The Impact of the Blood Safety and Quality Regulations 2005 on Hospital Transfusion Laboratories
The NHS Operational Impact Group (OIG) Report

CONTENTS

Notes and Glossary of Terms

BCSH – British Committee on Standards in Haematology

Blood Establishment – A term used in the Regulations to define an entity that is licensed by the Competent Authority to collect, process, store and distribute blood. Currently only the four UK Blood Services and their constituent Blood Centres are Blood Establishments.

Devolved Administrations – Northern Ireland, Scotland and Wales. Each UK country has its own Health Department that issues guidance to the NHS in that country. For brevity, references in the report to central guidance etc quote the title or Circular number used by the Department of Health in England. We have confirmed that equivalent guidance has been issued by Health Departments in the devolved administrations.

Hospital Blood Banks/Hospital Transfusion Laboratories – The Regulations refer to Hospital Blood Banks however in the report we use the term Hospital Transfusion Laboratory as this is now more widely used in the UK

HTL – Hospital Transfusion Laboratory
JPAC – The Joint Professional Advisory Committee (of the UK Forum)
OIG – The NHS Operational Impact Group
NBS – The National Blood Service (England)
NIBTS – Northern Ireland Blood Transfusion Service
NPSA – National Patient Safety Agency
NPfIT – The National Program for IT
NTC – National Transfusion Committee
RC Path – The Royal College of Pathologists
RTC – Regional Transfusion Committee
SHOT – The Serious Hazards of Transfusion reporting scheme
SNBTS – The Scottish National Blood Transfusion Service
WBS – The Welsh Blood Service
The Regulations – The Blood Safety and Quality Regulations 2005
The Directive(s) – European Directives 20002/98/EC and 2004/33/EC

The Competent Authority – The Medicines and Healthcare Products Regulatory Agency (MHRA) - acting on behalf of the Secretary of State

Trusts – A generic term used in the report to refer to all NHS hospitals in the UK

UK Blood Services (UKBS) – Each UK country has its own Blood Service, we have used the term UKBS throughout the report where we refer to or recommend action involving all UK Blood Services. Where a specific country or Blood Service is referred to, it is identified.

UK Forum – The meeting of the Chief Executives and Medical Directors of the UK Blood Services

EXECUTIVE SUMMARY

The report identifies the key areas of impact on hospitals of the new Blood Safety and Quality Regulations 2005 and makes recommendations for consideration by DH and MHRA. Implementation by 8th November 2005 presents a challenge but we believe that our recommendations will assist the task if they are agreed and disseminated to hospitals as soon as possible to provide the maximum lead-time for local action. The recommendations are derived from the direct requirements of the Regulations or, where we believe that although not a requirement of the Regulations, it is necessary to improve assurance and deliver improvements in patient outcomes.

The following paragraphs summarise the key areas of impact for hospitals and the main associated recommendations and costs.

Traceability - Hospitals must have total traceability of the fate of each unit of blood/blood component and retain relevant information for thirty years. We recommend a minimum dataset for retention to ensure compliance. Although we are aware that in the short term many hospitals may wish to continue to use patient notes to provide traceability, we do not believe that this is totally reliable. We recommend the introduction of a simple paper system to ensure that the information in the notes is returned to the hospital transfusion laboratory (HTL) for retention for traceability purposes. We estimate that this will cost between £7k - £25k per hospital depending on blood usage, with an additional staff cost, estimated at around £12k - 25k per post per year, to ensure the effective operation of the system.

For the longer term we also recommend that with the aid of IT, all hospitals should have the facility to record additional specified data. We believe that ultimately only effective IT systems can ensure total traceability and we recommend the inclusion of electronic blood tracking systems in the National IT programmes (i.e. NPfIT in England). We estimate the associated costs will range from around £180k - £600k per hospital depending on size however, inclusion in the National IT programmes may well reduce these.

Quality Systems – HTLs must have a comprehensive quality system in place; we recommend a full specification for such a system and identify the aspects that MHRA indicate must be in place by 8th November 2005 for compliance purposes. We recommend its early dissemination for implementation. We believe that effective quality management is essential to the delivery of compliance with the Regulations and we recommend the provision of appropriate resources to achieve this. We discuss options for how this might be achieved but estimate that a hospital transfusing more than 10,000 units per annum, would require a WTE Quality Manager at an estimated total cost of around £50k pa.

Activities restricted to licensed Blood Establishments ('Processing activities')
Some activities currently conducted by HTLs are, under the Regulations, regarded as 'processing' activities and thus reserved to Blood Establishments. MHRA have indicated that hospitals may seek a limited form of licensed Blood Establishment status and we make recommendations on a number of associated issues that need to be resolved as a prerequisite. We recommend that for planning purposes it should be assumed that hospitals will not undertake 'processing' activities from 8th November

2005 and that the UK Health Departments should initiate discussions with the UK Blood Services to ensure an adequate supply of products to avoid any disruption to patient care. We also recommend that HTLs and Transfusion Practitioners initiate discussions with clinical colleagues to discuss the likely impact of this change and the need for any local action.

It is likely that these changes will have cost implications. It is impossible for us to determine these costs with any degree of accuracy but we attempt in the report to identify potential cost factors to provide an indication of impact.

Training, Education and Communication - The Regulations only require the provision of training for HTL staff, however, we recommend that relevant training should be provided for all staff involved in the transfusion process, including those outside the HTL. We recommend that hospitals should, as soon as possible, develop a plan encompassing what training is required, who requires it and who will deliver it. Implementation of these recommendations will incur a significant, but currently unquantifiable cost around releasing staff to attend such training.

We believe that local Transfusion Practitioner staff are ideally placed to deliver such training and we recommend that Trusts without such a post should establish one. Around 32% of hospitals do not have a Transfusion Practitioner or equivalent. The cost of such a post is around £32k per year, a potential national cost of around £3.2m.

Northern Ireland, Scotland and Wales have established implementation groups to assist hospitals to work through the impact of the changes and to ensure compliance. We believe that England would benefit from such a planned approach. In the absence of a central resource to provide this co-ordination we recommend the use of either the Regional or National Transfusion Committee structure, to oversee this implementation. DH should consider the appointment of a project manager and an implementation structure made up of representatives from each regional hospital group. We also recommend that a formal mechanism be established to facilitate a continuing dialogue between hospitals and MHRA.

Haemovigilance – Work on Serious Adverse Event/Reaction reporting is continuing within a group chaired by MHRA, this will be the subject of separate guidance and cost assessment in due course. We recommend that the key parameters of any system must be to satisfy the requirements of the regulations, to maintain the integrity of the existing SHOT reporting system and to minimise the reporting burden on hospitals.

Compliance with the Regulations - We have developed an 'Implementation Planning Toolkit' for use by hospitals. We recommend that hospitals are formally advised of the criteria that have to be satisfied to demonstrate compliance on 8th November 2005 and in subsequent years, and that MHRA use a standard format for compliance reporting and publish criteria for any intended compliance inspection regimes. We also recommend that Trust Chief Executives should sign any statement on compliance required by MHRA.

The Impact of the Blood Safety and Quality Regulations 2005 on Hospital Transfusion laboratories

The NHS Operational Impact Group (OIG) Report

Introduction

1. OIG was initially established by the 'Appropriate Use of Blood' sub group of the NBS Blood and Tissue Safety Assurance Group. In June 2004 the Department of Health in England (DH) formally took over sponsorship of the group to provide recommendations about the impact on hospital transfusion laboratories (HTLs) of the European Directives and the subsequent transposing Regulations. To ensure a pan-UK approach, the Health Departments in the Devolved Administrations (N. Ireland, Scotland and Wales) agreed to participate and nominated representatives. The work of the group was publicised in the NHS via the Chief Executive's Bulletin (in England) and more generally in the papers published by DH as part of the public consultation on the Regulations. The members of the group are listed at Appendix 1; the terms of reference are detailed at Appendix 2.

Acknowledgements

2. We would like to thank the many contributors to our work, in particular:

- The parent NHS Trusts and UK Blood Services (UKBS) for allowing OIG members to provide a significant time commitment over the last nine months.
- Hospital and UKBS colleagues for participating in fact-finding enquiries.
- The Joint Professional Advisory Committee (JPAC) of the UK Blood Services Forum for allowing use of their website to disseminate OIG information.
- MHRA for its advice and co-operation since its appointment as Interim Competent Authority.
- Clinical Pathology Accreditation Ltd (CPA) – for its help and advice in seeking to establish the preparedness of hospitals.
- The National Blood Service (NBS) for providing the OIG secretariat.

Methodology

3. We established five sub-groups to consider the following key impact areas – (i) Traceability, Electronic tracking, and IT (ii) Serious Adverse Event/ Reaction reporting (iii) Quality Management Systems (iv) Potential 'Processing' activities (v) Training/Education and Communication.

4. The sub-groups conducted fact-finding enquiries with hospitals and UKBS. They and individual members also met with various Regional Transfusion Committees (RTCs) and professional groups, participated in workshops and contributed articles to professional publications. OIG met eight times in plenary session between July 2004 and May 2005 to consider sub-group findings, to seek advice from MHRA on potential solutions/proposals, and to agree conclusions/ recommendations. Monthly briefings and relevant papers were published on the JPAC website.

5. Work on Serious Adverse Event/Reaction reporting is continuing within a group chaired by MHRA with representatives of DH, OIG, UKBS, Serious Hazards of Transfusion (SHOT) and the National Patients Safety Agency (NPSA). This will be the subject of separate guidance and cost assessment in due course. The key

parameters for this work are to produce a system that satisfies the requirements of the Regulations, maintains the integrity of SHOT, involves the UKBS and minimises the reporting burden on hospitals.

Summary of activity

6. The main thrust of our activity has been to consider and consult on the impact of the Directive and subsequent Regulations on HTLs. Our initial task, in the absence of a functioning Competent Authority, was to suggest what might constitute hospital compliance and how it might be determined. As a starting point we sought to establish the extent to which existing systems could act as a guide/proxy for the requirements of the Directives, and the assurance that stakeholders could derive from these in terms of the requirements of the directive.

7. We concluded that extant central guidance in all UK countries actually covered the majority of the requirements of the new Regulations e.g.:

- "Modernising Pathology Services" (DH - February 2004) made it mandatory for Trusts to seek and achieve accreditation. It made reference to existing avenues of accreditation, in particular Clinical Pathology Accreditation Ltd (CPA). Most of the directive's articles relevant to hospital blood banks mirror the current CPA standard. A comparative analysis indicated that broadly, the current CPA standard incorporates all of the relevant requirements apart from those on traceability, serious adverse event/ reaction reporting and the clinical transfusion process.
- Circular HSC 2002/009 – 'Better Blood Transfusion' contains requirements on traceability, adverse incident reporting and the clinical transfusion process.

8. Despite these existing requirements, we established that the accreditation status of some 30% of NHS Trusts was unclear, that traceability systems needed improvement and that participation in incident reporting systems was not total. Consequently the assurances provided by existing systems do not meet all stakeholder needs. The transposition of the Directives into Regulations means that some of these shortcomings could potentially result in enforcement action by the Competent Authority.

9. It should be noted that in the UK only around 5% of HTLs are accredited under the current CPA standards. Around 70% are accredited under an earlier standard which is less demanding than the Regulations; as these accreditations come to be renewed the current standard will be used for assessment.

10. Our initial recommendation to DH in August 2004 was that Strategic Health Authorities should in the first instance, pursue those hospitals whose accreditation status is unclear so that their situation could be resolved by November 2005. Subsequently MHRA were appointed as Interim Competent Authority and able to consider and provide advice on compliance, so it was no longer necessary to pursue the question of accreditation status for the purposes of this report.

Recommendations concerning key impact areas

11. Appendices 3–6 contain recommendations on the key impact areas outlined at paragraph 3 above, the rationale for each recommendation, and estimates of potential

cost implications. Recommendations on some wider issues are at paragraphs 12-17 below, paragraph 18 summarises the overall cost implications.

Wider issues:

Compliance with the Regulations

12. There is some uncertainty in the hospital blood community about the various aspects of compliance and the role of the Competent Authority. It is important to provide clarity as soon as possible and **we therefore recommend** that:

- Hospitals are formally advised of the criteria that have to be satisfied to demonstrate compliance initially by 8th November 2005 and for subsequent years.
- MHRA publish criteria for any intended compliance inspection regime.
- A standard format is used for compliance reporting.
- MHRA establish and publish details of a contact number / name to deal with enquiries from hospitals about compliance.

13. To assist hospitals to assess their potential compliance position we developed a self-assessment 'Implementation Planning Tool Kit' and published it on the JPAC website. **We recommend** that it be published by DH/MHRA for local use in assessing both compliance status and the extent to which additional local resources are needed to achieve compliance. We believe that it is important that Trust Chief Executives are aware of their responsibilities under the Regulations and of the extent to which the arrangements in their hospitals are delivering compliance. **We therefore recommend** that the Trust Chief Executive should sign the annual statement on compliance required by the Competent Authority.

Further Technical Directive on Haemovigilance and Quality Systems

14. We have been kept informed on the progress of the continuing EC discussions on this Technical Directive. Although it is anticipated that the final content will simply amplify the requirements in the Regulations, **we recommend** that, prior to transposition, OIG be involved in consideration of the impact on hospitals.

Accreditation

15. Since the publication of "Modernising Pathology Services" (DH - February 2004) and similar guidance in the Devolved Administrations, laboratory accreditation is no longer voluntary:

> *"…Until recently, enrolment for accreditation was voluntary for NHS laboratories…Laboratory accreditation systems are a key part of clinical governance and quality improvement in the NHS. Therefore all NHS trusts should now ensure that pathology services locally are accredited or seeking accreditation with Clinical Pathology Accreditation (UK) Ltd (CPA) (or another relevant body accrediting to equivalent standards). Any laboratories which are not already accredited, or in the process of becoming accredited, should complete applications for accreditation as soon as practicable."*

16. Accreditation involves an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review. With the exception of the question of traceability, serious adverse event and

reaction reporting and the clinical transfusion process the requirements of the current CPA standard mirror those of the new Regulations. In future, hospitals will have to demonstrate compliance with Regulations and attain accreditation. **We recommend** that DH, MHRA and the accreditation bodies consider the extent to which these processes can or should be combined/rationalised to minimise any overlap or duplication of effort.

17. The terms of reference also asked us to consider any improvements to current arrangements with regard to systems of accreditation, traceability and serious adverse event/ reaction reporting, and to consider any additional arrangements necessary, in order to enhance the provision of assurance and deliver improvements in patient outcomes. Beyond our conclusion about assurance in paragraph 8, we believe that as both regulation and accreditation are ultimately about assurance, this subject might be better considered as part of the review recommended at paragraph 16 above.

Cost Implications

18. There may be additional costs arising from the work on Serious Adverse Event and Reaction reporting referred to at paragraph 5 above, these will be reported on separately as part of that work. Appendices 3-6 identify four main areas for potential cost arising from compliance with the Regulations – Traceability, the Quality Management System, Discontinuation of "processing activities" in hospitals and Training. In summary we estimate that the costs are as follows:

- **Traceability** - The costs associated with a simple paper system to satisfy the requirements of the Regulations and facilitate retention of traceability data in HTLs will range between £7k - £25k per hospital depending on blood usage. Furthermore, there is likely to be an additional staff cost, estimated at between £12k to £25k per post, to ensure the effective operation of the system (Appendix 3 paragraph 11). The longer term cost of IT systems to provide comprehensive traceability will range from around £180k - £600k per hospital depending on size (Appendix 3 paragraph 15) but may be reduced by inclusion in national IT programmes.

- **Quality Management System** - The main cost arises from the recommendation for the provision of capacity for a dedicated Quality Manager function (Appendix 4 paragraphs 6-7). Extending the Quality Management System into the clinical transfusion process and covering the new regulations for serious adverse event/ reaction reporting is new work which will require resource. Although it is for individual Trusts to determine how this is achieved and thus the associated cost, we estimate that a hospital transfusing more than 10,000 units per annum would require a WTE Quality Manager at BMS grade3 or equivalent. The total cost of each post would be around £50k per year. We estimate that there are currently around seventy such hospitals in England hence a potential total of around £3.5m.

- **Training** - If the recommendation at Appendix 6 paragraph 3 to provide training to non-HTL staff is agreed and implemented, there will be a significant, but currently unquantifiable cost around releasing staff to attend such training. As regards the delivery of the training, we believe that the Transfusion Practitioner, where such a post (or its equivalent) exists, has been shown to be best suited for the task. It is estimated that 32% of hospitals in England do not have a

Transfusion Practitioner or equivalent and the cost of such a post is around £32kpa plus "on costs" (Appendix 6 paragraph 5), this represents a potential national cost of around £3.2m.

- **Discontinuation of Processing in Hospitals** - MHRA have advised that some activities currently conducted by hospital blood banks will, under the Regulations, be regarded as 'processing' activities and thus reserved to Blood Establishments. Whilst we believe these changes will have significant cost implications it is impossible for us to estimate these with any degree of accuracy but we attempt in the report (Appendix 5, figure 1) to identify potential cost factors to provide an indication of impact."

Concluding Comments

19. Implementation of the new Regulations by 8th November 2005 presents a challenge to hospitals but we believe that our recommendations will significantly assist with the task. It would, in our view, have been preferable to have involved hospitals earlier in the process of developing the Directives, none-the-less we welcome the opportunity to input to the development of the Regulations and consideration of the impact of implementation. It is in our view imperative that our recommendations are considered and disseminated to hospitals in the form of guidance as soon as possible to provide the maximum lead-time for local action.

Appendix 1

OIG Membership

Joan Jones – Chair	Welsh Blood Service (WBS)
Martin Bruce	Director of Operations - Scottish National Blood Transfusion Service (SNBTS)
Angela Robinson	Medical Director – National Blood Service (NBS)
Jan Green	Transfusion Liaison Nurse – NBS
Teresa Turvey	Hospital Liaison – NBS
John Barker	Transfusion Laboratory Manager – Queen Elizabeth Hospital, Gateshead
Carol Cantwell	Transfusion Laboratory Manager - St Mary's Hospital, London
Brian Jackson	Transfusion Laboratory Manager – Manchester Royal Infirmary
Jan Gordon	Transfusion Practitioner – Chelsea & Westminster Hospital
Sasha Wilson	Transfusion Practitioner – Royal Free Hospital
Clare Taylor	Consultant Haematologist – Royal Free Hospital
Adrian Copplestone	Consultant Haematologist – Derriford Hospital
Claire Harrison	Consultant Haematologist – Guys and St. Thomas Hospital
Tom Kelly	Department of Health
Judith Chapman	British Blood Transfusion Society
Geoff Geddis	Quality Manager, Northern Ireland BTS
Audrey Savage	Transfusion Laboratory Manager – Link Laboratories, Belfast
Caroline Slopecki	NBS
Charlotte Edbury – Secretary	NBS

Sub-group membership

Traceability, Electronic Tracking & IT	John Barker, Brian Jackson, Jan Gordon
Quality Management System	Martin Bruce, Jan Green, Clare Taylor, Carol Cantwell, Geoff Geddis
'Processing' Activities	Angela Robinson, Caroline Slopecki, Teresa Turvey
Training/Education & Communication	Teresa Turvey, Audrey Savage, Adrian Copplestone
Serious Adverse Events/Reactions	Clare Taylor, Carol Cantwell, Sasha Wilson, and representatives from SHOT, NPSA, MHRA,

Appendix 2

NHS Operational Impact Working Group

Terms of Reference

1. To consider and make recommendations to Departments of Health and the UK Blood Services on:

i. Whether the scope of extant requirements on hospital blood banks reflects the minimum requirements of the directive.

ii. Any improvements to current arrangements with regard to systems of accreditation, 'traceability' and 'adverse incident reporting', any additional arrangements necessary, in order to enhance the provision of assurance and deliver improvements in patient outcomes.

Scope of Work

2. Assessing the impact of the directive on hospital transfusion processes, including a status assessment of current practice and, in relation to the issues in paragraph 1(ii) above, producing a prioritised action plan for improvement. The plan should reflect any differences between the UK countries and if necessary incorporate interim measures.

3. Assessing the potential resource implications including IT, identifying where in the NHS the costs fall and consider how these might be funded.

4. To liaise and communicate with all relevant interested parties, including the Transfusion Committee networks.

5. Deliver recommendations on part (i) of the terms of reference by August 2004 and on part (ii) by February 2005

Appendix 3

Traceability, Electronic Tracking & IT

1. This appendix deals with what is probably the most problematic aspect of the Regulations i.e. Regulation 9 (1) (e) requiring hospital transfusion laboratories. to *'maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank.'*

2. Despite the requirements in Health Circulars HC84/7 and HSC 2002/09 ("Better Blood Transfusion 2") and their equivalents in the devolved administrations, for hospitals to be able to trace each unit of blood from receipt to disposal, past look-back exercises have indicated that current systems are not totally effective. We believe that the future software developments planned within the Blood Stocks Management Scheme operated by the UKBS will inevitably assist with traceability requirements and **we therefore recommend** that all hospitals should participate in this scheme.

3. Traceability data may be found in various locations e.g. HTL computer systems and patients' notes. To gauge the extent of the potential problems, we conducted an exercise to obtain some measure of the effectiveness of current hospital tracking systems. Every hospital was provided with the donation numbers of several units that had been issued to them one, two and five years previously, and asked to provide a range of information including details of:

- Receipt of blood at the HTL (date and time)
- Issue to Wards (date and time)
- Unambiguous evidence of patient identity
- How information is recorded (electronically/manual/both)
- Where records are maintained (Ward/HTL/both)
- Traceability method (HTL computer/Ward feedback/Bedside scanning/Other)

4. 229 out of 403 hospitals (54.6%) responded. Each country collated and analysed its individual returns but there was no significant national variation. The data indicate that few hospitals have comprehensive systems fully meeting the requirements of the Regulations. The indications are that whilst some hospitals claim almost full compliance with the requirements, overall, current systems are only about 60% effective in meeting the essential requirements on traceability. We are satisfied that the results represent a reasonably accurate working model of the current situation.

5. HTLs are excellent at recording Donation number, Component Type, Blood Establishment and Date provided. However the trail is less reliable after blood has left the HTL. The Regulations mean that it is no longer adequate to assume, as many hospital systems currently do, that a blood component "issued" for a patient and not returned to the HTL/blood fridge, was in fact transfused to that patient. Resolution of this problem will require the Ward and the HTL to work together to ensure the traceability link is created. There are two key issues (i) the Data set required and (ii) the storage of this data.

6. **The Data Set –** To identify the essential data points, a process map of the transfusion chain is produced at Annex 1. It is apparent that non-HTL staff play a key

part in the chain and this highlights the need for them to receive training to emphasise the importance of their contribution to hospital compliance. (See also Appendix 6 paragraph 2)

7. In order to provide the traceability required from 8th November 2005, **we recommend** that the following minimum data must be recorded and kept in an accessible format by hospitals for 30 years, in respect of each unit of blood/blood component received:

- Donation Number
- Component Type
- Blood establishment that provided the blood component
- Date provided
- Identity of the patient who received the blood component or final fate if not transfused

8. We also believe that it is desirable, from a quality perspective, for hospital systems ultimately also to be able to record additional data. We acknowledge that currently the retention of such data is only feasible where adequate IT systems are in place, however, **we recommend** that ultimately all hospitals should have the facility to record the following additional data:

- Reconciliation with supplier
- The identity of the person who prescribed the blood component – GMC number (or name)
- Details of the "consent to transfusion"
- The reason for the transfusion
- The time, date and identity of the person who collected the blood (from HTL or blood fridge)
- The identity of the person(s) who undertook the bedside pre-transfusion checks
- The date and time of the transfusion
- Any adverse events relating to the transfusion

9. **The storage/retention of traceability data** - It is apparent from our survey that many hospitals do not have appropriate systems in place to ensure compliance with the essential traceability requirements. Currently most hospitals record the transfusion details in patients' notes; although such practice is acceptable under the Regulations (providing of course that it can be shown to work), we do not believe that it is a reliable method for guaranteeing traceability.

10. The Regulations require that the data to support full traceability must be retained for thirty years however, not all patient records are kept for that period. Many hospitals follow the HSC 99/053 ("For the Record") guidance that records are destroyed if the patient has not revisited the trust within eight years. In addition, current Royal College of Pathologists (RCPath) guidance on record retention recommends the storage of Blood Transfusion records for a maximum of eleven years. **We recommend** that DH initiate discussions with RCPath to ensure that their guidance is amended to reflect the requirements of the Regulations. Unless the

storage of patient notes for thirty years can be guaranteed, systems must be devised to retain the required data in suitable formats for retrieval when required.

11. Each hospital can decide how it will store the data to comply with the Regulations. Various methods are available, from simple paper based procedures to full electronic blood tracking systems. We have assessed a simple paper-based system used by some hospitals, which utilises a label attached to the blood component. The label is completed on the ward and returned to the HTL following transfusion (for details, see the toolkit). Even with this simple system there will be the need for HTL support staff to follow up on non-returns and we estimate additional staff costs of around £12k to £25k per hospital per year (for a hospital transfusing 10,000 units of blood). **We recommend** that hospitals using patient notes to provide traceability consider the introduction a simple paper system to ensure that the information in the notes is returned to the HTL for retention for traceability purposes. We estimate that the 'one-off' cost per hospital of introducing such a system would be around £5k for a Thermal Bar-code printer and a recurring cost of about £2k per 10,000 units of blood used for labels, cable ties etc.

12. It should be noted that paper and electronic records or a mix thereof, are acceptable. If a paper-based system is used, information may be transferred into a database and the original documentation discarded, providing the procedure is regularly audited and shown to be effective. If data are stored electronically, future technology must be able to access it.

13. HTLs will have to work very closely with other professionals within the hospital to introduce workable systems. HTLs will have to pursue, in real time, any non-conformance of traceability and this may require additional staff (paragraph 11 above). It may also be necessary to amend existing computer systems in order to introduce efficient systems – this could attract a non-recurring cost of up to £5 -£10k depending on the system.

14. It is essential that Standard Operating Procedures (SOP) are in place for all aspects of the process and personnel are competent in performing the procedures. Regular review will be required to provide assurance that the system is functioning. It is also essential that the system(s) covers all locations where Blood Transfusions are performed i.e. Hospital and in the Primary Care setting, and incorporates emergency blood.

The Longer Term

15. We believe that only Electronic Blood Tracking systems that support data retrieval and improve the clinical transfusion process will provide total assurance on traceability. Some hospitals already have such systems; other systems are currently being piloted in the NHS. Establishing the costs is difficult as requirements for different hospitals will vary considerably. Costs will be a function of the number of clinical areas utilising the system, whether wireless technology is used, and the amount of information required. The following broad costings have been established as a guide:

Hospital Size	Requirements and Costs
Small - (around 20 wards & 1 blood bank fridge)	• Positive Patient Identification System: £15000 + VAT • Fridge Tracking: Main System £16000 (every satellite fridge, £10000) excluding interface & VAT) • Approx. £7500 per clinical area covered (this will depend on methodology i.e. wireless/docking station) **Total : Approx. £180-£200K + VAT**
Medium - (around 30 wards & 2 blood bank fridges)	• Positive Patient Identification System: £22000 + VAT • Fridge Tracking: Main System £16000 (every satellite fridge, £10000) excluding interface & VAT) • Approx. £7500 per clinical area covered (this will depend on methodology i.e. wireless/docking station) **Total : Approx. Approx. £250-£300K +VAT**
Large - (around 60 wards & 5 blood bank fridges)	• Positive Patient Identification System: £30000 + VAT • Fridge Tracking: Main System £16000 (every satellite fridge, £10000) excluding interface & VAT) • Approx. £7500 per clinical area covered (this will depend on methodology i.e. wireless/docking station) **Total : Approx. Approx. £500 - £600K +VAT**

16. There may also be additional staffing costs depending on present staff complements and the system that is introduced. Amendments to Laboratory Information System (LIMS) may also be required as many, depending on the supplier, may require modification to store information. It is estimated that these costs would be of the order of £5 - 10K per hospital.

17. We believe that the introduction of electronic blood tracking systems into the UK should form part of the comprehensive National IT Initiatives program but we have been unable to establish whether such systems are on that agenda. **We therefore recommend** that DH consider the inclusion of these systems into these programmes. This is likely to reduce the scale of the costs identified at paragraph 15 above.

Associated issues

18. Consideration of traceability led us to examine two specific areas which are potentially problematic - the transfer of stock and of cross-matched blood between hospitals. Although policies are in place in most regions, it is essential that in future the traceability chain is clear and documented. **We therefore recommend** that the UK National Transfusion Committees consider establishing national policies; we believe the following to be essential elements of such policies:

- that blood is only transported via the HTL with appropriate documentation.
- that blood is transported and packed correctly to allow the "cold chain" to be confirmed.
- that the dispatching hospital transmits all blood/component information to the receiving hospital recording the location of the transferred blood in their LIMS.

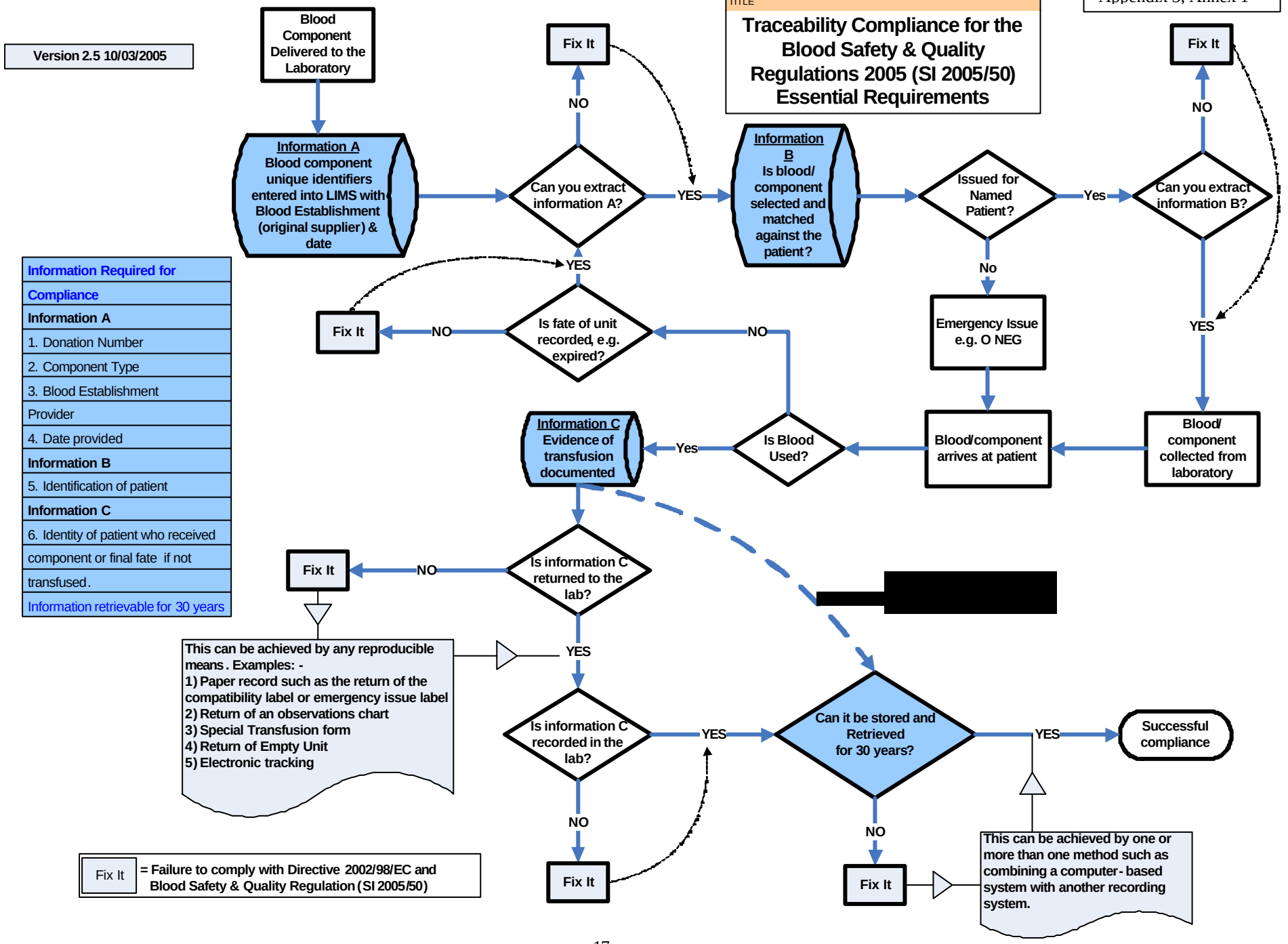
19. Pending the development of national policies, **we recommend** that RTCs or their equivalent check that policies are in place and conform to that recommended above. Alternatively, as the despatch of blood begins with the UKBS **we recommend** the liaison service of the local UKBS supplier develops a regional policy for transference between hospitals.

20. **We further recommend** that the 'receiving' HTLs should be responsible for recording the time, receipt and final fate of the blood; the hospital sending the blood should record when and to where it was dispatched. Sending and Receiving hospitals should make every attempt to record the fate of transferred crossmatched blood. If it bypasses the receiving hospital blood bank, both hospitals should work together to ascertain the fate of the units. This may require real time follow-up to assure compliance. It is important that hospitals have in place standard operating procedure(s) for the transfer of blood, cross-referenced to the current regional policy.

Version 2.5 10/03/2005

TITLE

Traceability Compliance for the Blood Safety & Quality Regulations 2005 (SI 2005/50) Essential Requirements



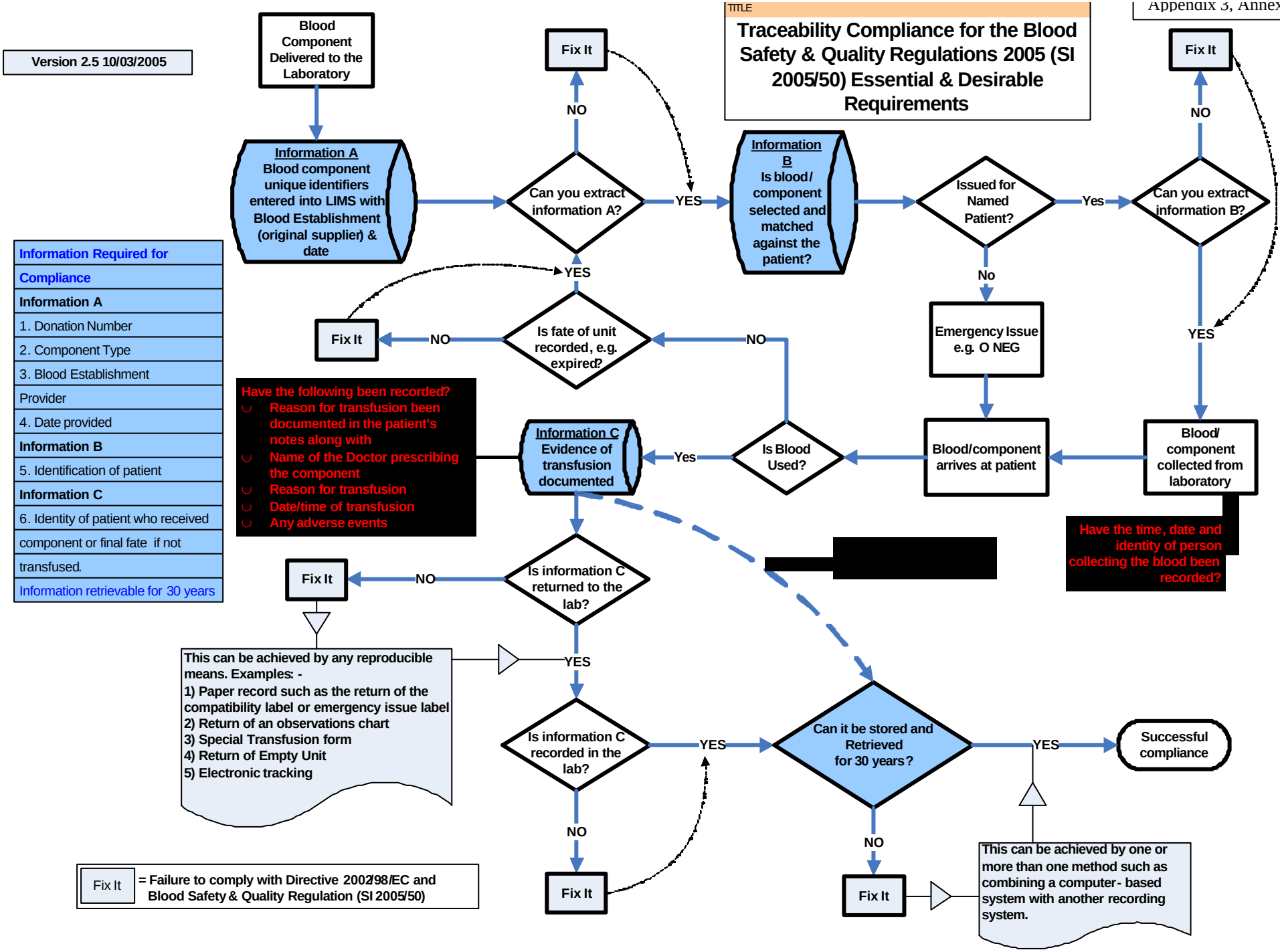
Information Required for Compliance
Information A
1. Donation Number
2. Component Type
3. Blood Establishment
Provider
4. Date provided
Information B
5. Identification of patient
Information C
6. Identity of patient who received component or final fate if not transfused.
Information retrievable for 30 years

TITLE

Traceability Compliance for the Blood Safety & Quality Regulations 2005 (SI 2005/50) Essential & Desirable Requirements

Version 2.5 10/03/2005

Information Required for Compliance
Information A
1. Donation Number
2. Component Type
3. Blood Establishment Provider
4. Date provided
Information B
5. Identification of patient
Information C
6. Identity of patient who received component or final fate if not transfused.
Information retrievable for 30 years



Appendix 4

Quality Management Systems

1. Regulation 9 (1) (b) requires hospital transfusion laboratories to: *'Establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice;'*

2. The 'principles of good practice' will be defined in the Technical Directive still under discussion (see paragraph 14 of the main report); however, as the regulation has to be implemented by 8th November it is imperative that hospitals be provided with guidance so that they may take appropriate action. At Annex 1 below is the specification for a HTL quality system devised by OIG. Although we do not anticipate that the detail of the additional Directive will negate the contents of our specification, to ensure its continuing validity, **we recommend** that the development of the additional directive be monitored.

3. In devising our system, we drew upon a number of expert sources, including the current CPA standard (paragraph 9 of the main report). The specification defines what we consider to be an appropriate system to provide assurance on the totality of quality in the HTL and clinical transfusion process. We acknowledge that this is beyond the strict requirements of the Regulations and reflects the more holistic approach taken in existing accreditation standards.

4. We have discussed our specification with MHRA. They have indicated broad approval of it as a statement of total quality but have explained that as Competent Authority, they will only require the attainment of, or progress towards attainment of, certain criteria within the specification in order to satisfy the requirements of the Regulations. Thus the specification contains three categories of criteria:

- Those which need to be in place by 8th November 2005 in order to demonstrate compliance – these are criteria 1, 2.3, 2.4, 4.1(bold typeface entries only), 4.2, 5.4, 5.5.13, 5.5.16 - 5.5.19, 6.1-6.2,
- Those upon which progress is being made towards attainment – these are criteria 5.3 and 7.1.
- The remainder, which although not a feature of the compliance report to MHRA, are nonetheless in our view, essential components of a meaningful quality system for HTLs.

5. **We recommend** that hospitals are informed of, and advised to implement, the contents of the specification, in particular those aspects which are relevant to the November 2005 compliance report.

6. We believe that the Regulations increase the scope and stringency of quality management within the HTL and clinical transfusion process. More onerous requirements apply for example to the storage and distribution of blood components; "cold chain management"; validation and calibration of processes and equipment. Criterion 2.3 of the specification refers to the Quality Manager role. Our enquiries indicate that very few hospitals in the UK have such a dedicated resource, however, in our view such a post is essential to deliver compliance with the Regulations and thus

the improvements in safety and quality they seek to achieve. Whilst it is unrealistic to suggest the appointment of such a post specific to the HTL, **we recommend** that Trusts ensure that each HTL has access to a Quality Manager with designated functional responsibility for, and authority to ensure the effective operation of, the Quality Management System.

7. It is for individual Trusts to determine how this is achieved e.g. a number of smaller hospitals might "share" a Quality Manager, alternatively, hospitals might "contract in" Quality Manager support from a Blood Establishment and thus have access to the significant quality expertise and back up therein. The costs of this recommendation will determined by the arrangements put in place but, it is likely that for example a hospital transfusing more than 10,000 units per annum would require a WTE Quality Manager at BMS grade3 or equivalent. We estimate that there are currently around seventy such hospitals in England and the cost of a post would be in the region of £50k pa per hospital i.e. a total of around £3.5m.

Appendix 4 - Annex 1

Specification for Hospital Blood Bank Quality System

1	**This specification should be incorporated within a Quality Manual, which describes the quality system in the hospital blood bank.**
2	***PERSONNEL***
2.1	There are competent and appropriately qualified personnel, in sufficient number, to ensure an appropriate service is delivered.
2.2	There is an appropriate organisational structure and approved job descriptions.
2.3	**There is an individual (the Quality Manager) who has designated responsibility and authority to ensure the effective operation of the Quality Management System.**
2.4	**Staff are provided with timely, relevant and regularly updated training including an induction programme.**
2.5	There are hygiene programmes relating to health and safety; personal hygiene and clothing.
2.6	Regular staff meetings are held to review services.
2.7	There is a staff appraisal system.
3	***PREMISES AND EQUIPMENT***
3.1	The facility must be provided with premises and equipment that are located, designed, constructed, adapted, validated and maintained to suit the intended operations;
3.2	Lay out, design and operation must be designed to minimise the risk of errors and permit effective cleaning and maintenance;
3.3	There is appropriate office and laboratory space.
3.4	There are adequate, suitably located staff facilities
3.5	Where applicable there are adequate facilities for patients
3.6	There is appropriate space available for specimen reception, handling, despatch and disposal.
3.7	There are appropriate and adequate data storage, retrieval and communication facilities.
3.8	The laboratory equipment meets the demands of the service and is properly validated, maintained and calibrated.
3.9	There is adequate and safe provision of lighting, heating, ventilation, power, gases, water and drainage.
3.10	There are adequate storage facilities for specimens, reagents and records.
3.11	Blood Bank facilities should comply with the current BCSH guidelines and other relevant standards (e.g. BS 4376). Where relevant, they will also comply with the requirements of Good Manufacturing Practice as laid out in Eudralex Volume 4 contained in the current version of "Rules and Guidance for Pharmaceutical Manufacturers", the Stationery Office.
3.12	There is a safe working environment in accordance with current legislation.
3.13	There are appropriately sited facilities available to support training and continuing education.

4	***DOCUMENTATION***
4.1	**There is a controlled document system in which written procedures describe the work processes and which are regularly reviewed to keep them error free and up to date; This should include:** • **A summary of the Quality Management System;** • Records; • Worksheets; • Labels; • SOPs; • Incident Management System; • Change control system; • Personnel documentation; including organisation chart, job descriptions and training records.
4.2	**Appropriate records are maintained within Health Boards/ Health Authorities/ Trusts. With regard to records which permit the traceability of blood from donor to patient (or final fate if not transfused) the following data items need to be available and accessible for 30 years:** • **Donation number** • **Component type** • **Blood establishment which provided the blood component** • **Date provided** • **Identity of patient who received the blood component or final fate if not transfused.** **Health Boards/ Health Authorities/ Trusts shall determine how this requirement is met e.g.; by entry into a computer database at ward or in the blood bank or by making a record available which is stored separately from the patients notes, possibly in the blood bank, to facilitate storage for 30 years.**
4.3	Compliance with this requirement for traceability will be verified periodically.
4.4	Additionally, it is highly desirable that the record keeping dataset be extended to include information about the transfusion. i.e.: • The identity of the person who prescribed the blood component – GMC number (or name); • Details of the 'consent to transfusion'; • The reason for the transfusion; • The identity of the person who collected the blood (from Blood Bank or Blood Fridge) and the date and time of collection; • The identity of the person(s) who undertook the pre-transfusion checks; • The date and time of the transfusion; • Any adverse events related to the transfusion. This data capture would best be achieved using a computerised system.
4.5	When electronic, photographic or other data processing systems are used instead of typed/ written documents, the system shall have been validated to demonstrate the data will be appropriately stored and can be accessed throughout the period of storage. Electronic data shall be protected against loss or damage of data during storage.
5	***PROCEDURES***
5.1	Procedures will be carried out according to pre-established and documented instructions in accordance with good practice.
5.2	All test methodology should be validated to demonstrate reliable performance before introduction. Tests must be performed by trained staff, using in-date reagents and appropriate controls. Acceptance criteria should be established for all test methods. If acceptance criteria are not met, then test results should not be reported.
5.3	There is a formal, documented system for change control.
5.4	**There is a formal, documented system in which management regularly reviews the performance of the Quality Management System.**
5.5	As a minimum, documented procedures should exist for the following key activities:
5.5.1	There is an up to date user manual.
5.5.2	Request forms for laboratory investigations and specimen labels include provision for unique patient identification and adequate supporting information.

5.5.3	Reports of laboratory results are validated prior to despatch, are timely, accurate and comprehensive. They must include unique patient identity, date of testing/reporting and name and location of requesting clinician.
5.5.4	Interpretative reports are unambiguous, comprehensive and clinically relevant.
5.5.5	There are written procedures relating to specimen collection, handling, retention, despatch and disposal. This includes clear instructions on how to deal with incorrectly labelled specimens and/or improperly completed request documents.
5.5.6	If the hospital where the department is sited is a potential receiving centre for a major accident, there is a readily accessible document within the department instructing staff on procedure.
5.5.7	There is a record of all reagents, calibration and quality control material.
5.5.8	There is a standard operating procedure for the performance of each test.
5.5.9	There is a standard operating procedure for oral transmission of results.
5.5.10	There are standard operating procedures for the regular maintenance of equipment.
5.5.11	There is a standard operating policy describing any out of hours service.
5.5.12	In hospitals, a nominated consultant in the microbiology department is responsible for infection control.
5.5.13	**There are standard operating procedures for the storage, distribution and transport of blood and blood components within and outwith the Hospital.**
5.5.14	There are standard operating procedures for the clinical transfusion process.
5.5.15	There are standard operating procedures to ensure the safety of transfusion in all settings.
5.5.16	**There are standard operating procedures covering temperature controlled storage, its monitoring and management of the "cold chain".**
5.5.17	**There are standard procedures for the validation and calibration of processes and equipment.**
5.5.18	**There are standard operating procedures for the notification of serious adverse events and reactions that satisfy the requirements of the Blood Safety and Quality Regulations 2005.**
5.5.19	**There are standard operating procedures that allow Blood Banks to accurately, efficiently and verifiably withdraw blood and blood components involved in serious adverse events or that are judged to have the potential to cause harm to patients.**
6	***SERIOUS ADVERSE EVENT AND INCIDENT REPORTING***
6.1	**Serious adverse events and serious incidents must be notified to the competent authority, or an agency approved by the competent authority, in a timely and efficient manner**
6.2	**There are procedures that allow Blood Banks to accurately, efficiently and verifiably withdraw blood and blood components involved in serious adverse events or incidents or that are otherwise judged to have the potential to cause harm to patients.**
7	***SELF INSPECTION***
7.1	There is an ongoing programme of self-inspections (audit) which includes periodic audit of compliance with the "traceability" requirements of the Blood Safety and Quality Regulations 2005.
7.2	There is a programme of external inspection/ accreditation.
7.3	Blood Banks participate in appropriate external proficiency testing schemes.
7.4	Blood Banks must have a formal policy for internal quality control
7.5	Where appropriate, the performance in quality assessment schemes is widely publicised in the department with regular formal review.
7.6	There is a programme of quality assurance evaluation which includes continuing audit of the service provided.

Appendix 5

Potential 'Processing' Activities

1. Some activities currently undertaken in HTLs will, from November 2005, be classified as 'processing' under the Regulations. Such activities can only be conducted by licensed Blood Establishments. Although the list below is not exhaustive, we believe that it encompasses the majority of the potentially problematic areas. Advice was sought from MHRA who confirmed that the following would be regarded as 'processing' activities:

- Pooling of Cryoprecipitate
- Irradiation
- Manipulation of Haematocrit/removal of plasma from red cell units
- Pre-operative Autologous Donation (PAD)
- Collection and Processing of Granulocytes
- Splitting of Components
- Washing of cellular blood components

2. However, MHRA also advise that under the Regulations, hospitals could apply for a limited form of blood establishment licence to undertake specific activities, but would have to be inspected prior to licensing. In order to understand the potential scale of the task involved in obtaining such limited licences, we sought advice from MHRA about the potential criteria. For example would the inspection undertaken to license for Irradiation be restricted only to the equipment and immediate environment /personnel involved therein, or would it encompass wider issues/areas that might mean the hospital faced a larger than anticipated compliance task?

3. At the time of writing MHRA are unable to provide specific advice and we are concerned that allowing hospitals to attain a form of Blood Establishment status might potentially have implications for the current roles of the UKBS. **We therefore recommend** that DH, before deciding that hospitals can seek Blood Establishment status, considers such implications. If it is considered appropriate for hospitals to seek Blood Establishment status, and until MHRA are able to advise the criteria required for specific limited licences, **we recommend** that any interested hospital contacts MHRA to obtain a clear understanding of the requirements and costs involved. **We also recommend** that MHRA provide a regularly updated list of activities regarded as processing functions.

4. In the event of it being decided that hospitals may seek limited Blood Establishment licences, MHRA indicate that the normal timescale from application to issue of licence is around three months. Consequently it will be important to advise hospitals as soon as possible of a deadline date for the submission of license applications in order to avoid potential breaches of the Regulations after 8^{h} November 2005.

5. In the light of these concerns we sought information on the incidence of the 'processing' activities in UK hospitals and an assessment of the potential impact and cost implications of the restriction of such activities to Blood Establishments i.e. the UKBS. The results are at Figure 1 below. It indicates that the three key areas of

impact are likely to be in respect of Irradiation, the pooling of Cryoprecipitate, and Pre-Operative Autologous Donation (PAD).

6. On the assumption that such blood components are clinically necessary, it is essential to ensure continuity of supply from 8th November 2005 to avoid any disruption to patient care. In view of this, and the issues raised above, **we recommend** that, for supply planning purposes, it should be assumed that from 8th November 2005, hospitals will no longer be able to make these blood components and UKBS will become the sole suppliers. UKBS must therefore be in a position to provide adequate supplies and **we recommend** that DH initiate discussions with UKBS to ensure the continuity of adequate supplies from 8th November 2005.

7. It is important that hospital users are aware of the changes surrounding these blood components and assess the impact on local practice. **We recommend** that DH/MHRA formally inform hospitals of the changes as soon as possible. **We further recommend** that HTLs and Transfusion Practitioners initiate discussions with clinical colleagues to discuss the likely impact of these changes and any local action that might be necessary, including liaison with UKBS colleagues.

8. MHRA have advised that thawing of frozen plasma components e.g. FFP or Cryoprecipitate is **not** regarded as a 'processing' activity and can therefore continue to be undertaken by HTLs. Our fact-finding indicates that currently some hospitals may not be following the BCSH (British Committee for Standards in Haematology) guidelines and **we therefore recommend** that HTLs follow this guidance and any instructions issued with the component by UKBS. Broken bags should be discarded and this will also apply if the outer bag splits allowing water to come into contact with the component bag.

9. **Cost Implications** – It is likely that the requirement for hospitals to cease making certain components and to obtain them from the UKBS will have cost implications. It is impossible for us to determine these costs with any degree of accuracy as they will depend on, for example, the current costs of hospital production (this will vary from location to location) and the costs to UKBS of increasing production (these cannot yet be assessed). We have attempted in figure 1 to identify potential cost factors to provide an indication of potential impact.

Figure 1. Incidence and impact of main hospital 'Processing' activities that will require to be performed in a Blood Establishment.

1. Pooling of Cryoprecipitate	
Incidence	Performed in up to 20% of UK Hospital Blood Banks
Impact	UKBS currently supply only in single units but are planning to provide a pooled component in due course, the timetable is not known. Until the UKBS pooled component is available Clinicians, nursing staff etc. will need to be made aware of the changes when transfusing cryoprecipitate as individual units. Until a UKBS pooled component is available, issuing of a single unit supplied by the UKBS should improve traceability for those hospitals who currently pool cryoprecipitate.
Costs	**Hospital**: Depends on cost of UKBS pooled component. If hospitals are currently pooling they should have had a laminar flow unit which may no longer be needed. **UKBS**: additional production costs of this component: NBS – n/k, SNBTS - £22,000, NIBTS - £6,000, WBS – Not applicable
2. Irradiation of Blood Components for Transfusion	
Incidence	Not undertaken in N.Ireland, Scotland, Wales. Undertaken by at least 14 hospitals in England some providing more than 5000 units per year
Impact	UKBS will need to be able to respond to increased demand for irradiated components. There may be increased requirements for O negative components. There will be a significant logistical impact especially where the blood establishment is some distance from the hospital, in particular in emergency/acute situations. Within the hospital good communications and organisation will be required to ensure that irradiated components are available for acute scenarios.
Costs	**Hospital costs**: 1. Additional cost for each irradiated unit (£6.61/unit), 2. De-commissioning costs of the irradiator (£30,000+), 3. Extra transport costs (Some could be offset by not needing to purchase Radsure labels). **UKBS**: Production & Transport costs
3. Manipulation of Haematocrit / removal of plasma from red cell	
Incidence	Not undertaken in N.Ireland, Scotland, Wales. Undertaken by a few hospitals in England for neonatal transfusions
Impact	Some impact on those neonatal units doing it. Local and UKBS Clinicians will need to discuss and agree the provision of this product.
Costs	Expected to be minimal
4. Pre-operative Autologous Donation (PAD)	
Incidence	England: Initially estimated that some 49 hospitals do this, although this figure has considerably reduced since awareness has been raised. In N. Ireland, Scotland & Wales – undertaken by blood services for hospitals,
Impact	Apparently particularly prevalent in Paediatric Orthopaedic surgery. In England, local clinicians must engage with NBS to establish whether and how the service will be provided and the associated logistics. Alternative autologous procedures are available for both adult and paediatric surgery but will need to be assessed for suitability. Evaluations may be required prior to such decisions and the time for this needs to be taken into account Hospital Transfusion Practitioners should encourage clinicians to look at alternatives to PAD. Training for operators in both intra-operative cell salvage (ICS) and postoperative drainage (POD) should not be underestimated.
Costs	**Hospital**: Unable to quantify however 1. Cost if PAD red cells units need to be bought from the blood service 2. Changing to ICS or POD (and associated training time and costs) **UKBS**: Unable to quantify however there will be a cost in providing a PAD service.
5. Collection and processing of Granulocytes	
Incidence	Done by some hospitals in respect of treatment post BMT/Inherited Immune disorders
Impact	UKBS will need to supply component - possible difficulties around weekend/bank holiday collections and issues regarding stimulated donors

6. Splitting of Components	
Incidence	Not undertaken in N.Ireland, Scotland, Wales. Undertaken by a few hospitals in England
Impact	None identified and consequently minimal additional costs are anticipated
7. Washing Cells	
Incidence	Not undertaken in N.Ireland, Scotland, Wales. Possibly undertaken in 1 or 2 hospitals
Impact	None and consequently no additional costs are anticipated

Appendix 6

Education, Training and Communication

1. **Education and Training** – Regulation 9 (1) (a) requires hospitals to ensure the provision of specific, regularly updated training to staff involved in the testing, storage and distribution of blood components. Our fact-finding indicates that Blood Bank Managers/Training Officers currently provide such training. Training records must also be available for all staff; including staff working outside of core hours and temporary staff.

2. As regards training records for HTL staff **we recommend** that as a minimum:

- There should be documentary evidence that each member of staff has appropriate qualifications for their position. This should be supported through a current job description and person specification
- There should be documentary evidence that training has been performed
- Each Individual should have a training record, which should form part of their personal portfolio.
- Training should be task based and records should include e.g. date of training, details of task/procedure, procedure reference number, details of all staff trained to undertake the task, details of the trainer and a training review date
- Individual training records should contain copies of any assessment criteria and certificates of training or competence when they have been provided

3. MHRA have advised that the Regulations do not require staff involved in the transfusion process outside the HTL e.g. Doctors, Nurses, ODAs, Porters etc, to receive such training. However, in our view, unless it is provided for these staff and relevant records kept, it is unlikely that hospitals will be able to effectively implement the requirements in the Regulations about traceability and serious adverse event/ reaction reporting (see the process maps at Annexes 1&2 to Appendix 3). **We therefore recommend** that relevant training be provided for all staff involved in the transfusion process i.e. including those outside the HTL and relevant records kept. It should be noted that this is a requirement of Circular HSC2002/009 – 'Better Blood Transfusion 2' and the Clinical Negligence Scheme for Trusts in England.

4. **Resource implications** - It is acknowledged that these recommendations will have resource implications for hospitals. Significant numbers of 'non-HTL staff' are likely to require the training recommended in paragraph 2 above. A survey in England in 2004 indicated that transfusion training at induction had been undertaken for:

- Phlebotomists in 97% of Trusts;
- Porters in 80% of Trusts;
- Nurses in 73% of Trusts
- Medical staff in 60% of Trusts

5. This indicates the potential training task still remaining and **we recommend** that hospitals should, as soon as possible, develop a plan encompassing what training is required, who requires it and who will deliver it. As regards the delivery of such training, our fieldwork indicates that Trusts with a Transfusion Practitioner or

equivalent post generally find it easier to provide effective information and training on transfusion matters. It is estimated that 32% of hospitals in England do not have a Transfusion Practitioner or equivalent post and **we recommend** that these Trusts, depending on size, provide such a post(s) to ensure the effective delivery of the recommended training. The cost of such a post is around £32k pa plus "on costs".

6. **Communication** - The new Regulations represent for hospitals a significant change from past practices, not least in the need for the Chief Executive to make a formal annual statement on compliance to the Competent Authority. Several of the recommendations in this report identify or emphasise the need for effective communication about the impending changes. In achieving change, experience has shown that a co-ordinated approach provides the most likely route for success and we believe that this is particularly applicable in the context of the new Regulations.

7. N. Ireland, Scotland and Wales have established implementation groups to assist hospitals to work through the impact of the changes and establish mechanisms to ensure compliance and the continued provision of a high quality service. We believe that such a planned approach to implementation is necessary in England whilst acknowledging that the scale of the task is much larger. It would appear that there is not a central resource that could provide co-ordination, there are, however, existing mechanisms in England that could be utilised to provide an implementation network for co-ordination and the interchange of ideas. **We recommend** that DH/MHRA consider using either the Regional/National Transfusion Committee structure or the NBS Hospital Liaison structure to provide this formal co-ordination. It is likely that either source will require funding in order to deliver the service.

8. We assume that DH and/or MHRA, having issued guidance to hospitals will want to gauge the likely outcome of the first compliance report in November 2005. Strategic Health Authorities could be utilised for this and might therefore wish to be involved in the co-ordinated implementation network recommended above. It is also apparent that the initial work on implementation is likely to require a continuing dialogue between MHRA and hospitals. **We recommend** that a formal mechanism be established for that dialogue. It may be that the continuation of OIG might provide an appropriate vehicle for this.

Appendix 7

NHS Operational Impact Group – Implementation Planning Tool Kit

The forms, which are attached, are for use within the Hospital/Trust and do not form part of the notification of compliance which will be necessary for MHRA. It is envisaged these could be used to show progress within your organisation regarding compliance with the Blood Safety and Quality Regulations 2005 (50)

Part 1.

Action	Information available	By Whom	Date Completed
Trust Awareness Senior Management awareness to include: • Chief Executive, • Medical Director, • Director of Nursing, • Clinical Governance group, • Pathology Executive • HTC • HTT	-Regulations 2005 (50) -Information supplied by OIG:- • Briefing papers, • Background papers • Recommendations • Toolkit • Implementation group (devolved countries)		
Project Lead Appoint project lead Define implementation process for Trust / Hospital Project Team	Senior appointment Support from HTT/HTC Determined by Trust Board		
Communication strategy • Develop and issue a strategy for use within the Trust • Provide regular updates to defined personnel • Log process • Develop and issue a timetable for compliance and progress	Project lead with support from HTT/HTC and Senior management		

Part 2.

Hospital Self Assessment - Review of compliance

Name of person completing **Date Completed**

Designation of person completing the self assessment

Process / Issue where compliance with the Regulations needs to be assured	Is this process performed in your hospital Y/N	Compliance with Regulations (Full, Partial or Non)	Work / resources required to achieve full compliance
Processing Issues Preoperative Autologous Donation undertaken			
Blood Component Irradiation Undertaken Red Cells Platelets			
Manipulation of components Adjustment of Hct Splitting of components Washing of components			
Pooling Cryoprecipitate			
Collection of Granulocytes for clinical use			
Thawing FFP / Cryoprecipitate • Compliance with BCSH/ UKBS guidance			

Process / Issue where with the Regulations needs to be assured	In place Y/N	Compliance with Regulations (Full, Partial or Non)	Work / resources required to achieve full compliance

Training & Education
• Laboratory staff
  o Competency assessments
  o training records
• Medical staff
  o training records
• Nursing staff
  o training records
• Porters
  o training records
• Others (please define)			

Traceability
Compliant with traceability
• Receipt in lab from Blood Establishment
• Donation No.
• Date
• Supplying centre
• Component
 	
Unambiguous fate of Units
• Transfused
  o Patient identification
• Not used
  o Wasted
  o Date expired
  o Transferred as stock
  o Transferred with patient
 	
Method of traceability
• Full IT system
• Partial IT system
• Paper system returned to Blood Bank
• Notes			

Process / Issue where compliance with the Regulations needs to be assured	In place Y/N	Compliance with Regulations (Full, Partial or Non)	Work / resources required to achieve full compliance
Quality Management System **Fully compliant by 8th November 2005** • Quality Manual • Access to Quality person with dedicated Quality Management function • Staff training • Controlled document system • Traceability system • Management reviews • SOPs • "Cold chain" management • validation and calibration of process & equipment • SOP for adverse event reporting • SOPs for withdrawal of components • Notification to competent authority Working towards compliance • Internal audit programme • Document change control process			
Adverse Event Awaiting information			