**HOSPITAL BLOOD BANK INSPECTIONS**
Assessment may include, but is not limited to, the following:

### Introductory Meeting
- Introductions – Scope of Inspection - Overview of Blood Bank Activities
- Future Plans and Development
- Check Compliance Report
- Organisational Chart and Staff numbers
- Review of Responses to Previous Inspection (if applicable)
- Changes since previous Inspection (if applicable)

### Quality System – To be reviewed in general and in detail at point of use.
- Standard Operating Procedures
- SAE and SAR reporting (SABRE)
- Equipment Qualification and Process Validation (including computers)
- Self Inspection Plan
- Technical Agreements/Service Level Agreements
- Customer Complaint procedures & records
- Record retention
- Document Control and Change Control
- Traceability system/Lookbacks
- Equipment – Usage, Maintenance and Calibration.
- Process records – completion
- Staff training (including out of hours)
- Quality Incident Reports, Process Deviations
- Recall procedures, records and investigations

### Pre-transfusion Testing
- Sample acceptance
- Equipment – Usage, Maintenance and Calibration
- ABO Rh and antibody screen
- Compatibility testing (computer crossmatch or manual methods)
- Results Transfer/Recording for component release
- Back –up system in the event of routine system failure
- Test methodology
- Equipment qualification
- Batch acceptance for test kits and reagents
- Validation of test methods used
- Out-sourced (Contract) testing
- External QC Accreditation scheme (NEQAS)

### Warehousing and Storage
- Suitability of area
- Inventory Control System
- Temperature monitoring
- Controls to ensure critical supplies are of the required specification

### Secondary Processing of Components - Thawing of components
- Selection of components
- Relabelling components for expiry date/time change
- Critical process controls
- Equipment used

### Labelling and Release of components
- Inspection of components
- Production of labels
- Concessionary / exceptional release
- Release/issue process controls
- Line clearance
- Back –up system in the event of routine system failure
HOSPITAL BLOOD BANK INSPECTIONS
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**Distribution of components**
- Customer approval of supplied sites
- Back-up system in the event of routine system failure
- Delivery
- Handling of returned components
- Order receipt and processing
- Packing of components for shipment
- Stock Controls
- Storage of components

**Transport**
- Contract delivery companies and subcontractors
- Breakdown contingencies

**Facilities**
- Temperature monitoring and controls
- Pest control and Security
- Back-up Power
- Planned preventative maintenance calendar

**IT**
- Function and role
- Change controls (hardware, software updates)
- User access rights
- Data archiving
- Maintenance of hardware and software
- Backups and storage - disaster recovery
- Server room security and controls

**Closing Meeting** – reporting of deficiencies – explain next steps.

**Reference Documents**
- Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book).
- Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components.
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide).
- PIC/S Guidance documents (Pharmaceutical inspectors cooperation scheme).
- British Committee for Standards in Haematology (BCSH) Guidelines