
STATUTORY INSTRUMENTS

2005 No. 2898

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

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(1), 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;

(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.”.