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STATUTORY INSTRUMENTS

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**2005 No. 1098**

**HEALTH AND SAFETY**

**The Blood Safety and Quality (Amendment) Regulations 2005**

*Made* - - - - *4th April 2005*  
*Laid before Parliament* *7th April 2005*  
*Coming into force* - - *8th April 2005*

The Secretary of State for Health, being a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to health protection measures regulating the use of material of human origin, in exercise of the powers conferred on him by the said section 2(2), hereby makes the following Regulations:—

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Blood Safety and Quality (Amendment) Regulations 2005 and shall come into force on 8<sup>th</sup> April 2005.

(2) In these Regulations, “the principal Regulations” means the Blood Safety and Quality Regulations 2005<sup>(3)</sup>.

**Amendment to regulation 4 of the principal Regulations**

2. In regulation 4 of the principal Regulations (authorisation of a blood establishment), in paragraph (4)—

- (a) for “paragraph (4)” substitute “paragraph (3)”; and
- (b) in sub-paragraph (a)(iii), for “or which” substitute “of which”.

**Amendment to regulation 5 of the principal Regulations**

3. In regulation 5 of the principal Regulations (suspension or revocation of authorisation), in paragraph (4), in sub-paragraph (b), for “regulation 4(4)” substitute “regulation 4(3)”.

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(1) S.I.2004/3037.

(2) 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.

(3) S.I. 2005/50.

**Amendment to regulation 12 of the principal Regulations**

4. In regulation 12 of the principal Regulations (objections to suspensions, revocations etc.)—
- (a) in paragraph (1), for “or be or” substitute “or to”;
  - (b) in paragraph (9), insert, at the beginning of the paragraph, “Subject to paragraph (11),”; and
  - (c) in paragraph (11), for “Paragraph (10)” substitute “Paragraphs (9) and (10)”.

**Amendment to regulation 16 of the principal Regulations**

5. In regulation 16 of the principal Regulations (records to be kept by the Secretary of State), in paragraph (1), in sub-paragraph (e), for “8th February1005” substitute “8th February 2005”.

**Amendment to regulation 17 of the principal Regulations**

6. In regulation 17 of the principal Regulations (powers of entry, etc.), in paragraph (1), in sub-paragraph (e), omit “subject to paragraph (6),”.

**Amendment to regulation 18 of the principal Regulations**

7. In regulation 18 of the principal Regulations (criminal offences), in paragraph (7), for “paragraph (5)” substitute “paragraph (8)”.

**Amendment of regulation 19 of the principal Regulations**

8. In regulation 19 of the principal Regulations (penalties), for “6 months”, in each place those words appear, substitute “3 months”.

Signed by authority of the Secretary of State for Health

4th April 2005

*Melanie Johnson*  
Parliamentary Under Secretary of State,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Blood Quality and Safety Regulations 2005.

Regulation 4 (b) and (c) amend the provisions which provide that where an objection is made to a notice served by the Secretary of State suspending or revoking a blood establishment authorisation, or requiring a hospital blood bank to refrain from certain activities, that notice shall not take effect until the process for considering such objections has been completed. The amendment provides that this does not apply in a case where the Secretary of State determines in the interests of public safety that the notice should take effect from the date originally specified.

Regulation 8 concerns penalties for criminal offences. The principal Regulations provided in error that the maximum period of imprisonment to which a person could be sentenced on summary conviction for certain offences should be six months. Regulation 5 substitutes the term of three months.

Regulations 2, 3, 4(a), 5, 6 and 7 make minor corrections.

A Regulatory Impact Assessment has not been prepared for these Regulations as they have no effect on business.