 months ahead of the implementation date in July 2023. The MHRA would conduct an assessment of the Approved Body to review their records, systems, procedures and processes to ensure readiness and compliance with the relevant new requirements ahead of the implementation date.

**Q25.6 Do you think the transitional arrangement above for 'roll over' of Medical Device & Active Implantable Medical Device Approved Body designation is suitable? ('Yes' / 'No' / 'Don't Know/No Opinion').**

**Q25.7 Please explain your reasoning to question 25.6 and expand on what you consider would be suitable criteria for this 'roll over' if any.**

25.7 The MHRA considers that the UK medical devices regulations could be amended so that in the event that the MHRA withdraws, restricts or suspends an Approved Body designation, the MHRA would be required to:

- a. assess the impact on the certificates issued by the Approved Body
- b. require the Approved Body to suspend or withdraw, within a reasonable period of time determined by the MHRA, any certificates which were unduly issued to ensure the safety of medical devices on the market
- c. ensure the certificates are marked as suspended or withdrawn on the MHRA registration system (see Chapter 4 on registration).

**Q25.8 Do you think that the MHRA should be required to perform the tasks set out in paragraph 25.7 in the event of Approved Body designation withdrawal, restriction, or suspension? ('Yes' / 'No' / 'Don't Know/No Opinion')**

25.8 The MHRA considers that the UK medical devices regulations could set out circumstances where Certificates of Conformity will remain valid on an ongoing basis

or within a defined time period, in the event that the Approved Body designation has been withdrawn. For example it could set out that certificates shall remain valid where the MHRA has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction, and has outlined a timeline and actions anticipated to remedy the suspension or restriction.

**Q25.9 Do you think that the UK medical devices regulations should set out the circumstances in which certificates shall remain valid on an ongoing basis or for a defined time period in the event of designation withdrawal? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q25.10 If you have answered 'yes' to question 25.9 please outline any circumstances in which certificates should remain valid on an ongoing basis or for a defined time period.**

25.9 The MHRA considers that the UK medical devices regulations could be amended to introduce requirements for Approved Bodies in relation to how they conduct their activities, this could include requirements to:

- a. make their fees available on request to any interested party
- b. where they cease their activities unexpectedly, inform the MHRA and the manufacturers concerned as soon as possible
- c. where they plan to cease their activities, inform the MHRA and the manufacturers concerned one year before ceasing their activities
- d. where they have ceased their activities (planned or unexpected) take any reasonable actions to find a suitable Approved Body to take on their clients

**Q25.11 Do you think the UK medical devices regulations should introduce requirements set out in paragraph 25.9 for Approved Bodies in relation to how they conduct their activities? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q25.12 Please outline any other requirements which should be introduced in relation to how Approved Bodies conduct their activities.**

**Q25.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 25.1-25.12, including any impacts on you or other stakeholder groups.**