
STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Inspections, etc.

15.—(1) The Secretary of State shall conduct a regular inspection of each site of a blood establishment, not less than once every two years, for the purpose of ensuring that—

- (a) blood establishments comply with the requirements of these Regulations; and
- (b) problems relating to compliance with those requirements are identified.

(2) The Secretary of State may conduct such additional inspections of blood establishments sites as he considers necessary for the purpose of ensuring compliance with the requirements of these Regulations.

(3) The Secretary of State may also serve a notice on a blood establishment requiring that it furnish him with such information concerning its compliance with these Regulations as shall be specified in the notice within such period as shall be specified in the notice.

(4) Any blood establishment which receives a request or information in accordance with paragraph (3) shall provide the information requested within the period specified in the notice.

(5) The Secretary of State may inspect hospital blood banks [^{F1}and facilities] with a view to ensuring that—

- (a) hospital blood banks [^{F1}and facilities] and persons responsible for the management of such blood banks [^{F1}and facilities] comply with the requirements of these Regulations; and
- (b) problems relating to compliance with those requirements are identified.

(6) The Secretary of State may also serve a notice on the person responsible for managing a hospital blood bank [^{F2}or a facility] requiring that he furnish him with such information concerning the compliance of the blood bank [^{F2}or a facility] with these Regulations as shall be specified in the notice within such period shall be specified in the notice.

(7) Any person responsible for management of a hospital blood bank [^{F3}or a facility] who receives a request for information in accordance with paragraph (6) shall provide the information requested within the period specified in the notice.

(8) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the Secretary of State shall request such information or conduct such inspections in accordance with this regulation as he shall consider appropriate.

(9) Any reference to an inspection of a site which the Secretary of State is required or empowered to conduct by virtue of this regulation, shall be construed so as to include an inspection of premises within the UK at which any of the activities listed in regulation 3(2) are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a blood establishment or, as the case may be, a person responsible for management of a hospital blood bank.

(10) The Secretary of State may appoint such persons to be inspectors as he thinks necessary for the proper discharge by them of his functions set out in these Regulations, and he may appoint such persons upon such terms and conditions (including conditions as to remuneration, benefits, allowances and reimbursement for expenses) as he thinks fit.

Textual Amendments

- F1** Words in reg. 15(5) inserted (31.8.2006) by [The Blood Safety and Quality \(Amendment\) Regulations 2006 \(S.I. 2006/2013\)](#), regs. 1(1), **9(a)**
- F2** Words in reg. 15(6) inserted (31.8.2006) by [The Blood Safety and Quality \(Amendment\) Regulations 2006 \(S.I. 2006/2013\)](#), regs. 1(1), **9(b)**
- F3** Words in reg. 15(7) inserted (31.8.2006) by [The Blood Safety and Quality \(Amendment\) Regulations 2006 \(S.I. 2006/2013\)](#), regs. 1(1), **9(c)**

Changes to legislation:

There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, Section 15.