Blood Safety and Quality Regulations

Thursday 29 September 2005
Hastings Stormont Hotel, Belfast

September/October 2005
A Blood Establishment Authorisation is needed for the following:

- Whole blood collection
- Autologous whole blood collection
- Testing donor samples
- Apheresis collection of components
Processing Whole Blood into:

- Red cells
- Platelets
- Granulocytes
- Fresh frozen plasma
- Recovered plasma (for discard)
- Cryoprecipitate
- Cryoprecipitate depleted plasma
- Buffy coat
Components processed into:

- Methylene blue treated plasma
- Irradiated components
- Washed components
- Splitting into paediatric (small volume) packs
- Pooling cryoprecipitate
- Manipulation of haematocrit
Statistics

- 629 letters sent out to blood authorities, transplant centres and hospitals (health service and private)
- 553 have replied
- To date the YES responses are 13 – 9 hospitals and the four National Blood Authorities

<table>
<thead>
<tr>
<th>Hospital Region</th>
<th>Letters Sent</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>England</td>
<td>295</td>
<td>276</td>
</tr>
<tr>
<td>Wales</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Scotland</td>
<td>82</td>
<td>63</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Private</td>
<td>175</td>
<td>141</td>
</tr>
<tr>
<td>Transplant Centres</td>
<td>48</td>
<td>45</td>
</tr>
</tbody>
</table>
WHAT

Application for a Blood Establishment Authorisation

3 sections:

• Section 1: Background information, any other licences held

• Section 2: Applicant details

• Section 3: Site information – including multiple sites for one applicant
  Activity
  Processes
  Personnel – Responsible Person (Blood)
  Hospitals and Blood Banks supplied (UK & overseas)
  Facilities on site
  Signed declaration

• Application form and guidance notes on its completion are available on
  the MHRA web site www.mhra.gov.uk
Responsible Person (Blood)

- At least one person must be nominated - can be multiple nominations.
- The application must include a CV for each nominated person and each person must sign that section containing their details.
- The Responsible Person has very specific tasks including the quality assurance processes, labelling and traceability and disclosure of information.
Qualifications

The SI is very specific regarding qualifications – that person must have:

- a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of a university study course OR a course recognised as an equivalent course by the Secretary of State*

and

- practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 2 years, in an establishment (or more than one establishment) authorised in any member state to undertake activities related to the collection or testing or both of blood and components or to their preparation, storage and distribution.
WHEN

DEADLINE - 8th November 2005

Assessment of Application:

- Review the application
- Review the suitability of the Responsible Person (Blood)
- Trigger inspection
- Inspector assesses suitability of premises and quality management system
- Blood Establishment Authorisation issued when inspector confirms suitability

Any establishments not authorised by 8th November 2005 must cease those processes covered by this Statutory Instrument.
Contacts

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Blood Safety and Quality Regulations

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Compliance Reports

Barbara Morris
Definition of Hospital Blood Bank

- Article 3(f) of Directive 2002/98/EC

Citation, commencement and interpretation of SI 2005/50

“… any unit within a hospital which stores and distributes, and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities”. 
Dilemma

- Competent authority required to ensure hospital blood banks comply with requirements for personnel, quality system, storage, transport, distribution, traceability, reporting serious adverse events and reactions etc.
Requirements for Hospital Blood Banks

Regulation 10 of SI 2005/50- Annual Report

• Systems in place to ensure compliance with regulations

• Report any changes which may affect compliance
Hospital Blood Bank Compliance Report

- Completed reports due to MHRA by 31/12/2005
- Assessment of reports to be completed by MHRA by the end of March 2006
- Blood banks which do not appear to be in compliance will be inspected by the MHRA
Hospital Blood Bank Compliance Report

Information required

• Status of CPA accreditation

• Details of personnel recruitment and training

• Details of Quality Management System
Quality Management System

- Quality Incident Reports
- Self inspection
- Technical Agreements
- Complaints
Quality Management System

• Component Recall
• Receipt and storage of components
• Distribution of components
• Traceability
• Adverse reactions and Events
MHRA Expectations

Quality Incident Reports

• Reporting incidents
• Investigation to root cause
• Corrective action
• Preventing recurrence
• Tracking/Trending
MHRA Expectations

Personnel

• Suitably qualified
• Documented work instructions
• Trained to work instructions for tasks performed
• Records of training
MHRA Expectations

Distribution

• Satellite units supplied
• Transport conditions
• Responsibility for satellite unit
• Maintenance of equipment
MHRA Expectations

Traceability/Component Recall

- Final disposition of ALL components
- Linkage between donation number and recipient
- Records of final disposition
- Written procedure for Recall of components
MHRA Expectations

Self Inspection

• Regular review of all activities
• Process for correcting deficiencies
Compliance Report

See example form in handout

Note - not a final version
MHRA Process

Report submitted to licensing

Referred to inspectors and reviewed

Acceptable?

No

Further information

Response Acceptable?

No

Inspection

Yes

Letter of compliance sent to blood bank
Blood Safety and Quality Regulations

Thursday 29 September 2005
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Inspection of Blood Banks and Blood Establishments

Barbara Morris
Reasons for Inspection

Blood Establishments
- Routine inspection once every two years
- Additional inspections if considered necessary
- Response to Serious Adverse Event or Serious Adverse Reaction

Hospital Blood Banks
- Application for Blood Establishment Authorisation (BEA)
- Response to Serious Adverse Event or Serious Adverse Reaction
- Compliance report follow-up
When is a blood bank **not** a blood bank??

- Collection of whole blood or apheresis components for transfusion.
- Secondary processing of components
  - Irradiation of blood components
  - Pooling/splitting components
  - Washing blood components
Overview of Inspection Process

- Inspection arranged
- Inspection conducted
- Follow-up completed

BEA
Inspection Process

- Preparation
- Opening Meeting
- Departmental visits, staff interviews, document review
- Closing Meeting
- Issue of post inspection letter, containing list of deficiencies
- Review of responses
- Closure of inspection, report issued
Preparation

Inspector
Site Information
Review BEA application
or Compliance Report
Previous report
Haemovigilance reports

Site
Update site information
Review documents
Review processes
Opening Meeting

• Opening Meeting by the Inspector
  – Introduction of inspection team
  – Information gathering
  – Tentative schedule
• Opportunity for establishment to present an overview of activities
• Opportunity to ask questions
The Actual Inspection

Obtaining Information
- Witnessing Tasks being performed
- Reviewing Documented Procedures
- Investigating Issues - Why?
Inspection process

System Inspection based upon:

- Quality management
- Personnel
- Premises and Equipment
- Documentation
- Blood Processing
- Complaints/component recall
- Self Inspection
Inspection: Quality System

QUALITY SYSTEM

• Documented procedures
• Training records
• Change control
• Self inspection/ supplier audits
• Component recall/customer complaints
• Technical agreements
Closing Meeting

• Closing meeting by inspector
• Presentation of findings
• Opportunity for establishment to provide further information
• Acceptance of findings
• Notification of next steps
Review of responses

• Responses from the establishment received by the inspector 28 days after delivery of the post inspection letter.
• Corrective action taken/to be taken reviewed
• Further information requested if required to provide satisfactory correction of the deficiency
• Close-out letter sent when inspector assured that the deficiencies have been adequately addressed
Common deficiencies

Blood Establishments

• Equipment
  – validation, calibration, verification

• Quality System
  – incident reporting, technical agreements self inspection

• Documentation
  – records incomplete, corrections, illegible

• Personnel
  – training, training records
Common deficiencies

Hospital Blood Banks

• Quality System
  - lack of documented system for quality incidents
  - lack of written procedures for required processes
    (self inspection, component recall etc)

• Equipment
  - maintenance, calibration, validation
For Further Information

www.mhra.gov.uk

For information on SABRE please email:
sabre@mhra.gsi.gov.uk

For electronic copies of presentations please email:
conferences@mhra.gsi.gov.uk
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