List of deficiencies arising from blood bank inspections classified as major

The average over the 27 sites is approximately 2.1 major deficiencies per site. The minimum major deficiency per inspection is zero, as we have had one or two sites which have had only 'other' deficiencies cited. I think around five majors is the maximum cited so far at a site.

27 inspections carried out so far with the following major deficiencies cited: -

Where appropriate, information has been redacted with **XXXX** to protect the identity of the inspected blood bank.

Quality system related

The quality system was inadequate in that:
- There was no formal procedure for change control.
- Corrective actions were not being completed and closed out in a timely fashion.
- Self-inspection schedule for 2006 was not being maintained.

[SI 2005/50 Section 9 (1) b and d]
[GMP 1.2 and 9.1]

The quality system was inadequate in that:
- There was no formal procedure for change control.
- Corrective or preventative actions were not appropriately documented in quality incident reports, with no final sign off to indicate closure of the procedure.
- The severity of the quality incident was not documented in quality incident reports.
- Quality incidents were not numbered or logged, therefore, there was no assurance that all incidents were being managed appropriately.
- The self-inspection senior management escalation procedure was not being followed when corrective actions were not completed in a timely fashion.
- The customer complaint procedure did not link into the quality incident reporting system when the complaints related to product quality issues.

[SI 2005/50 Section 9 (1) b and d]
[GMP 1.2, 1.3 and 8.2]

The quality system was inadequate in that:
- There was no formal procedure for quality incident reporting.
- There was no formal procedure for change control.
- There was no validation master plan or formal validation procedure.
- The procedure for reporting haemovigilance issues did not state MHRA should be informed.
- No procedure was in place for review of out of specification results.
- There was no formal customer complaints procedure.

[SI 2005/50 Section 9 (1) b, c, d, f and g]
[GMP 1.2, 1.3, 5.21, 8.2 and Annex 15.6]

There was no self inspection procedure or programme.

[GMP 9.1]

There was no formal recall procedure in place.

[GMP 8.9]

The Quality Management System is deficient in that:

- The Quality Management System is in the early stages of development, and there is insufficient evidence available of adequate staffing resource to operate the proposed system in order to maintain acceptable standards for compliance to the Blood Safety and Quality Regulations.
- At the time of inspection there had been no self inspection (internal audit) activity performed, and no proposed audit calendar was in place. The established self inspection SOP does not include an assessment of compliance to Good Practices, or the requirements of the Blood Safety and Quality Regulations.
- The established change control SOP is insufficiently detailed with respect to training and validation requirements associated with a change.
- There is no SOP relating to qualification and validation.
- Records available during the inspection indicate the incomplete documentation of corrective and preventative actions (CAPA) which have been implemented following errors or procedural deviations.
- There is no Technical Agreement (service level agreement) in place with the external hospitals supplied with blood components from **XXXX** Hospital. This should include specific responsibilities with respect to traceability and haemovigilence.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) b, c, d,]
[EU GMP Guide Chapters 1, 7 (Principle), 9; para 4.5, Annex 15]

The Quality Management System is deficient in that:

- Standard Operating Procedure (SOP) **XXXX** does not fully describe the systems in place to document, investigate and record preventative and corrective actions (CAPA) associated with adverse incidents, errors etc.
- There is incomplete documentation of investigations and CAPA.
- There is no SOP for internal recall. The established recall SOP does not include the recall of assigned (cross-matched), non-transfused units.
- There is no SOP for self inspection (internal audit).
- There is no SOP to describe equipment, computer or process validation.
- There is no system for controlling change, and proactively assessing the impact of a proposed change on other associated systems, training requirements or validation status.
- Documentation controls are insufficient.
    - Amended SOPs were noted to contain the same issue date and version identifier as superseded copies of the same document.
    - There is inadequate security of master documents available to all laboratory staff on the shared computer drive.
- There is no inclusion of the relevant responsibilities of SABRE reporting or traceability in the Technical Agreement with **XXXX** Hospital.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) b, c, d, g]
[EU GMP Guide Chapters 1, 7 (Principle), 9; para 4.5, 8.10, 8.11, 8.14-16, Annex 15]

The Quality Management System is deficient in that:

- There is no defined system to record and investigate deviations, errors or unexpected events, which fall outside the scope of the Trust Incident System.
- Incident reports available during the inspection contained insufficient documentation of investigations and corrective / preventative actions arising. Potential ‘systems’ risks arising from individual reported incidents are not fully considered.

- There is no formally documented change control system.
- The **XXXX** documentation control system was introduced without full consideration of GMP controls and completion of the operational documentation required. At the time of inspection there had been no documented system qualification, and Standard Operating Procedures (SOPs) regarding access control, system use, and control of staff assigned temporary 'supervisor' access for population of data, had not been issued.
- There is no system for GMP training and update.
- SOP **XXXX** (Community site standards for reporting blood transfusion adverse events and incidents) does not include the requirement to notify the supplying blood bank of adverse events.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) a, b, f(i)]
[EU GMP Guide Chapters 1, para 2.9, Annex 15]

The Quality Management System is poorly defined and insufficiently robust in that:

- There is a lack of resource available to the Quality Management function, as evidenced by:
  - At the time of inspection, Quality Systems were incomplete
  - Non-adherence to the established systems was noted
  - Systems improvements previously identified by site staff had not been actioned
- There are incomplete systems to record and investigate all relevant laboratory deviations, errors or unexpected events, particularly those which fall outside the scope of the Trust Incident System. Corrective and preventative actions arising from reported errors are not fully documented. There is no evidence of the periodic review of deviations and incidents.
- There is no formal system for the recording and investigation of complaints.
- Training records are incomplete, and do not identify training events with specific Standard Operating Procedure (SOP) version numbers. There is no provision for relevant GMP training.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) a, b]
[EU GMP Guide Chapters 1, para 2.9, 8.2, 8.3, 8.5, 8.6]

Quality systems are deficient in the following respects:

- Forms are uncontrolled and lack references.
- The non-conformances/complaints system is weak is that:
  - The system is not within the formal SOP system.
  - There is no reference made to the need to report incidents to SABRE.
- The Recall procedure is deficient in that:
  - Not all Staff are trained
  - The procedure does not contain a formal requirement to challenge the system on a periodic basis.
- There is no Record retention procedure and the policy for NHS **XXXX** does not currently apply to the **XXXX**.
- There is no Self Inspection procedure (to include the establishing of an annual plan and ensuring information is available to demonstrate compliance with that plan).
- There is no approved Technical Agreement / Service Level Agreement in place with your contract testing Laboratory (**XXXXX**).

[SI 2005/50 Regulation 9, EU GMP Chapter 1, 7, 8, 9, 4.3, 4.4]

The Quality system was deficient in the following respects:

- There is no formal Complaints process to manage Complaints to the Transfusion Laboratory for example, from the supplied hospitals including the **XXXX** hospital. It would appear that the hospital complaints process relates

to patients and would not handle Complaints with regards the Laboratory service.

- There is no system to track and trend the actions from the incidents system.
- There is no Change Control process to manage changes to processes, systems etc in line with Annex 15. The system should be introduced and used for the upcoming introduction of the **XXXX** system.
- There are no procedural based training records.
- There is no routine programme for Good Practice training to include but not be limited to such topics as good documentation practice, storage controls / regimes and hygiene.
- There is no procedure to define the system for granting / removing access to the Laboratory IT systems / equipment or the hospital wide **XXXX** system.
- No controlled SOP for traceability or the reconciliation process was available at the time of the inspection.

[SI 2005/50 Regulation 9]
[EU GMP 8, 5.15,.Annex 15, 43,44, 2.8,2.9, Annex 11, 8]

Quality systems are deficient in that:

- The procedures are currently predominately in a draft state / unapproved.
- Staff training in procedures relevant to the job tasks conducted cannot currently be demonstrated.
- There is currently no self inspection plan or evidence of internal audits.
- There is no procedure for the development of Service Level Agreements (Technical Agreements) and no such documents are in place with facilities supplied outside of the Trust (ie. **XXXX**) to include, as a minimum, the responsibilities for Recall, reporting to SABRE and management of the Fridges.
- Reportedly draft procedures have dates indicating that they are active (eg. SOP **XXXX**, dated effective 02/06/06).
- Reportedly draft procedures have Staff signatures that indicate Staff have been trained in the procedure. (eg. SOP **XXXX**, Recall).
- Significant incidents have not been appropriately addressed in a suitably timely manner. An example being the occasion when an incorrect unit of blood was collected as detailed in incident 2006/**XXXX**, dated 09/03/06. The member of Staff that had signed for the incorrect unit had not been trained in blood collection and as of 24/07/06 the Staff member remained untrained.
- There are no systems in place to ensure that only suitably trained personnel collect blood.
- SOP **XXXX** “Management of Complaints, incidents and Corrective and Preventative actions” does not actually address Corrective and Preventative actions.
- The planned SOP **XXXX** details the responsibilities of the Laboratory IT manager to add / remove Staff from the Systems. It is unclear how the Laboratory IT manager will be made aware of who has joined / departed.
- **XXXX** Using the **XXXX** label printer, gives no instructions to ensure that the equipment is clear of all previous labels / information prior to creating a print run.
- Traceability is currently only achieving 75% of the required full traceability.

[SI 2005/50 Regulation 9]
[EU GMP Chapter 1, 8, 9, 2.8,2.9,4.3, 5.15, Chapter 7 Principle.]

The Quality system and adherence to that system was deficient in the following respects:

- The Complaints process was deficient in the following respects:

    - The Complaints Policy (**XXXX**) and the procedure Departmental Complaints (**XXXX**) both require that a QIF (Quality Improvement Form) is completed for all complaints. In practice this is not done.
    - An uncontrolled flow chart describes the hospital Complaints process. Contrary to the Policies / Procedures the Hospital Complaints Secretary will determine when a QIF is required. The decision making process for that decision is unclear.
    - **XXXX** Departmental Complaints states that the Quality manager decides which Complaints are to be kept a record of.
- Procedure **XXXX** Requirements for Change Control in a hospital blood bank has not been followed for the introduction of max/min thermometers for all storage area monitoring.
- Non conformances / Quality incidents are not currently recorded, investigated and addressed for routine laboratory incidents such as temperature excursions / calibration failures / failure to follow the Standard operating Procedures.
- The process for managing the actions detailed in Non conformance notes relating to the self inspection process is not detailed in the procedures. At the time of the inspection three out of six actions due 01/07/06 appeared to be overdue.
- The procedure **XXXX** Composition of an SOP does not include the content requirements of non-method related SOPs.
- The procedure **XXXX** Document Control does not specify the Review and Approval process sufficiently to ensure a review for compliance to Regulations and Corporate Policies and Procedure.
- No Service Level Agreement / Technical Agreement is in place with **XXXX**. The current contract with **XXXX** and **XXXX** does not address the three key aspects of (i) Reports to SABRE (ii) Responsibilities for the cold chain (iii) Traceability.
- SOP **XXXX** Record Storage currently refers to document retention of 11 years. 15 years is increasingly the expectation.
- There is no routine programme for Good Practice training to include but not be limited to such topics as good documentation practice, storage controls / regimes and hygiene.
- Document completed was seen to be poor with errors noted such as empty boxes, obliteration of entries and overwriting.

[SI 2005/50 Regulation 9]
[EU GMP 4.3,4.4, 4.5, 5.15, Chapter 7 Principle. 2.8, 2.9, 4.7, 4.8]

The Quality system was deficient in the following respects:

- There is no formal Complaints process to manage Complaints to the Transfusion Laboratory for example, from the supplied hospitals including **XXXX**. It would appear that the hospital complaints process relates to patients and would not handle Complaints with regards the Laboratory service.
- There is no Service Level Agreement with **XXXX** hospital to include key aspects of (i) Reports to SABRE (ii) Responsibilities for the cold chain (iii) Traceability.
- There is no system to track and trend the actions from the incidents system.
- There is no Change Control process to manage changes to processes, systems etc in line with Annex 15. The lack of the system is evidenced by the lack of documented control concerning the introduction of the **XXXX** system.
- There are no procedural based training records.
- There is no routine programme for Good Practice training to include but not be limited to such topics as good documentation practice, storage controls / regimes and hygiene.

- There is no procedure to define the system for granting / removing access to the Laboratory IT systems / equipment or the hospital wide **XXXX** system.

[SI 2005/50 Regulation 9]
[EU GMP 8, 7, 5.15,.Annex 15, 43,44, 2.8,2.9, Annex 11, 8.]

The quality system was inadequate in that:
- There was no formal procedure for change control.
- Process deviations were not being reported as quality incidents.
- Corrective actions were not being completed and closed out in a timely fashion.
- No self-audits were undertaken in 2005 and the corrective actions arising from audits held this year were not being closed out effectively.

[SI 2005/50 Section 9 (1) b and d]
[GMP 1.2 and 9.1]

The quality system was inadequate in that:
- There was no formal procedure for quality incident reporting.
- There was no formal procedure for change control.
- There was no validation master plan or formal validation procedure.
- There was no formal procedure for reporting haemovigilance issues.
- The back-up system for issuing blood components was not formalised in a procedure.
- There was no formal customer complaints procedure.

[SI 2005/50 Section 9 (1) b, c, d, f and g]
[GMP 1.2, 1.3, 5.21, 8.2 and Annex 15.6]

There was no self inspection procedure or programme.

[GMP 9.1]

There was no formal recall procedure in place.

[GMP 8.9]

The quality system is insufficiently robust with respect to the following:
- The Standard Operating Procedure (SOP) Blood/Blood Product Recall does not include details of the action to be followed in the case of a locally initiated recall.
- There is no SOP regarding reporting Quality Incidents and there is no procedure in place for the tracking and trending of incidents which are not entered into the Trust incident reporting system.
- There is no formal documented procedure for the validation of equipment and processes.
- There are no Service Level Agreements currently in place with community hospitals supplied with blood components by **XXXX** Hospital.
- Although there is a process in place for self inspection and inspections are being conducted, there is no SOP for this procedure
- Uncontrolled job aids were seen to be in use in several areas of the department and the copy of SOP **XXXX** used for reference is not the same as the controlled version.
- There are no records to show that all staff working in transfusion have been adequately trained for the tasks performed. This is of particular relevance for those staff participating in the Continuous Pathology Processes (CPP) who do not routinely work in Blood Transfusion.

[The Blood Safety and Quality Regulations 2005 - Regulation 9a, 9b, 9c]
[EU GMP - Chapter 1, Chapter 2]

The quality system was inadequate in that:

- There was no formal procedure for change control.
- No formal procedures were in place with hospitals receiving blood components to define responsibilities in relation to traceability and haemovigilance.
- There was no recall procedure in place.
- No procedure was in place for reporting and investigating process deviations in the Transfusion laboratory.
- Clinical investigation reporting did not include appropriate follow-up to ensure timely completion of corrective actions, sign off and closure.

[SI 2005/50 Section 9 (1) b and d]
[GMP 1.2, 1.3, 8.9, 9.1 and Annex 15 point 4 (f)]

There was no procedure or programme of self-inspection being undertaken.

[SI 2005/50 Section 9 (1) b]
[GMP 1.2, 9.1, 9.2 and 9.3]

No system had been implemented to ensure full traceability, blood components issued from the blood bank were assumed to have been transfused.

[SI 2005/50 Section 9 (1) e]

The control of quality related incident investigations and Corrective and Preventative actions was deficient in that:

- The investigation into the mis-transcrition of a blood grouping result to the system for release for components and the subsequent issuing and transfusion of an incorrectly matched unit identified the preventative measure of introducing testing equipment that interfaced directly with the release computer. Although the equipment had been purchased and had been within the laboratory for approximately 6 months the system was not in use.
  - It was noted that a purely manual check system had been implemented but the Inspector questioned the security that this system provided.
- There was no procedure detailing the control and performance of quality related incident investigation e.g. trending, analysis of root causes, systems to monitor and ensure the timely completion of investigations and related corrective and preventative actions.

[EU GMP Guide Chapter one principles]

The Quality Management System was deficient in that:

- The recall procedure did not detail the quarantining of components returned due to an internally generated recall nor did it cross-reference the procedure for SABRE recording.
- There was no complaint procedure.
- There was no procedure detailing the process for the validation of equipment and facilities.
- There was no procedure for controlling changes to equipment and facilities. This was of particular concern in view of the imminent move of the laboratory to a new facility
- Document control was weak in that:
  - There was no evidence that procedures had been reviewed annually as stated in the Document control procedure (this procedure itself had not been reviewed as required).
  - A large number of procedures were still in an old format.
  - The document control procedure referenced the use of the **XXXX** system. However at the time of the inspection this system was not in use in the transfusion laboratory.

- Training was weak in that:
  - There was no procedure detailing the training policy.
  - GMP training was not performed.
  - Not all laboratory personnel had training records.

[SI 2005, 50: Regulation 9(1)a,b,d,f and g]
[EU GMP Guide para 2.9,4.5,5.15, Annex11 and 15]

There was no predefined schedule or procedure for the self-inspection of all critical steps performed in the transfusion laboratory.

[SI 2005/50 Section 9 (1) b]
[GMP 1.2, 9.1, 9.2 and 9.3]

The Quality Management System is deficient in that:

- The control of quality related incident investigations was weak in that:
  - There was no procedure detailing the control of investigations using the **XXXX** system (e.g. allocation of proposed closure dates, actions to be taken in the event of failure to close investigations in a timely manner, trending of the data and control of subsequent corrective and preventative actions).
  - **XXXX** does not detail the process for performing investigations into SAE and SARs.
  - The Trust Policy and Procedure guidance for investigations into quality incidents did not include a cross-reference to the SABRE reporting procedure.
  - Not all quality related incidents were reported into the Quality system e.g. The two incidents from the **XXXX** blood bank temperature monitoring on 6th June and5th August 2006.
  - Some of the investigations reviewed lacked detail as to the investigation or the required Corrective and Preventative actions e.g. actions were to retrain with no explanation of why the original training had not been effective. - Investigations into test control failures in the laboratory were not formerly documented in the Quality Management System.
- The recall procedure did not include full details of the process for quarantine of returned units or cross-reference the SABRE reporting procedure.
- There was no procedure detailing the handling of complaints at the local departmental level.
- Processes for controlling qualification of equipment and facilities were weak in the following respects:
  - There was no procedure detailing the qualification of equipment and facilities
  - The **XXXX** system was being tested for feasibility with no formal protocols or project documentation.
- There was no procedure for controlling changes to equipment or facilities.
- The training procedure was weak with the following regards:
  - There was no requirement for periodic GMP retraining.
  - There was no assessment of the effective GMP training.
- Control of procedures were weak in that:
  - During the inspection two of the procedures reviewed were the incorrect version (**XXXX** and **XXXX** procedures)
  - There was no evidence that **XXXX** procedure had undergone the required annual review.
- There was no procedure or predefined schedule for self-inspection covering all of the quality critical processes.

[SI 2005, 50: Regulation 9(1)a,b,d,f and g]
[EU GMP Guide para 2.9,4.5,5.15., Annex11 and 15]

Premises related

The premises were inadequate in that:

- The blood bank was cramped and overcrowded for the level of activities undertaken.
- Windows and doors to the blood bank were propped open.
- An appropriate room temperature was not being maintained during the Summer months for the laboratory reagents being stored in the blood bank.

[GMP 1.3, 3.4, 3.5, 5.7, 5.10 and 5.16]

The condition of the laboratory is unsatisfactory for its intended use, in that:

- At the time of inspection there was open access from the laboratory to the roof void, due to the loss of a large light-fitting diffuser.
- Windows throughout the laboratory are corroded.
- Laboratory windows were open to provide ventilation, placing open containers of laboratory reagent (e.g. in the Diamed Gel Station equipment) at risk of contamination.
- The laboratory area was noted to be dirty.
- Significant corrosion and damage was noted to a number of work surfaces.
- Wall finishes are damaged.
- There is no temperature monitoring of the area, which is also used to store reagents and other temperature sensitive products.

[EU GMP Guide Chapter 3 Principle, and para 3.1, 3.2, 3.3]

The laboratory facility was deficient in that:

- It was too small and logical process flows were not evident.
- At the time of the inspection the area was cluttered with records stored in an ad-hoc manner.

It was noted the laboratory will be moving to a new facility in 2007.

[EU GMP Chapter 3 principles]

Documentation related

Documentation was inadequate in that:

- No document control system was in place.
- Many illegible, unsigned and undated changes to documents were observed.
- Numerous uncontrolled aide memoires were observed throughout the facility.

[SI 2005/50 Section 9 (1) d]
[GMP 4.2, 4.3, 4.4, 4.5 and 4.7]

Not all laboratory practices and procedures have been documented in Standard Operating Procedures. A full review of all processes should be undertaken to identify gaps in the documentation system, and rectify these areas. Specific examples include, but are not limited to:

- Incomplete information relating to sample label acceptance
- Lack of SOPs to describe group / screen and crossmatching using the Autovue equipment
- Actions to be taken in the event of failure of laboratory controls, and associated investigations into potentially implicated analytical results.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) d]

At the time of inspection, not all stated systems of work had been formally described by controlled Standard Operating Procedures (SOPs). Examples include, but are not limited to:

- A number of procedures were noted to contain insufficient detail, for example procedures relating to:
    - Stock receipt (e.g. components from **XXXX**)
    - Patient sample receipt and barcode labelling
    - Centrifuge cycle parameters are not controlled within approved procedures, and are not available at the point of use.
    - The 'exceptional release' of blood components which may be suitable for transfusion, but not classified as compatible.
- A number of procedures were not included in the documentation system, such as:
    - Actions to be taken where Test method Quality Control checks fail.
    - Operational controls related to possible contingency actions in the event of the loss of a critical system (e.g. Diamed Gel Station equipment).
    - Interpretation of reaction classification for manual techniques.
    - Labelling and issue of blood components following acceptable cross-match.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) d]

At the time of inspection, not all stated systems of work had been formally described by controlled Standard Operating Procedures (SOPs).

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) d]

At the time of inspection, not all stated systems of work had been formally described by controlled Standard Operating Procedures (SOPs). Examples include, but are not limited to:

- A number of procedures were noted to contain incorrect information, for example:
    - The manual grouping SOP (**XXXX**) refers to a method no longer used, and information on daily controls is incorrect.
    - The SOP for issue of emergency O negative red cells (**XXXX**) refers to the use of the superseded computer system
- A number of procedures were not included in the documentation system, such as:
    - There is no SOP to describe equipment and process validation.
    - There is no SOP to describe the control of changes to processes or equipment, in order to adequately consider the necessary amendments to documentation, training and validation status of associated systems.
    - There is no SOP to describe the return of blood components to the laboratory for re-issue.
    - There is no SOP to describe the antibody panel analysis on the Autovue equipment.
    - There is no SOP to describe the manual issue of blood components in the event of computer failure.
    - There is no SOP to describe the 'exceptional' issue of components which are considered suitable for transfusion, but not compatible.
- A number of uncontrolled documents were in use within the laboratory.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) d]
[EU GMP Guide Chapter 4 Principle, and Annex 15]

The documentation control process is deficient in that:

- Document Control Procedure (**XXXX**) has not been followed for the creation of the current transfusion laboratory SOPs / Procedures. Procedures were placed directly into the Active section of **XXXX** thereby skipping the Draft section and therefore the Approvals process.
- Document Control Procedure (**XXXX**) requires that all original master documents are signed for approval but in practice this is not done.
- A number of the current procedures are dated November 2005 but were reportedly not approved for use until August 2006. As a consequence training does not appear to have been conducted in a timely manner and activities may appear to have been out of compliance with the procedures for the Nov to Aug period.

[SI 2005/50 Regulation 9. EU GMP 4.3, 4.4, 4.5.]

Documentation was inadequate in that:
- No document control system was in place.
- Many illegible, unsigned and undated changes to documents were observed.
- Hand written annotations were noted to laboratory protocols and computer product codes.

  Numerous uncontrolled aide memoires were observed throughout the facility.

[SI 2005/50 Section 9 (1) d]
[GMP 4.2, 4.3, 4.4, 4.5, 4.6 and 4.7]

The control of documentation was inadequate in that:
- All formal procedures in use were expired, often by several years.
- Uncontrolled aide memoires were observed throughout the facility.
- Hand written annotations were noted to some formal procedures.

[SI 2005/50 Section 9 (1) d]
[GMP 4.2, 4.5 and 4.6]

Testing related

The current method of transcribing group and screen results from the Autovue report to the computer system work queue list does not adequately protect against the possibility of cross-over or transcription error.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) b]
[EU GMP Guide para 4.17]

Laboratory computer controls are inadequate in that:
- At the time of inspection there were no records available relating to the validation of the computer system critical functions.
- There is no system to control system upgrades, and their impact on the system validation status.
- There is no SOP for the control of remote access by **XXXX** computer engineers.
- There has been no assessment of the effectiveness of a system restore from back-up data.

[EU GMP Guide Annex 11 and 15]

At the time of inspection, not all stated systems of work had been formally described by controlled Standard Operating Procedures (SOPs). Examples include, but are not limited to:
- Changes in daily Autovue controls had not been incorporated into the relevant SOP(s).

- There was no SOP to describe reaction interpretation for blood grouping and antibody screening.
- There was no SOP to describe the process of 'exceptional release' of suitable, but not compatible, blood components.
- There was no SOP to describe the process of manual component issue in the event of computer failure.
- There was no SOP to describe component issue, labelling and area clearance to minimise the risk of mix-up.
- There was no SOP to describe the blood components returns process.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) d]

Operational activities were deficient in that:

- Examples were noted where the Blood transfusion record label was not fully completed.
- The Printed blood bank report is to be checked by a second person against the test cards but this check does not reportedly include a check of the completed Blood transfusion record label.
- The procedure for the receipt of test kits and reagents is unclear as to what the kit/reagent insert is to be checked for (ie. to ensure that the currently procedure defined process remains unaffected).

[SI 2005/50 Regulation 9]
[EU GMP 4.8 6.16, 6.21]

The management / storage of materials was deficient in the following respects:

- The display chart for the Lab cold blood bank on ward **XXXX** showed a trace of 6.5°C to 7°C for the week of the inspection. This is outside the required 2 – 6°C limit. The high temperature appeared to date from maintenance work on 12/7/06. Charts since this time have been reviewed and approved without the excursion being noticed.
- Reagents / liquids are present in the laboratory without identification / dates of manufacture or expiry. For example the PBS.
- The receipt check of test kits / reagents is not documented to check the reference number for changes to the method.
- Storage of materials is deficient in that:
  - compliance to the required storage temperatures cannot be demonstrated,
  - Stock is stored in the floor.
  - Human Albumin is stored in the open, contrary to the storage requirements to protect from light
  - The Human Albumin, stored on the floor, was adjacent to the thermogenesis unit. On moving the thermogenesis unit the floor was found to be unclean.

[SI 2005/50 Regulation Part 4(i),Regulation 9 (i) d, h.]
[EU GMP 3.41]

The monitoring / control of temperature is deficient in that:

- The theatre fridge temperature limits are set at 2 to 8°C, not the required 4°C +/- 2°C.
- The theatre fridge alarm was challenged during the inspection and failed to result in an audible alarm.
- The temperature chart records for the blood stock fridge appeared to be missing for -30 May to 6 Jun 06 and dual sets of data appeared to be present with no explanation for 15 / 17 Jun and 6 / 7 Jul 06.
- The calibration certificate for incubator **XXXX** was not available.

[SI 2005/50 Regulation Part 4(i),Regulation 9 (i) d, h.]
[EU GMP3.41]

The Operational Activities were deficient in the following respects:

- The management of the blood storage fridges was deficient in the following respects:
    - There are no cleaning records for the Laboratory or Theatre fridges.
    - The space used for Quarantine material in the Laboratory Fridge is not labelled.
    - The storage fridges have not been temperature mapped.
    - At the time of the inspection it was not possible to confirm the alarm conditions for the Theatre fridge.
    - The laboratory fridge reportedly had the alarm set at 1.5°C contrary to the required lower storage condition of 2°C.
    - The buzzer on the Theatre fridge has been silenced.
- The water bath is not calibrated to a National Standard and no calibrated thermometer is in use.
- On receipt of test kits / reagents the version control on the insert is not checked to identify any potential changes to method / process.
- A Bar code label had been left on the labelling machine at sample receipts. There is no line clearance requirement.
- A bottle of Haztab labelled “Expired 7/4/06” was in use for wipe down of the sides at sample receipt.
- At the time of the inspection the multi-pipettes for the Diamed system could not be shown to be calibrated.
- 4 of the 6 **XXXX** pipettes were calibrated over a year ago. The pipettes were not labelled, contrary to the Equipment – General SOP (**XXXX**)
- There is currently no programme / schedule for planned maintenance / calibration.

[SI 2005/50 Regulation Part 4(i),Regulation 9 (i) d, h]
[EU GM P3.41 6.7, 6.21, 6.20, 5.45]

Training related

Training is deficient in that:

- There is no SOP to describe the systems for training and competency assessment.
- There is no formal provision for update training.
- There is no system for recording initial competency assessments of staff to authorise unsupervised activity in key tasks.
- Training records available during the inspection contained insufficient information.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) a]

Training was inadequate in that:

- No training records were available, verbal approval by Chief BMS was given for staff to undertake blood bank activities unsupervised.
- No GMP awareness training had been provided to staff.

[SI 2005/50 Section 9 (1) a]
[GMP 2.8 and 2.9]

Equipment validation, calibration and maintenance related

Equipment maintenance and calibration is deficient in that:

- At the time of inspection, there was no system or SOP for the site control of planned preventative maintenance scheduling. Inappropriate reliance is placed on external servicing companies initiating each planned service visit.
- Not all critical equipment is subject to planned preventative maintenance (e.g. blood storage fridges)
- There was no evidence available to indicate that the Transfusion Laboratory has sight of, or control over, maintenance scope and specifications.
- The Transfusion Laboratory does not possess adequate records of all maintenance activities.
- There are no records available on site to indicate that senior site staff have checked and approved the available equipment service reports.
- There was no validation or documented acceptance of the upgrade of **XXXX** software from version **XXXX** to **XXXX** between 9th September 2005 and 8th March 2006.
- There is no system for recording non-routine operator equipment maintenance.
- There is no programme for the calibration or verification of temperature control for the **XXXX** FFP thawing equipment.

[EU GMP Guide para 3.34, 3.35, 3.41, Annex 15]

The monitoring of controlled temperature storage facilities is deficient in that:

- Temperature limits applied to routine monitoring and alarm settings are not appropriate to the requirements of the materials under storage. At the time of inspection, there was no formal justification or scientific assessment of the validity of the current practice of setting alarm limits outside the storage limits stated on material labels.
- There was inadequate temperature monitoring (and associated records) of the main Blood Bank fridge between 10th April and 7th August 2006, following damage to the chart recorder.
- There is no monitoring of the storage temperature of Human Albumin solution.

[Blood Safety and Quality Regulations (SI 2005/50) Regulation 9 (1) h]
[EU GMP Guide para 1.2 viii]

The implementation of the **XXXX** computer system in March 2006 was not carried out in a manner which demonstrates acceptable control or verification of critical functions.

- Data migration from the legacy system remains incomplete.
- No documentation was available to demonstrate validation of all critical system functions.
- Validation work carried out was not documented in accordance with GMP requirements.
- There was no evidence available to indicate that the **XXXX** system had been formally accepted (signed off) for use in the laboratory.
- No training was provided to staff in advance of the implementation date for a number of key functions, for example data upload from the **XXXX** system.
- There are no approved, controlled SOPs relating to the use of the **XXXX** system.

[EU GMP Guide Chapter 4 Principle, and Annexes 11 and 15]

Equipment and process qualification and validation is deficient in that:

- There is no Standard Operating Procedure (SOP) to describe the system for qualification and validation, to ensure compliance with GMP requirements.
- At the time of inspection, there was no documentation available to demonstrate the acceptable validation of the critical functions of the **XXXX**

laboratory computer system. Appropriate retrospective validation should be performed.

[EU GMP Guide Annex 11 and 15]

Validation is deficient in that:

- There is no authorised validation policy or procedure available for validation of Methods, Equipment.
- There is no Validation master plan and no documented assessment of the validation requirements carried out before purchase/installation.
- There is no / minimal validation in place for equipment or methods.
- No validation data is available to support the use of the **XXXX** transport boxes.

[SI 2005/50 Regulation 7.1c]
[EU GMP Annex 15]

The Validation and equipment management systems are weak in that:

- There is no authorised validation policy or procedure available for validation of Methods, Equipment or Computer systems.
- There is no Validation master plan and no documented assessment of the validation requirements carried out before purchase/installation.
- There is no evidence of validation of key equipment. Including but not limited to:
  - The **XXXX** system.
  - The interface from the **XXXX** to the **XXXX** system.
- There is no evidence of temperature mapping of the cold storage stock fridge.
- The Limits for the **XXXX** system are not set at the required 4°C +/- 2°C.
- Access to change the limits in the **XXXX** system is not controlled.
- There is no temperature monitoring of the water bath used for FFP defrosting.
- Evidence of calibration of the water bath used for FFP defrosting was not available at the time of the inspection.
- Validation of the blood storage boxes has not been conducted at the limits of available packing formations. The blood is reportedly transported packed in formations different from those formations that are currently validated. There is no procedure to define the acceptable packing formations to ensure maintenance of the 4°C +/- 2°C limits (ie. those formations that are validated).

[SI 2005/50 Regulation 7.1c]
[EU GMP Annex 15]

There was no assurance that temperature control of thermally controlled equipment was appropriate as the equipment themselves and the minimum / maximum thermometers used for daily checks were not calibrated.

[SI 2005/50 Section 9 (1) h]
[GMP 3.41]

Planned Preventative Maintenance (PPM) of equipment shows the following deficiencies:

- There were no records available at the time of the inspection to show that the refrigerators and freezers were routinely maintained.
- There were no records available at the time of the inspection to show that all critical pieces of equipment had been calibrated.
- The equipment logs, used to provide a history of each piece of equipment, do not contain a full accurate record of all maintenance and repairs.

[EU GMP – Chapter 4]

The control of maintenance and calibration was deficient in that:

- Records were not adequately reviewed by the laboratory personnel, as evidenced by the incorrect alarm limits reported on the last calibration report for the temperature monitoring system.
- There was no schedule for equipment maintenance.
- Not all servicing was performed in a timely manner. The **XXXX** stated maintenance schedule was six monthly however several Services had been performed outside of this limit.
- There were no predefined specifications for contractor performed maintenance and calibration.
- As found results were not reported.

[EU GMP Guide, Chapter 3 principles, para 3.41]

The systems for temperature controlled storage were weak in that:

- There was no procedure detailing actions to be taken in the event of out of limit temperature alarms.
- A large number of out of limit alarms were noted but these had not been adequately investigated or appropriate actions taken.
- The alarm limits for the platelet agitator were incorrectly set at 22 to 35°C.
- Critical alarm settings were not routinely checked.
- The temperature alarms were inappropriately set with a 15 minutes delay despite thermocouples being located in fluid buffers.

[SI 2005, 50: Part 4 section 1]