STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Authorisation of a blood establishment

4.—(1) The Secretary of State may grant an authorisation to a blood establishment to carry out any of the activities referred to in regulation 3(2).

(2) An application for authorisation under paragraph (1) shall be made to the Secretary of State.

(3) An application must—

(a) include the information set out in paragraph (4); and

(b) be accompanied by a fee of the amount prescribed in regulation 22(2)(a).

(4) The information referred to in paragraph (4) is—

(a) the name and address of the blood establishment and general information about its activities which shall include—

(i) details of each site at which it wishes to carry out any of the activities referred to in regulation 3(2),

(ii) a description of the activities which it wishes to carry out at each site,

(iii) where it has or intends to enter into a contractual arrangement with any person to carry out any of the services in respect or which it is seeking authorisation, the name and address of that person and of the services which he will carry out,

(iv) the name, qualifications and contact details of the responsible person for the establishment,

(v) the list of hospital blood banks which it supplies; and

(b) a description of the quality system in place at each site for each activity in respect of which the application for authorisation is made, which shall include the following information—

(i) documentation, such as an organisation chart, setting out the responsibilities of responsible persons and reporting relationships,

(ii) documentation, such as a site master file or quality manual, describing the quality system and explaining how it meets the requirements of Part 5 of the Schedule,

(iii) details of the number and qualifications of personnel,

(iv) details of hygiene provisions,

(v) details of premises and equipment, and

(vi) a list of standard operating procedures for—

(aa) recruitment, retention and assessment of donors,

(bb) processing, testing, distribution and recall of blood and blood components, and

(cc) the reporting and recording of serious adverse reactions and events.

(5) The Secretary of State may—

(a) grant or refuse any application for authorisation made under paragraph (3); and

(b) grant such application—

(i) in respect of particular sites or activities only, and

(ii) subject to conditions.

(6) Where the Secretary of State grants an application for authorisation, he shall give notice in writing to the blood establishment specifying—

(a) the activities which the blood establishment may undertake under these Regulations at each site in respect of which authorisation is granted; and

(b) the conditions which apply to the undertaking of those activities.

(7) Subject to the requirements of paragraph (8), the Secretary of State may at any time remove or vary any of the conditions referred to in paragraph (5)(b)(ii), or may impose additional conditions.

(8) Where the Secretary of State removes or varies any condition or imposes any additional condition pursuant to paragraph (7), he shall serve a notice on the blood establishment in question which shall—

(a) give details of the conditions which he proposes to remove, or of the variation which he proposes to make to any existing conditions, or of any additional condition which he proposes to impose;

(b) give the reasons for his decision; and

(c) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition shall apply.

(9) A blood establishment may not make any substantial change in the activities which it undertakes without the prior written approval of the Secretary of State.

(10) Any application for approval to make a substantial change in its activities shall be made in writing to the Secretary of State, and shall be accompanied by a fee of the amount prescribed in regulation 22(2)(b).

(11) For the purpose of this regulation, a substantial change in a blood establishment's activities is any change—

(a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;

(b) which would result in breach of these regulations or of any condition specified by the Secretary of State pursuant to this regulation; or

(c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the blood establishment has been authorised to undertake pursuant to this regulation.