EXPLANATORY MEMORANDUM TO THE

BLOOD SAFETY AND QUALITY (AMENDMENT) REGULATIONS 2005

2005 No. 1098

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) ("the principal Regulations") to correct certain errors and are being issued to all known recipients of the principal Regulations free of charge.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 These Regulations will come into force on the date after the date on which they are laid before Parliament. The reasons why the Department considers it appropriate to depart from the conventional 21 day laying period in the case of these Regulations are set out below.

3.2 Regulation 19 of the principal Regulations purports to impose a maximum sentence of 6 months on persons convicted for certain offences under the Regulations on summary conviction. However, as the Regulations were made in exercise of powers conferred by section 2(2) of the European Communities Act 1972, there is no power to impose a sentence of more than 3 months (paragraph 1(d) of Schedule 2 to the Act). The Joint Committee on Statutory Instruments has reported regulation 19 on the ground that there is doubt whether it is *intra* vires, as acknowledged by the Department (see the Tenth Report of Session 2004-5). This instrument corrects that error.

3.3 The Department considers it is important that the error is corrected as soon as possible. The Department's policy intention was to impose the maximum sentence permitted by the 1972 Act. Regulation 19 of the principal Regulations purports to confer on a magistrates' court a power impose a maximum term of imprisonment in excess of that permitted by the enabling power. The Department's view is that as the principal Regulations are drafted, a court would not be able to impose a sentence in excess of 3 months and it is doubtful whether the court would have any power to impose a sentence of imprisonment at all (as opposed to a fine). There is a clear risk that a magistrates' court would not have appropriate sentencing powers available in order to deal with an offence arising under these

Regulations before this instrument came into force. It is clearly desirable that any legal uncertainty relating to sentencing for criminal offences should be cured as soon as practicably possible. The Department have therefore provided for the instrument to come into force the day after being laid before Parliament, in breach of the conventional 21 day period.

3.4 The Department has also taken the opportunity to include certain other corrections in this instrument.

3.5 The Joint Committee also reported regulations 22 and 24 of the principal Regulations for making an unexpected use of the enabling power. As the Department indicated in its memorandum to the Joint Committee of 14th February, the Department has revised its policy and will amend the principal Regulations accordingly. The provisions in question, which relate to fees, will not have any effect until the first anniversary of the grant of an authorisation to a blood establishment under the principal Regulations At the earliest this could be in February 2006. The Department is proposing to make making certain other changes to the fees provisions later in the year. The Department will include an appropriate amendment in those amending regulations to address the Joint Committee's point.

4. Legislative Background

4.1 The principal Regulations were made under section 2(2) of the European Communities Act 1972 and transpose into UK law two European Directives (2002/98/EC and 2004/33/EC) relating to standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. The Regulations provide that persons who contravene various provisions of the regulations shall be guilty of a criminal offence.

5. Extent

5.1 This instrument applies to all of the United Kingdom

6. European Convention on Human Rights

Not applicable

7. Policy background

7.1 The UK supports the Directives and has been instrumental in their development and negotiation. Much of their content is already current practice in UK Blood Services and the NHS. The principal Regulations significantly improve the assurances available about the safety and quality of the blood supply.

8. Impact

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

9. Contact

Gerard Hetherington at the Department of Health e-mail: Gerard.Hetherington@dh.gsi.gov.uk can answer any queries regarding the instrument.