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STATUTORY INSTRUMENTS

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**2008 No. 525**

**FEES AND CHARGES  
HEALTH AND SAFETY**

**The Blood Safety and Quality (Fees  
Amendment) Regulations 2008**

*Made* - - - - - *27th February 2008*  
*Laid before Parliament* *5th March 2008*  
*Coming into force* - - - *1st April 2008*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1) and section 56(1) and (2) of the Finance Act 1973(2).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to health protection measures regulating the use of material of human origin(3).

The Treasury has consented to the making of these Regulations as required by section 56(1) of the Finance Act 1973.

**Citation, commencement and interpretation**

1.—(1) These regulations may be cited as the Blood Safety and Quality (Fees Amendment) Regulations 2008 and shall come into force on 1<sup>st</sup> April 2008.

(2) In these Regulations “the principal Regulations” means the Blood Safety and Quality Regulations 2005(4).

**Amendment of regulation 22 of the principal Regulations**

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

(2) In paragraph (2)—

(a) in sub-paragraph (a), for “£2,688” substitute “£2,927”;

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(1) 1972 c.68. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to 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 relation to implementing these obligations continues to be exercisable by him as regards Scotland.

(2) 1973 c.51.

(3) S.I. 2004/3037

(4) S.I. 2005/50, as amended by S.I. 2005/1098, 2532 and 2898, S.I. 2006/2013 and S.I. 2007/604.

- (b) in sub-paragraph (b), for “£449” substitute “£493”;
- (c) in sub-paragraph (c), for “£387” substitute “£440”.
- (3) In paragraph (2A), in sub-paragraph (b) for “£432” substitute “£468”.
- (4) In paragraph (3), for sub-paragraphs (a) – (f) substitute the following sub-paragraphs—
  - “(a) for an inspection where the time taken to carry out the inspection at the site is not more than 7 hours, the sum of £2,452; and
  - (b) for an inspection where the time taken to carry out the inspection at the site is more than 7 hours, the sum in sub-paragraph (a) and thereafter at the rate of £1,226, for each additional period of 3 hours and 30 minutes or less taken to make the inspection.”.
- (5) In paragraph (3A), for “£600” substitute “£650”.
- (6) In paragraph (3C), in sub-paragraph (c), for “£432” substitute “£468”.
- (7) In paragraph (5), for sub-paragraphs (a) – (c) substitute the following sub-paragraphs—
  - “(a) for an inspection where the time taken to carry out the inspection at the site is not more than 7 hours, the sum of £2,452; and
  - (b) for an inspection where the time taken to carry out the inspection at the site is more than 7 hours, the sum in sub-paragraph (a) and thereafter at the rate of £1,226, for each additional period of 3 hours and 30 minutes or less taken to make the inspection.”.
- (8) In paragraph (5B), for sub-paragraphs (a) – (c) substitute the following sub-paragraphs—
  - “(a) for an inspection where the time taken to carry out the inspection at the site is not more than 7 hours, the sum of £2,452; and
  - (b) for an inspection where the time taken to carry out the inspection at the site is more than 7 hours, the sum in sub-paragraph (a) and thereafter at the rate of £1,226, for each additional period of 3 hours and 30 minutes or less taken to make the inspection.”.
- (9) In paragraph (5C), for sub-paragraph (a) – (c) substitute the following sub-paragraphs—
  - “(a) for an inspection where the time taken to carry out the inspection at the site is not more than 7 hours, the sum of £2,452; and
  - (b) for an inspection where the time taken to carry out the inspection at the site is more than 7 hours, the sum in sub-paragraph (a) and thereafter at the rate of £1,226, for each additional period of 3 hours and 30 minutes or less taken to make the inspection.”.
- (10) Omit paragraph (5D).
- (11) In paragraph (6) omit the definitions of “major site”, “minor site”, “regular inspection” and “standard site”.
- (12) After paragraph (6) insert the following—
  - “(6A) For the purposes of this regulation if an inspection is carried out by more than one inspector, the time taken by the Secretary of State to carry out the inspection is the aggregate of times taken by each inspector in carrying out the inspection at the site.”.

Signed by authority of the Secretary of State for Health.

27th February 2008

*Dawn Primarolo*  
Minister of State,  
Department of Health

We consent

26th February 2008

*Alan Campbell*  
*Steve McCabe*  
Two of the Lords Commissioners of her  
Majesty's Treasury

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## 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<sup>(5)</sup> and related Commission Directives<sup>(6)</sup>.

Regulation 2 amends regulation 22 of the principal Regulations and increases the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance. It introduces new methods of calculating the rates, and new rates for inspections. The overall average fee increase is around 8%.

A full regulatory impact assessment of the effect that this instrument will have on the costs of the business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

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<sup>(5)</sup> OJNo. L33, 8.2.2003, p.30.

<sup>(6)</sup> Commission Directive [2004/33/EC](#) (OJ No. L91, 30.3.2004) p.25, Commission Directive [2005/61/EC](#) (OJ No. L256, 1.10.2005, p.32) and Commission Directive [2005/62/EC](#) (OJ No. L256, 1.10.2005, p.41).