STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Powers of entry, etc.

17.—(1) For the purposes of enforcing compliance with these Regulations or conducting inspections pursuant to regulation 15, an inspector appointed in accordance with regulation 15(10) shall, upon production of evidence that he is so authorised, have the right—

- (a) at any reasonable hour to enter any premises, other than premises used only as a private dwelling house, which he has reason to believe it is necessary for him to visit, including—
 - (i) any premises owned or managed by a blood establishment or person responsible for management of a hospital blood bank, or at which the blood establishment or person responsible for management of a hospital blood bank carries out any of the activities referred to in regulation 3;
 - (ii) any premises of any person who carries out any of the activities referred to in regulation 3(2) on behalf of, and pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank; and
 - (iii) where any facilities for donor evaluation and testing are in the premises of any person other than a blood establishment or hospital blood bank, those facilities in that person's premises;
- (b) to carry out at those premises during that visit inspections, examinations, tests and analyses as he considers necessary;
- (c) to require the production of, and inspect any article or substance at, the premises;
- (d) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record (in whatever form it is held) at, or (in the case of computer data or records) accessible at the premises;
- (e) subject to paragraph (6), to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record (in whatever form they are held) at, or (in the case of computer data or records) accessible at, the premises;
- (f) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
- (g) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;
- (h) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;

but nothing in this paragraph shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for disclosure in an action in the High Court or, as the case may be, on an order for production of documents in an action in the Court of Session.

- (2) If a justice of the peace is satisfied by any written information on oath that there are reasonable grounds for entry into any premises, other than premises used only as a private dwelling house, for any purpose mentioned in paragraph (1), and—
 - (a) admission to the premises has been refused or is likely to be refused and notice of intention to apply for a warrant under this sub-paragraph has been given to the occupier;
 - (b) an application for admission, or the giving of such notice, would defeat the object of the entry; or
 - (c) the premises are unoccupied or the occupier is temporarily absent and it might defeat the object of the entry to await his return,

the justice may, by warrant signed by him, which shall continue in force for a period of one month, authorise an inspector to enter the premises, if need be by force.

- (3) An inspector entering premises by virtue of paragraph (1) or of a warrant under paragraph (2) may take with him when he enters those premises such equipment as may appear to him necessary and any person who is authorised by the Secretary of State to accompany him on that visit.
- (4) On leaving any premises which an inspector is authorised to enter by a warrant under paragraph (2), he shall, if the premises are unoccupied, or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he found them.
- (5) Where, pursuant to paragraph (1)(e), an inspector takes possession of any article, substance, book, document, data or record, he shall leave at the premises with a responsible person, or if there is no such person present on the premises, leave in the premises in a prominent position, a statement giving particulars of the article, substance, book, document, data or record sufficient to identify it and stating that he has taken possession of it.
- (6) Where, pursuant to paragraph (1)(e) an inspector takes a sample for analysis, the Secretary of State may, subject to the requirements of paragraph (7), make such arrangements for analysis of that sample as he considers appropriate.
 - (7) The requirements of this paragraph are—
 - (a) that the Secretary of State shall inform the responsible person of the blood establishment or person responsible for the management of the hospital blood bank from which the sample was taken that he intends to make arrangements for analysis of the sample, and of the tests which he intends should be made; and
 - (b) that if the responsible person or person responsible for the management of the hospital blood bank so requests, the Secretary of State shall divide the sample of which an analysis is to be made into three equal parts and deal with those parts in accordance with the requirements of paragraph (8).
 - (8) The requirements of this paragraph are—
 - (a) that the Secretary of State shall make arrangements for the testing of one part of the sample;
 - (b) that one part of the sample shall be sent to the responsible person of the blood establishment or person responsible for the management of the hospital blood bank; and
 - (c) that one part of the sample shall be retained by the Secretary of State for a reasonable period in case of dispute.