EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations impose safety and quality requirements on human blood collection and storage. The requirements apply to blood transfusion services in England, Scotland, Wales and Northern Ireland. Many of the provisions of the Regulations also apply to hospital blood banks.

The Regulations implement Directive 2002/98/EC of the European Parliament and Council of 27 January 2003 setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ("the Directive") – *see* OJ L 33, 8.2.2003, p30. They also implement Commission Directive 2004/33/EC – *see*, OJ L91, 30.3.2004, p25, which contains certain technical requirements relating to blood standards.

Regulation 2 provides that the Secretary of State is to be the competent authority for the purposes of the Directive and outlines the scope of the Regulations.

Regulation 3 prohibits the carrying on of certain activities relating to blood, unless they are a person authorised by the Secretary of State to act as a blood establishment or carried out by hospital blood banks or persons acting on behalf of an authorised blood establishment or a hospital blood bank. Regulation 4 sets out the procedures to be followed in respect of an application for authorisation and regulation 5 sets out the circumstances tin which the Secretary of State may suspend or revoke such authorisation.

Regulations 6 to 8 impose requirements on blood establishments, including requirements relating to "responsible persons" at blood establishments (regulation 6) and the labelling of blood (regulation 8). Regulations 9 and 10 impose requirements on persons responsible for management of hospital blood banks, including requirements to provide information to the Secretary of State (regulation 10). Regulation 11 provides for the service of notices on hospital blood banks by the Secretary of State requiring them to undertake certain actions where they contravene the requirements of these regulations or where there are concerns as to safety.

Regulation 12 makes provision for objections to suspensions and revocations of blood establishment authorisations and to notices served on blood establishments and hospital blood banks by the Secretary of State under regulations 5 and 11.

Regulation 13 prohibits the import of blood or blood components which do not meet the standards of safety and quality equivalent to those specified in Part 5 of the Schedule to the Regulations.

Regulation 14 imposes restrictions on the disclosure of information obtained under the Regulations.

Regulations 15 to 21 provide for enforcement and related matters, including powers of inspection notices to provide information, offences and penalties for breaches of the Regulations.

Regulation 22 provides for fees payable in relation to blood establishment authorisations and inspections of blood establishments and blood banks.

Regulation 23 provides that in the event of a specific epidemiological situation such as a disease outbreak, which necessitates the adoption of deferral criteria additional to those specified in Part 3 of the Schedule, the Secretary of State is to notify the Commission and blood establishments, who are to adopt any additional deferral criteria specified by the Secretary of State.

Regulation 24 makes transitional provision for blood establishments and hospital blood banks so that they may continue to operate under existing provisions until 8th November 2005.

Regulation 25 makes consequential amendments.

A Regulatory Impact Assessment and a Transposition Note have been prepared for these Regulations and a copy of each has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment and the Transposition Note are published on the Department of Health's website (www.dh.gov.uk) and can be obtained from room 631B SKH, Department of Health, Skipton House, 80 London Road, London SE1 6LH.

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005.