EXPLANATORY MEMORANDUM TO THE

THE BLOOD SAFETY AND QUALITY REGULATIONS 2005

2005 No.50

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

This memorandum does not contain information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Regulations are made under Section 2 (2) of the European Community Act and transpose into UK law two European Directives (2002/98/EC and 2004/33/EC). They set 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 also cover the collection and testing of blood and blood components for autologous use. In effect therefore, they cover the whole process from donor to patient – from 'vein to vein'.

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

3.1 None

4. Legislative Background

4.1 These Regulations implement Directive 2002/98/Ec and Directive 2004/33/EC. The Regulations are made under Section 2(2) of the European Communities Act. Directive 2002/98/EC governs the safety and quality of blood and blood components. Directive 2004/33/EC is the first of three Technical Directives that support 2002/98/EC. Directive 2002/98 imposes statutory requirements on Blood Establishments and Hospital Blood Banks including the reporting of adverse incidents and events and requires the Competent Authority, the Secretary of State (whose enforcement obligations under the Regulations will be discharged on his behalf by the Medicines and Healthcare products regulatory Agency (MHRA) an executive agency of the Department of Health) to monitor compliance with the Regulations and to carry out inspections of Blood Establishments.

Blood Establishments are the four National Blood Services in the UK, which collect, process and distribute blood and blood products whilst the Blood banks

with the hospitals cross match the blood and distribute to patients on request of the clinician.

Two further Directives (one on haemovigilance/traceability and one on quality systems are currently under discussion in the Commission's Expert Working Group on blood. They should be completed by the end of this year thus fulfilling the requirements laid down in Article 29 of Directive 2002/98/EC. This Instrument will therefore require amendment in due course to implement the requirements of those further technical Directives.

The coming into force date of both Directives is 8 February 2005; however, Article 7 of Directive 2002/98/33 allows national provisions to remain in force for a further nine months until 8 November 2005. To allow all concerned to fully meet the requirements of the Regulations it is the Department's intention to avail itself of this extra transition period. At present blood establishments are licensed as manufacturers of medicinal products under the Medicines Act. In order to avoid double regulation the regulations will however amend the Medicines Act so that human blood and blood components will fall outside the scope of the Medicines Act and be regulated in future solely by the regulations. The amendments to the Medicines Act will come into force on 8th November when the transitional period ends.

A Transposition Note in relation to the Regulation is attached as an Annex to this Memorandum.

Explanatory Memorandum were produced for the Scrutiny Committee's in June and December 2002

5. Extent

5.1 This instrument applies to all of the United Kingdom

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Blood Safety and Quality Regulations 2005 are compatible with the Convention rights

7. Policy background

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

The Instrument will introduce requirements on hospital blood banks, blood establishments and on the Competent Authority.

a) Article 5 requires blood establishments to be licensed in accordance with the requirements of the Directive. The blood establishments are currently licensed under the Medicines Act 1968 and legislative changes will be made so that they can operate in future under the new Blood Safety Regulations rather than the Medicines Act. In essence nothing should change in this respect.

b) Under Article 6 Hospital Blood Banks do not have to be licensed but do have to meet other requirements such as having a quality system in place, trained personnel etc. The Blood Establishments will have to satisfy the Competent Authority that they satisfy the requirements of the Regulations.

c) Article 15 requires adverse events and incidents to be reported to the Competent Authority. Work is in progress to provide advice as to how this will happen in advance of the Haemovigilence Directive being agreed and implemented.

d) Article 4 requires a Competent Authority to be set up. In the UK the Competent Authority, the Secretary of State (whose enforcement obligations under the Regulations will be discharged on his behalf by the Medicines and Healthcare Products Regulatory Agency, an Executive Agency of the Department of Health) will monitor compliance with the Regulations and carry out relevant inspections.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum

The regulations require Blood Establishments (the existing four UK Blood services) to be inspected and licensed/accredited, a process very similar to that which they are currently subject to under the Medicines Act. In addition, the regulations impose certain requirements on hospital blood banks, for example the need to have good quality systems and the requirement to provide evidence of such systems to the Secretary of State. The regulations provide the Secretary of State with adequate powers to satisfy himself that these requirements are being met but do not require the inspection, licensing or accreditation of hospital blood banks.

Article 4 of Directive 2002/98/EC requires Member States to designate a Competent Authority to implement the requirements of the Directives. For the purposes of the regulations, the competent authority is the Secretary of State. He may delegate this function and the recent review of Arms Length Bodies concluded that the new Regulatory Authority for Fertility and Tissue (RAFT)

should take on this role when established. However, with a coming into force date of 8 February 2005, the Medicines and Healthcare products Regulatory Authority (MHRA) have been appointed as interim Competent Authority.

Article 7 of the Directive allows Member States to maintain existing national provisions for nine months after the coming into force date consequently the implementation date for the regulations is 8 November 2005.

A public consultation exercise was held from 11th November 2004 to 8th January 2005. Fifteen responses were received representing the views of Blood Establishments, Hospital Blood Banks, the British Blood Transfusion Society and other interested parties. All responses welcome the regulations as a positive step to improve quality, safety and patient care.

The responses focus on issues around impact and implementation such as timescales, resources, technology – particularly in relation to the requirement for 'vein to vein' traceability, and the need for prompt and adequate guidance and training. The need to clarify the position on some activities currently undertaken by hospital blood banks that will in future have to be undertaken by Blood Establishments also featured. The NHS Operational Impact Group (OIG) is actively considering all the above issues and will be making recommendations and producing guidance for the field. The UK Blood Services have identified that the regulations require some changes in their current practices and procedures.

OIG, the Blood Establishments and other interested parties are also in discussions with the Competent Authority (MHRA) to ensure clarity about what needs to be achieved by when in terms of compliance.

9. Contact

Gerard Hetherington at the Department of Health Tel: 0207 972 5376 or e-mail: Gerard.Hetherington@dh.gsi.gov.uk can answer any queries regarding the instrument.

Transposition Note for Blood Safety and Quality Regulations 2005

Directive
Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 - setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
Commission Directive 2004/33/EC – implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

Directive 2002/98/EC			
Article	Objectives	Implementation	Responsibility
1 & 2	To lay down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection. The Directive applies to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion. It does not apply to blood stem cells.	Regulation 2 (2) of the Blood Safety and Quality Regulations 2005 provides that: • , the requirements of the Regulations apply to the collection and testing of blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when they are intended to be used for transfusion. and Regulation 2 (4) provides that • the Regulations do not apply to blood stem cells.	The Medicines and Healthcare products Regulatory Authority (MHRA) (an Executive Agency of the Department of Health) will discharge the enforcement obligations of the Secretary of State who is designated the competent authority for the purpose of the se Regulations. As the MHRA does not have a separate legal personality therefore the Regulations refer throughout to Secretary of State.
3	To provide definitions of terms	Regulation 1 (3) incorporates the definitions in the Directive	the Regulations made by Secretary of State
4	To designate the competent authority responsible for implementing the requirements of this Directive.	Regulation 2 (1) designates the Secretary of State as the Competent Authority.	regulations made by Secretary of State
5	To ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.	Regulations 3 (1) and (2) list the activities which blood establishment undertake and provide that no person other than a Blood Establishment authorised by the Secretary of State may carry any of these activities otherwise than in accordance with an authorisation granted under regulation 4. Regulation 3(3) creates exceptions to the general prohibition for permitted activities undertaken by hospital blood banks and for subcontractors of blood establishments and hospital blood banks.	MHRA on behalf of the Secretary of State

		Breach of regulation 3(1) is a criminal offence (regulation 18(1)). Regulations 4 (4) and (5) list the information that must be provided To the Secretary of State in an application to be authorised as a blood establishment. Regulation 4 (7) enables the Secretary of State to vary the conditions in regulation 4 (5) Regulation 4 (9) prevents Blood Establishments from making any substantial change in their activities without the prior written approval of the Secretary of State. Regulations 5 enables the Secretary of State to suspend or revoke licenses	
6	To specify that Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 also applyto Hospital Blood Banks	Regulations 9 and 10 provide that the person responsible for the management of a hospital blood bank shall ensure that all the requirements specified are satisfied.	The person responsible for the management of a hospital blood bank MHRA on behalf of the Secretary of State for enforcement
7	To provide that existing provisions may be maintained for nine months after the coming into force date of 8th February 2005	Regulation 24 provides that the regulations shall not apply before 8th November 2005 to blood establishments and hospital blood banks	Regulations made by the Secretary of State
8	To ensure that the competent authority organises inspections and appropriate control measures in blood establishments to ensure that the requirements of the Directive are complied with and describe the interval of such inspections and the powers of inspectors.,	Regulation 15 provides for regular inspections of blood establishments not less than once every two years. Regulation 15(9) provides that the inspection requirements also apply premises of any third party contractor with whom the blood establishment contracts to carry out any of the activities covered by its authorisation. Regulation 16 describes the records to be kept by the Secretary of State in respect of these inspections. Regulation 17 describes the powers of inspectors and provides that they may take samples for analysis (Regulation 17(6)) and examine documents regulation 17(1).	MHRA on behalf of the Secretary of State
9	To appoint a 'responsible person' in each blood establishment with specified responsibilities, and to specify the qualifications that the appointed person must have.	Regulation 6 provides for the appointment of a responsible person, specifies their responsibilities and the required qualifications. It also provides for the Competent Authority to be notified of and approve all such appointments and changes.	Chief Executive of each blood establishment. MHRA on behalf of the Secretary of State for enforcement Secretary of State to publish details of qualifications recognised

			by him
10	To ensure that personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.	Regulation 7 (1) (a) provides that: the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood components for the blood establishment must be qualified to perform those tasks and are provided with timely, relevant and regularly updated training. ; Regulation 9(1)(a) makes similar provision for hospital blood banks	The Responsible Person of each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State
11	1. To require that all necessary measures be taken to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice. 2. The Commission shall establish the Community standards and specifications referred to in Article 29 (h) for the activities relating to a quality system to be carried out by a blood establishment.	1. Regulation 7 (1) (b) provides that all blood establishments shall establish and maintain a quality system for blood establishments based on the principles of good practice. Regulation 9(1)(b) makes similar provision for hospital blood banks. 2. The specifications for the quality system for blood establishments will be the subject of a further technical directive later in 2005 and the Regulations will be amended in due course to take account of this.	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State
12	To ensure the maintenance by blood establishments of documentation on operational procedures, guidelines, training and reference manuals, and reporting forms. And that access is provided to these documents for officials entrusted with inspection and control measures referred to in Article 8	Regulation 7 (1) (d) provides that blood establishments shall maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under regulation 15 Regulation 9(1)(d) makes similar provision for hospital blood banks. Regulation 15 (1) provides that the Secretary of State shall conduct a regular inspection of each site owned or operated by a blood establishment, not less than once every two years, for the purpose of ensuring that blood establishments comply with the requirements of these Regulations. Regulation 15 (3) provides that the Secretary of State may also serve a notice on a blood establishment requiring that it furnish him with such information concerning its compliance with these Regulations as shall be specified in the notice within such period as shall be specified in the notice.	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State
13	To ensure the maintenance by blood establishments of records of the information required in Annexes II and IV and under Article 29(b), (c) and (d). The records shall be	Regulation 7 (4) – (6) specifies the records to be kept by blood establishments and that they be kept for a minimum period of 15 years. Regulation 16 (1) requires the Secretary	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary

	kept for a minimum of 15 years. 2.To ensure that The competent authority keeps records of the data received from the blood establishments according to Articles 5, 7, 8, 9 and 15.	of State to keep such records of information which he receives from or relating to blood establishments as he considers appropriate and specifies that, in particular, records relating to the following shall be kept: (a) Authorisations under regulation 4; (b) the designation of responsible persons under regulation 6; (c) notification of serious adverse events by such establishments pursuant to regulation 7(1)(d); (d) inspections or requests for information under regulation 15; (e) the operation of blood establishments licensed under section 8 of the Medicines Act 1968, prior to 8th November 2005.	of State
14	To ensure that all blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa. 2. To specify the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed. The system must unmistakably identify each unique donation and type of blood component.	Regulations 8 and (9) (e) provide for a system encompassing blood establishments and hospital blood banks, for the identification of each single blood donation, blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The data needed for full traceability shall be kept for at least 30 years. The requirements of the system will be the subject of a further technical directive later in 2005. and the Regulations will be amended in due course to take account of this.	Regulation 8 - The Responsible Person for each blood establishment Regulation 9 – the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State
15	To establish a system for notification to the Competent Authority of any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components. For blood establishments to have in place a procedure to accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.	Regulations 7 (1) (e) & (f) and 9 (1) (f) & (g) provide for a system for reporting to the competent authority and withdrawal of blood and blood components encompassing blood establishments and hospital blood banks. The notification procedure and format will be the subject of a further technical directive later in 2005. and the Regulations will be amended in due course to take account of this.	Regulation 7 - The Responsible Person for each blood establishment Regulation 9 – the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State

16	To specify the information that shall be provided to donors	Regulation 7 (2) (a) and Part A of Part 2 of the Schedule require the specified information to be provided	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State
17	To specify the information required from donors	Regulation 7 (2) (b) and Part B of Part 2 of the Schedule require blood establishments to obtain the specified information from donors	The Responsible Person for each blood establishment Enforcement by MHRA
18	To specify t procedures for the evaluation of donors	Regulation 7 (2) (c) – (f) provide for the specified evaluation procedures to be operated	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State
19	With regard to the eligibility of donors, to specify the terms of the examination including the provision and receipt of information	Regulation 7 (2) (f) require an examination and assessment of donors by specified staff	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State
20	To encourage voluntary and unpaid donations	Regulation 7 (2) (g) provides for the encouragement of voluntary, unpaid donations Regulation 7(9) provides for blood establishments to make an annual report to the Secretary of State as to the steps they have taken to comply with this obligation.	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State
21	To specify the requirements for the testing of donations	Regulations 7 (3) (a), 7 (7) – (8) provide for the testing requirements and for the Secretary of State to issue guidance which blood establishments must take into account if he considers that additional tests are necessary	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State Guidance to be issued by the Secretary of State with regard to additional tests.
22	To specify storage, transport, and distribution conditions	Regulation 7 (3) (b) for blood establishments and 9(1) (h) for hospital blood banks and Part 4 of the Schedule specify these requirements,	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State
23	To specify the quality and safety requirements	Regulation 7 (3) (c) and Part 5 of the schedule specify these requirements	The Responsible Person for each blood establishment Enforcement by MHRA
24	To specify data protection and confidentiality requirements	Regulation 14 provides for the data protection and confidentiality	The Responsible Person for each blood

	in respect of data supplied by blood donors	requirements,	establishment The person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State.
27	To require penalties for infringements to be laid down	Regulations 18 and 19 specify the offences and penalties in respect of breaches of these regulations	Regulations made by the Secretary of State Enforcement by MHRA on behalf of the Secretary of State.
29	The adaptation of technical requirements	The requirements relating to raceability, quality management systems and procedure for notifying serious adverse reactions and events will be the subject of a further technical directive(s) later in 2005 and will be implemented by amendments to these Regulations to transpose those Directive(s) in due course. The requirements relating to information to be provided to donors, information to be obtained from donors, dereffal criteria, storage transport and distribution requirements,quality and safety requirements and requirements as to autologous transfusion are specified in Commission Directive 2004/33/EC and have been transposed in these regulations as set out in the table below.	Regulations made by the Secretary of State where applicable.
32	To specify a transposition date of 8th February 2005	Regulation 1 (2) provides for transposition date of 8th February 2005	Regulations made by the Secretary of State

Commission Directive 2004/33/EC			
Article	Objectives	Implementation	Responsibility
1	To specify definitions or certain technical terms	Part 1 of the Schedulecontains the specified definitions	regulations made by theSecretary of State
2	To specify requirements as to the provision of information to prospective donors	Regulation 7 (2) (a) and Part A of Part 2 of the Schedule require the specified information to be provided	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State.
3	To specify the information to be required from donors.	Regulation 7 (2) (b) and Part B of Part 2 of the Schedule require blood establishments to obtain the specified information from donors	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State.
4	To specify the eligibility criteria for donors, paragraph 2.3 of Annex III (referred to in Article 4) provides that	Regulation 7 (2) (d) and Part 3 of the schedule specify the eligibility criteria for donors, Regulation 23 provides that that for specific epidemiological	The Responsible Person for each blood establishment

	additional criteria may be appropriate for specific epidemiological situations and that such deferrals are to be notified to the Commission with a view to community action. Paragraph 2.4 of Annex III (referred to in Article 4) provides that Member States have a discretion to specify deferral criteria for applicable to autologous donations for certain specified conditions	situations such as disease outbreaks the Secretary of State may require blood establishments to adopt additional deferral criteria and requires the Secretary of State to notify the commission of such criteria and of the situation giving rise to them. The discretion to specify deferral criteria for autologous donations for particular conditions has not been exercised at present. If it is decided to exercise it in the future, appropriate amendments will be made to the Regulations.	Enforcement by MHRA on behalf of the Secretary of State. For the provisions relating to specific epidemiological situations, The Secretary of State, The Responsible Person for each blood establishment, and Enforcement by MHRA on behalf of the Secretary of State.
5	To specify the storage, transport and distribution conditions for blood and blood components.	Regulation 7 (3) (b) for blood establishments and 9(1)(h) for hospital blood banks and Part 4 of the Schedule impose obligations to comply withthese requirements	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State.
6	Quality and safety requirements for blood and blood components Paragraph 1.5 of Annex V (as referred to in Article 6) requires member states to regulate new blood components and notify such components to the commission with a view to community action. Paragraph 2.3 of Annex V (as referred to in Article 6) requires that Member States take necessary measures to ensure that imports of blood and blood components into the community meet equivalent standards of quality and safety to those laid down in the Directive	Regulation 7 (3) (c) Part 5 of the Scheduleimpose obligations to comply with these requirements The requirement to regulate new blood - components will be dealt with by appropriate amending regulations in the event that any new blood components are discovered. Regulation 13 provides that no person may import any blood or blood components from a county or territory outside the European Community unless these requirements are met. Breach of this Regulation is a criminal offence (Regulation 18(1))	The Responsible Person for each blood establishment Enforcement by MHRA on behalf of the Secretary of State Regulations made by the Secretary of State
7	To specify the requirements for Autologous donations Part a of Annex II (referred to in Article 2) requires that certain information be provided to prospective autologous donors, Paragraph	Parts 2, 3 4 and 5 of the Schedule specify these requirements	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank

	2.4 of Annex III (referred to in Article 4) specifies the deferral criteria applicable to autologous donations, paragraph 3 of Annex IV (referred to in Article 5) specifies additional labelling requirements for autologous donations Annex V (as referred to in Article 6) specifies that certain quality contraol testing requirements are recommendations only in the case of autologous donations		Enforcement by MHRA on behalf of the Secretary of State.
8	To require the validation of all testing and processes	Regulation 7 (1) (c) for blood establishments and regulation 9(i)(c) for hospital blood banks provides for this	The Responsible Person for each blood establishment the person responsible for the management of each hospital blood bank Enforcement by MHRA on behalf of the Secretary of State.
9	To specify a transposition date of 8th February 2005	Regulation 1 (2) provides for transposition date of 8th February 2005	Regulations made by the Secretary of State