STATUTORY INSTRUMENTS

2005 No. 2898

HEALTH AND SAFETY

The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005

Made - - - -	*17th October 2005*
Laid before Parliament	*17th October 2005*
Coming into force - -	*8th November 2005*

The Secretary of State, being a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to health protection measures regulating the use of material of human origin, in exercise of the powers conferred on her by the said section 2(2) and, with the consent of the Treasury, of the powers conferred by section 56(1) and (2) of the Finance Act 1973(**3**), makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Blood Safety and Quality (Amendment) (No. 2) Regulations 2005 and shall come into force on 8th November 2005.

(2) In these Regulations, "the principal Regulations" means the Blood Safety and Quality Regulations 2005(**4**).

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (3), for the definition of "blood establishment" substitute the following definition—

> ""blood establishment" means any person who carries out any of the activities specified in regulation 3(2) which require an authorisation by virtue of that regulation;".

(**1**) S.I.2004/3037.
(**2**) 1972 c. 68. Under section 57(1) of the Scotland Act 1998 (c. 46), despite the transfer to the Scottish Ministers of functions in relation to implementing obligations under Community law in relation to devolved matters, the functions of the Secretary of State in relating to implementing these obligations continues to be exercisable by her as regards Scotland.
(**3**) 1973 c. 51.
(**4**) S.I. 2005/50; as amended by S.I. 2005/1098.

Amendment of regulation 6 of the principal Regulations

3. In regulation 6 of the principal Regulations (the responsible person for a blood establishment) —

(a) in paragraph (7), after "paragraph (2)" insert "or that he is failing to carry out the tasks specified in paragraph (1) adequately or at all"; and

(b) in paragraph (8), after "paragraph (2)" insert "or that he is carrying out the tasks specified in paragraph (1) adequately".

Amendment of regulation 10 of the principal Regulations

4. In regulation 10 of the principal Regulations (requirement for hospital blood banks to provide information to the Secretary of State)—

(a) in paragraph (1)—

(i) for "As soon as practicable after the end of the reporting year" substitute "On or before the date specified in paragraph (1A)", and

(ii) for "an annual report" substitute "a report"; and

(b) after paragraph (1), insert the following paragraph—

"(1A) The date referred to in paragraph (1) is—

(a) in relation to the reporting year ending on 31st March 2006, 31st December 2005; and

(b) in relation to each subsequent reporting year, 30th April following the end of that year.".

Amendment of regulation 18 of the principal Regulations

5. In regulation 18 of the principal Regulations (criminal offences), in paragraph (8), for "married, his spouse" substitute "married or a civil partner, his spouse or civil partner".

Amendment of regulation 22 of the principal Regulations

6.—(1) Regulation 22 of the principal Regulations (fees) is amended as follows.

(2) In paragraph (2), after sub-paragraph (b) insert the following sub-paragraph—

"(bb) in respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by blood establishments, an annual haemovigilance fee calculated in accordance with paragraph (2A); and".

(3) After paragraph (2), insert the following paragraph—

"(2A) The fee payable under paragraph (2)(bb) shall be—

(a) in respect of the reporting year ending on 31st March 2006, £156; and

(b) in respect of each subsequent reporting year, £375.".

(4) After paragraph (3), insert the following paragraphs—

"(3A) In respect of each reporting year in which a hospital blood bank has operated, the person who is responsible for management of that hospital blood bank shall pay to the Secretary of State a fee of £400.

(3B) Subject to paragraph (3D), in respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by hospital blood banks, the person who is responsible for management of a hospital blood bank shall pay

to the Secretary of State an annual haemovigilance fee calculated in accordance with paragraph (3C).

(3C) The fee payable under paragraph (3C) shall be—

(b) in respect of the reporting year ending on 31st March 2006, £156; and

(c) in any other case, £375.

(3D) No fee shall be payable under paragraph (3B) by a person responsible for the management of a hospital blood bank if that person is authorised as a blood establishment under these Regulations.".

(5) After paragraph (5), insert the following paragraphs—

"(5A) Where the Secretary of State carries out an inspection of a contract laboratory, he may charge the person having control of that laboratory and that person shall, if so charged, pay to the Secretary of State a fee calculated in accordance with paragraph (5B).

(5B) Subject to paragraph (5C), the fee payable under paragraph (5A) shall be—

(a) if the laboratory carries out only one type of analytical work, £2,000;

(b) if the laboratory carries out two types of analytical work, £3,000; and

(c) if the laboratory carries out three types of analytical work, £4,000.

(5C) Where an inspection referred to in paragraph (5A) takes place at the same time as an inspection by a person appointed by the Good Laboratory Practice Monitoring Authority under regulation 3(4) of the Good Laboratory Practice Regulations 1999(**5**), for the purposes of ascertaining whether the contract laboratory complies with the principles of good laboratory practice, the fee payable under paragraph (5A) shall be—

(a) if the laboratory carries out only one type of analytical work, £500;

(b) if the laboratory carries out two types of analytical work, £1,250; and

(c) if the laboratory carries out three types of analytical work, £2,000.

(5D) The types of analytical work referred to in paragraphs (5B) and (5C) are—

(a) physico-chemical analysis,

(b) microbiological analysis including sterility testing, and

(c) biological analysis.".

(6) In paragraph (6), before the definition of "major site" insert the following definition—

""contract laboratory" means a laboratory carrying out testing of blood or blood components on behalf of, and pursuant to a contractual arrangement with—

(a) a blood establishment which is authorised under these Regulations; or

(b) a person responsible for management of a hospital blood bank;".

(7) In paragraph (7)—

(a) at the beginning insert "Subject to paragraph (7A),"; and

(b) after sub-paragraph (ii) insert the following sub-paragraphs—

"(iia) any fee payable pursuant to paragraph (2)(bb) or (3B) shall be payable—

(aa) if it is payable in respect of the reporting year ending on 31st March 2006, on 31st December 2005, and

(bb) if it is payable in respect of any subsequent reporting year, on 30th April during that year;

(**5**) S.I. 1999/3106; as amended by SI 2004/994.

(iib) the fee payable pursuant to paragraph (3A) shall be payable—

(aa) if it is payable in respect of the reporting year ending on 31st March 2006, on 31st December 2005, and

(bb) if it is payable in respect of any subsequent reporting year, on 30th April following the end of that year;".

(8) After paragraph (7), insert the following paragraph—

"(7A) In the case of a blood establishment granted an authorisation under regulation 4 before 8th November 2005, the periodic fee payable pursuant to paragraph (2)(c) shall be payable on 8th November 2006 and, while the blood establishment continues to be authorised to operate as such pursuant to these Regulations, annually thereafter.".

Signed by authority of the Secretary of State for Health

Caroline Flint
Parliamentary Under Secretary of State,
14th October 2005 Department of Health

We consent,

Dave Watt
Vernon Coaker
Two of the Lords Commissioners' of Her
17th October 2005 Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Blood Safety and Quality Regulations 2005 ("the principal Regulations"), which implement Directive 2002/98/EC of the European Parliament and of the Council setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**6**) and Commission Directive 2004/33/EC(**7**), which contains certain technical requirements relating to blood standards.

Regulation 2 substitutes, in regulation 1(3) of the principal Regulations, a new definition of "blood establishment". The amendment has the effect that a person responsible for management of a hospital blood bank may also be a blood establishment for the purposes of the principal Regulations, if the hospital blood bank is carrying out activities which require an authorisation under regulation 3 of those Regulations (in particular, the collection, testing and processing of blood and blood components).

Regulation 3 amends regulation 6 of the principal Regulations, so as to enable the Secretary of State to require a blood establishment to remove a person acting as a "responsible person" under that regulation, if he considers that they are failing to carry out their duties adequately or at all.

Regulation 4 amends regulation 10 of the principal Regulations, so as to provide that the date on or before which a hospital blood bank must provide a report under that regulation, in relation to the reporting year 1st April 2005 to 31st March 2006, is 31st December 2005, and in relating to each subsequent reporting year, on 30th April following the end of that year.

Regulation 5 amends regulation 18(8) of the principal Regulations. Regulation 18(8) provides that the provision of regulation 18(7) making it an offence for a person to obstruct, or fail to comply with any requirements made of him by, an inspector acting under the Regulations shall not require a person to answer any question if it would incriminate his or her spouse. The amendment extends the protection against incrimination to civil partners (i.e. persons in a civil partnership).

Regulation 6 amends regulation 22 of the principal Regulations, which relates to fees payable in respect of blood establishments and hospital blood banks. In particular, regulation 6 provides: that blood establishments and hospital blood banks shall pay an annual haemovigilance fee of £156 for the reporting year 2005/6 and £375 in subsequent years; that hospital blood banks shall pay an annual fee of £400; for fees payable in respect of inspections of laboratories which carry out testing of blood or blood components on behalf of blood establishments or hospital blood banks; and that for blood establishments granted an authorisation before 8th November 2005 (the date the regulations are to apply to establishments previously licensed under the Medicines Act 1968), the first annual fee will be payable on 8th November 2006 and annually thereafter.

The increase in total annual fees payable by blood establishments by 2007 is 123% (from £304 to £679). The increase for hospital blood banks is from no fee to £775 by 2007 (or £400 if also authorised as a blood establishment).

A full regulatory impact assessment of the effect that these Regulations will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the library of each House of Parliament.

(**6**) OJ No. L33, 8.2.2003, p.30.
(**7**) OJ No. L191, 30.3.2004, p.25.