# Monitor with solid fillINVITATION TO SUPPLY A TRANSFUSION LIMS SOLUTION

LIMS

SPECIFICATION

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**INTRODUCTION**

**INSTRUCTIONS FOR BIDDERS**

* The enclosed specification represents the technical requirements that the chosen information management system has to meet. If there are any areas of the specification that are under development, these **MUST** be clearly indicated with a statement regarding availability.
* Please respond to the technical specification by the stated deadline.
* Throughout this document the use of the word ‘system’ may be taken by the supplier to mean all equipment proposed as part of the package.
* The solution proposed may contain specific information technology from more than one supplier but **MUST** be presented as a single solution from a single supplier.
* The supplier must be able to conform to the specification or give a reasonable alternative. If unable to conform, please state the reason. Alternative solutions will be considered based upon the information provided by the supplier and will be evaluated solely upon that information.
* It is a requirement that the current laboratory output must be maintained during installation and acceptance testing of the offered system.
* The supplier will be expected to give detailed guarantees that they can meet all standards of ISO15189, MHRA and BSH concerning information management systems. This must include written detail of how they will meet the verification and validation criteria.
* Scored questions will be graded as follows:
  + **Pass/Fail –** A fail on any of these questions will result in your company not being taken any further in the procurement process. This will need to be demonstrated in the response.
  + **Scored –** This will determine the degree to which you have demonstrated having met the expectations and will attract a score of between 0 and 5. Please refer to Table 1 below.
  + **Weighting –** Each scoring question has been allocated a weighting determined by the relative importance of the requirement to the Trust. Final score will be the product of the score x weighting
* Table 1

| **COMPLIANCE** | **SCORE** | **DEFINITION OF SCORE** |
| --- | --- | --- |
| Unacceptable | 0 | Fails to address the issue or cannot be judged against the criterion due to missing or incomplete information |
| Poor | 1 | Below expectations |
| Fair | 2 | Meets some expectations / fails in some aspects |
| Acceptable | 3 | Meets expectations |
| Good | 4 | Exceeds expectations in some aspects |
| Excellent | 5 | Exceeds expectations in all aspects |

* The successful contractor will be required to meet and maintain the standards set out in the Specification and related key performance Indicators (outlined in the document ’KPIs’) throughout the term of the contract. A copy of the KPI’s are provided for you to review consider and comment on as part of this process. Failure to consistently meet these obligations may lead to early termination of the contract at the contractor’s expense

* Appendices will be accepted please label using the question number it is associated with and the name of the attachment. Responses should be clear, concise and relevant to the specific requirement. Should bidders have any questions relating to the tender these can be asked through the designated contact within the designated clarification window.

Note to supplier:

* The validation plan will be shared with the successful bidder, this is a living document and may be subject to change during the validation period in the event of changes to national standards or recommendations. Any changes will be discussed and agreed with the supplier.
* It is accepted that the LIMS may not comply with all aspects of the validation plan upon installation. Where aspects of non-compliance are identified the criticality of the non-compliance will be determined by the purchasing organisation laboratory management. The supplier will be expected to work with the laboratory to resolve the non-compliance(s) in a time frame that is reasonable with respect to the criticality and agreed between both parties.
* In the event that the LIMS must be approved into use with outstanding non-compliances, workarounds must be implemented and agreed by both parties. The workarounds must be risk assessed by the purchasing organisation and the resolution(s) time frames must be reasonable with respect to the criticality and agreed between both parties. The resolution actions must be recorded as part of the risk assessment process to allow transparency for Trust senior management.

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| **Question**  **Number** | **Question** |
| **1** | Essential System Requirements |
| 1.1 | There must be a bidirectional interface between the LIMS and any of the fully automated analytical systems used in the UK and specially with the system currently in use in the transfusion laboratory.  The system must be capable of transmitting messages containing patient and blood testing results from all of these in a bidirectional interface. Interface specification and scope for these systems are available on request.  The supplier must commit to the development of an interface to any new analyser purchased |
| 1.2 | There must be a bidirectional interface between the LIMS and the electronic blood tracking system |
| 1.3 | There must be a bidirectional interface between the LIMS and the electronic ordering system/electronic patient record. |
| 1.4 | There should be a bidirectional interface between the LIMS and the referral system (NPEx) |
| 1.5 | The LIMS must be able to communicate with the following systems:  Electronic Request Systems  Electronic Blood Administration (tracking) Systems  Electronic Delivery Note (EDN NHSBT) (Electronic dispatch notes (EDN) meeting the standardised specification written by Standing Advisory Committee for Information Technology (SACIT)(MacLennan 2013) are available from UK Blood Services).  GP Order Comms |
| 1.6 | To ensure operational security and performance, supplier must state:   * number of concurrent users allowed on system at any one time; * maximum transaction rate; * resilience to single point of failure (at least dual redundancy, for system and interfaces), please explain how this is achieved |
| 1.7 | The system must support multiple environments with a minimum of two environments to allow a separation of live and validation/training environments. |
| 1.8 | It MUST be possible to replicate the LIVE system in the TEST environment, prior to validation of system updates, on demand |
| 1.09 | The supplier must specify the number and type of environments supplied, including interfaces with related systems, and how the validation/training environment will be populated with transactional data for testing purposes. |
| 1.10 | Data migration is the transfer of essential information (data) from an existing to a replacement system. It will be necessary to migrate the following data (at a minimum) to the new system from the current system:  All blood groups, antibody screen results  Antibody specificity  Antigen negative requirements  Patient special requirements (e.g irradiated, CMV negative)  Most recent cffDNA results, pertaining to current pregnancy (results <6 months)  Records pertaining to transfusion of any blood components/batch products  Special interest notes (patient specific, e.g bone marrow transplant))  The supplier must confirm that migration of data is possible and detail how this will be achieved |
| 1.11 | The maintenance requirements of the new system must include:  ● clear definition of services to be provided;  ● responsibilities and duties of the hospital transfusion laboratory (customer);  ● responsibilities and duties of the hospital IT department;  ● responsibilities and duties of the system supplier;  ● key Performance Indicators (KPIs);  ● problem management procedures;  ● disaster recovery.  ● definition of service period and termination of agreement;  ● warranties;  ● review periods.  Supplier must explain how the requirements are met and provide details of these arrangements |
| 1.12 | The supplier must provide change management procedures; release notes must be supplied in a timely manner to allow for validation of the changes in the test system prior to release into the live system |
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| **2** | Stock Management |
| 2.1 | It is a requirement of the Blood Safety and Quality Regulations (as  amended) (BSQR 2005) and the EU Directive 2001/83/EC (EU 2001) that records are retained allowing tracing of all components and products from source to recipient or final fate and vice versa.  The system must support fating of all blood components/batch products electronically via the blood tracking system and manually, including the date/time of transfusion (or other fate) |
| 2.2 | There must be a process for updating the fate of a blood components/batch product , if required, including a full audit trail (date/time, user and reason) |
| 2.3 | The system must hold a local reference table of blood components and batch products (plasma derivatives) in which label barcodes are associated with descriptions and internal codes.  For blood components the system must comply with the NHSBT “Guidelines for the Blood Transfusion Services in the United Kingdom” 8Th edition  Please explain how this is achieved for batch products |
| 2.4 | There should be the facility to update the local reference table to allow for new components and products to be added by appropriately authorised personnel. |
| 2.5 | The system should be able to record the origin and supplier details for all blood components and batch products receipted into stock. |
| 2.6 | For cells and tissues imported from outside the UK there should be a procedure on entering information into the LIMS to ensure the donor/patient traceability chain is maintained |
| 2.7 | The system must have a comprehensive stock control capability with a configurable rule base able to trigger actions based on stock levels and user definable requirements  The supplier must detail how this is achieved |
| 2.8 | The system stock inventory system must be configurable to support stock levels of different antigenic phenotypes (e.g. stock target of 6 group O R1R1, 4 group O R1r, 2 group O R2r etc).  Please state how this is achieved |
| 2.9 | A secure method of input is required to ensure the correct information regarding each component and batch product is held within the LIMS.  The LIMS must allow for storage of the following minimum information for  each unit:  · donation number;  · ABO and D group (where supplied);  · component/product code, including division numbers, as provided by the supplier;  · expiry date;  · expiry time (where appropriate);  · date and time of receipt into the laboratory and /or time booked into the  LIMS;  · source of component (from a Blood Establishment, external supplier or transferred from another hospital)  . Cost  .Volume  .Concentration in appropriate unit |
| 2.10 | The LIMS must also allow for the following component characteristics to  be retained against the component (all attributes as detailed in the EDN):  · antigen typing;  · Cytomegalovirus (CMV) antibody status;  · gamma/Xray Irradiation;  · Hb S status;  · high titre flags;  · comment field. |
| 2.11 | The system must record if the above information was received electronically or entered manually. |
| 2.12 | The LIMS must support the current UK combinations of ISBT 128 and codabar labelling systems and commit to the potential future NHSBT implementation of ISBT128 and the introduction of two-dimensional DataMatrix codes. |
| 2.13 | When the delivery is received at the hospital each component received must be reconciled to the information captured from the EDN. This must be achieved by scanning the relevant pack barcodes, e.g. donation number and component type. Other information must be transferred electronically, including additional information such as red cell antigen typing, which may not be barcoded on the label.  Please state how this is achieved |
| 2.14 | The LIMS must be able to store the EDN delivery information in a manner that can be searched to support selection of appropriate antigen negative units. The search function must support search by:  • Location  • ABO group  • RhD group  • Antigen negative attribute (when searching for units that are negative for multiple antigens the search must be based on “and”, not “or”)  • Status (free or allocated to patient) |
| 2.15 | For batch/blood products the system must store the following details of the product:  ● date and time of receipt;  ● manufacturer;  ● name of product;  ● batch number, including provision for unique barcoded batch number with sequential vial number and barcoded product code (for administration and fating through the electronic tracking system);  ● expiry date;  ● quantity of units received;  ● batch comments, including volume and amount of product/bottle (e.g. IU/mL  or bottle), where appropriate.  •Cost of the product  ● supplier if different to manufacturer;  ● type of product;  ● ABO group (if applicable). |
| 2.16 | In general batch/blood products are only identified by the manufacturer down to the level of batch number. The purchasing organisation require allocation of local serial numbers to individual items within the batch to allow full traceability of each item  The unique numbers must be transferrable to the BloodTrack system  Please state how this will be achieved |
| 2.17 | The system should support the international standard bar coding of plasma derivatives/batch products. Information on this is available from the  supply chain standards organisation GS1.  <http://www.gs1.org/sites/default/files/docs/barcodes/BD_Implementation_Guide_v1_0_24_aug_2010.pdf> |
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| 3 | Stock Tracking |
| 3.1 | The system should allow the location of stock to be recorded and must support transfer of stock between multiple locations with appropriate audit trails and linked to electronic tracking storage locations. |
| 3.2 | The LIMS must be able to support electronic de-reservation of blood components/products and the production of a list of units which are beyond their reservation period.  The dereservation date/time should default to (whichever is the shortest):   * Date/time specified by the NHSBT on the product label * The date/time that the sample validity ends * 24 hours from the time that the blood component is required * A configurable date/time for batch products |
| 3.3 | The system must support the recall of units and maintain records of the reason and any incidents related to the component/product.  Please state how this is achieved |
| 3.4 | The system must allow units to be retrieved from being issued/allocated to a patient and returned to the stock of unallocated units. |
| 3.5 | Units which are no longer suitable for use (e.g. past their expiry date or out of temperature control) must be blocked from being returned to stock for re-issue.  Please state how this is achieved |
| 3.6 | There should be the facility to record the fate of discarded and transferred units in accordance with user definable codes.  It must be possible to include additional fate codes if required |
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| 4 | Managing the patient record |
| 4.1 | Correct patient demographics are a key feature of any IT system involved in the transfusion process. This applies to the Electronic Patient Record, the LIMS, Electronic Blood Administration (tracking) Systems and any electronic communication system (e.g. Order Comms) used to make requests of the transfusion laboratory. The supplier must guarantee the maintenance of data integrity during transfer of information.  Please state how data integrity is maintained during transfer of information across the systems |
| 4.2 | When the patient demographic details are amended/updated, the previous patient details should be retained against any sample associated with the previous details.  The supplier must detail how their solution achieves this requirement |
| 4.3 | The LIMS system should support the use of the NHS number (or equivalent) (NPSA 2007) in addition to other numbering systems as required by the user,  e.g. A&E or temporary numbers.  This must be compatible with patient numbering system used within the electronic patient record system |
| 4.4 | The system must be capable of holding the following essential information:  · basic patient demographic information including first and last name, DOB,  gender, address and postcode;  · all previous transfusion/grouping records relating to a patient;  · historic blood group and related testing information;  · special requirements;  · patient antibodies and antigens (should be coded to the international coding structure for antibodies/antigens) (ISBTa) |
| 4.5 | The system should be capable of holding the following essential information:  · previous names and addresses if applicable;  · patient diagnoses/clinical details/reason (justification) for transfusion (coded in accordance with BCSH Guidelines for the specification, implementation and management of information technology (IT) systems in hospital transfusion laboratories 2014). |
| 4.6 | Requests may be received associated with patients who have not yet been fully identified. The system needs to support entry of partial patient records and to allow patient details to be updated as they become available in accordance with local risk management policy |
| 4.7 | There will be occasions when records from one individual will need to be associated with another individual’s record and the LIMS system must support this. e.g. mother with infant and partner association in pregnancy associated testing. |
| 4.8 | Duplicate patient records within a healthcare database have the potential to create a serious risk to patient safety by increasing the risk of incorrect or inappropriate actions from a lack of recognition of previous results. There must be a method available to merge/link duplicate records in a way which ensures the integrity of the transfusion record. |
| 4.9 | Locally defined rules for merging records should be in place and must address  the following:  ● only nominated staff with appropriate password privileges can use the  merge function;  ● the retention of all historic grouping and screening information, special requirements (e.g. irradiation) and any specific antibody investigation information plus the identity of the person undertaking the merge must be retained following the merge  ● the system must maintain Traceability requirements (as listed in the Blood Safety and Quality Regulations 2005) met, and provide an audit trail of the individual records merged to form the single record. |
| 4.10 | The system must identify and alert the user in the event that the records to be merged have:  ● different ABO and/or D blood groups;  ● different antibody and/or antigen profiles;  ● different special transfusion requirements |
| 4.11 | Differences should be resolved or accepted by an appropriately qualified person before the merge can proceed. Password control must be in place in order to override routine control criteria. |
| 4.12 | The audit trail should include  ● the full patient details of both records prior to the merge;  ● the date/time of the merge;  ● the relevant details of the individual who performed the merge |
| 4.13 | It should be recognised that undoing a merge is a high risk process which has the potential to compromise mandated traceability. A system should be in place to ensure that all information prior to the time of the merge reverts to the original state, and that subsequent information is correctly assigned to the appropriate record.  An audit trail must be maintained |
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| 5 | Generating Transfusion Requests |
| 5.1 | The system must be capable of accepting transfusion requests generated in the following ways:   * Manually input by authorised staff * Electronically via an order comms/electronic patient record system within the Trust * Electronically via an order comms system outside of the Trust (eg. NPeX or GP order comms) |
| 5.2 | Receipt of samples, including the electronic transmission of all associated demographic and request data should be achievable by a single barcode scan. Please state how this is achieved |
| 5.3 | Laboratory staff should be alerted to all electronic requests where there are no accompanying samples.  Please explain how this is achieved |
| 5.4 | When patient demographics are entered onto the LIMS manually from the request form, the LIMS must be able to identify if the patient is already known and provide options to match to a record in the system.  If no match is found a new patient record must be created. If during this process it is identified by the LIMS that a potential duplicate record is being created (i.e. same/similar details but different unique patient identifier entered) the user should be alerted. |
| 5.5 | All samples must have a unique barcoded laboratory number associated with them.  Please state how this is achieved |
| 5.6 | Any necessary record association (e.g. mother, infant) should be made at the point of request entry  Please state how this is achieved |
| 5.7 | Where there is an electronic transfer of information from Order Comms to LIMS. The request must always be identified with the unique number. |
| 5.8 | The matching of the request to the appropriate LIMS patient record is a critical point in the system. Date and time the sample is collected must be electronically entered into the LIMS. |
| 5.9 | Any special requirements (eg irradiated, CMV negative) noted in the order comms system must be transmitted to the LIMS |
| 5.10 | Any necessary record association (e.g. mother, infant) should be transmitted to the LIMS |
| 5.11 | The system should include a process to identify urgent requests from routine requests. |
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| 6 | Analytical Processes |
| 6.1 | The LIMS should be able to interpret raw results from the analytical system into a derived ABO/D blood group result.  Please state how this is achieved |
| 6.2 | Where interpreted results are sent from the analyser to the LIMS, any results which have been flagged as edited on the analyser should be recorded in the LIMS. This is important for the algorithm for electronic issue (EI). |
| 6.3 | It must be possible to identify testing undertaken against a specific request at a specified time, as the immunological status of the patient can change. The date and time of all result entry MUST be recorded in the LIMS |
| 6.4 | The LIMS should be able to order both individual tests and profiles, based on user configurable rules |
| 6.5 | The LIMS should be able to respond to test results that trigger further laboratory investigation by allocating follow up tests (reflex testing) the following are examples of good practice:    Antiglobulin profile reflexed from Positive direct antiglobulin test    FMH estimation reflexed from D positive result for cord associated with a D negative mother    Antibody Identification reflexed from Positive antibody screen |
| 6.6 | The system SHOULD be capable of reflex testing based on patient location and coded clinical reason for request (e.g., phenotype request for patient on the haematology ward or patient with clinical details aligned with haematological malignancy) |
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| 6.7 | The system should be able to produce worksheets, configured to user requirements, possible to view and update worksheets on screen, or print copies for manual completion |
| 6.8 | Where manual interpretation and/or entry are required, procedures should be in place to reduce the risk of a manual error remaining undetected (e.g. use of double blind interpretation and entry, or second checking/2 level verification) A full audit trail of these activities must be retained by the LIMS.  Please explain how this is achieved |
| 6.09 | Where results are entered manually into the LIMS the historic results should not be displayed on screen. |
| 6.10 | Robust ABO and D typing, and storage of results are essential for safe transfusion practice. Any discrepancies between current ABO/D results and historic results must be flagged by the system |
| 6.11 | Positive antibody screening results (from the automated analyser system or manually input) should alert the user and should automatically trigger a request for antibody identification.  The LIMS must display any previously detected antibodies |
| 6.12 | Antibody identification results should be stored as individual results against each reagent screening cell by each technique and as a composite result |
| 6.13 | Antibody identification interpretation should be entered as separate specificities, using drop down (coded) lists or equivalent with controls in place to minimise the risk of manual error and facility for free text result comment entry if required.  Please state how this is achieved |
| 6.14 | The system should have the ability to categorise antibody specificities according to their clinical significance and use this information to support the generation of reports using standard comments (e.g. possible delay in provision of red cells). The system should allow adjustment of these comments in specific cases.  Please state how this is achieved |
| 6.15 | Crossmatch results for each unit tested must be stored as individual results by technique and as a composite conclusion. These results must be transferrable electronically from an analyser or entered manually.  Whatever the method of entry the following information must be stored:  ● patient identifier;  ● donation number;  ● test conclusion or results of individual test by technique and reaction grade;  ● date, time and identity of personnel/analyser for all actions. |
| 6.16 | If the results are entered manually the second check (independent verification) step should be prompted with full audit trail  Please explain how this is achieved |
| 6.17 | Antenatal testing: The IT system should store the following additional information to that identified above:  ● number of weeks gestation and EDD (where EDD only has been supplied the LIMS should automatically calculate and display the weeks of gestation);  ● partner phenotype (where relevant);  ● Free fetal DNA results where relevant  ● titre/quantitation results where clinically significant antibodies are present;  ● date anti-D prophylaxis administered and dose |
| 6.18 | Antenatal testing: On the basis of patient information and the results entered the LIMS should be able to:  ● provide recall testing information against a user defined algorithm with reference to the Guidelines for Blood Grouping and Antibody Testing in Pregnancy (BCSH 2016).  ● indicate requirements for Routine Antenatal anti-D Prophylaxis (RAADP). |
| 6.19 | The system must be able to accept test results for automated extended phenotyping profiles including at least the following antigens:  Rh (CcEe), K, M and N  Fy(a and b), Jk(a and b), S, s and k  Please state how antigen profiles are managed within the system |
| 6.20 | The LIMS should be able to support automated authorisation (“auto validation”) when results are transferred from a fully automated analyser, with provision of exceptions based on user definable rules eg; there has been no editing of results; and where there are no discrepancies identified from previous results. |
| 6.21 | All results which do not fulfil the above criteria (6.21), manual and automated, must be reviewed and approved by authorised staff. Staff performing the review must have access to all information associated with the results. |
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| 7 | Quality Assurance of Analytical Processes |
| 7.1 | The method of recording and storing IQC data might depend on whether the data is generated on automation linked to the LIMS, or in manual systems. However this is handled, it SHOULD be possible to associate all tests in the LIMS with valid IQC. |
| 7.2 | For automated testing, where the automated system validates IQC data prior to transfer of test results, IQC data should still be retained by the LIMS |
| 7.3 | The system should include a reagent management module – please state how this is achieved |
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| 8 | Component selection |
| 8.1 | The LIMS must ensure that components selected for a patient meet all necessary requirements to ensure their suitability (e.g. antigen negative units, neonatal requirements, irradiated etc.)  Please state how this is achieved |
| 8.2 | In clinical emergencies some requirements may need to be overridden in accordance with pre-agreed protocols and any concessions must be documented and retained in a full audit trail on the LIMS |
| 8.3 | It must be possible to take into account the special requirements flagged for the individual patient. Patient special requirements may be known from previous transfusion history/testing; specified on the sample request; identified through current testing; or determined by the application of predefined demographic/clinical rules  Please state how this is achieved |
| 8.4 | The system must support selection of red cells along one of the following paths:  ● serological crossmatch (manual or automated);  ● electronic Issue (EI) without serological crossmatch;  • Remote Issue (RA) at a blood fridge without serological crossmatch  ● emergency issue of red cells. |
| 8.5 | In all cases the LIMS must ensure that the controls and rules expressed in the Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013) are followed. Guidance below addresses the management of some of these requirements by the LIMS.  The following requirements apply:  • the LIMS must not allow selection of ABO incompatible red cell units;  • the LIMS must prevent use of results from an invalid sample;  • the LIMS must not allow issue of units where pre-transfusion tests remain outstanding, except in emergency situations, where a controlled override should be possible, with a full audit trail.  • The LIMS must be capable of selecting red cells based on age and gender rules, configurable by the laboratory  Please state how these are achieved |
| 8.6 | Controls in the LIMS must prevent the following unless appropriate override has been authorised:  ● selection of D positive blood for a D negative patient;  ● selection of incompatible units for a patient with known antibodies.  • Selection of components that do not comply with any special requirements or antigen negative flags on the patient record |
| 8.7 | Units for serological crossmatch must be reserved on the LIMS using only barcoded entry of selected donations. |
| 8.8 | The system should be capable of accepting serological crossmatch results via the analyser interface or by manual entry. |
| 8.9 | The system should have a process of identification of crossmatch results that have been transferred automatically or entered manually. |
| 8.10 | The system must not issue or print compatibility labels for any units that are resulted as incompatible without valid override reason. |
| 8.11 | The LIMS must perform checks to ensure that all the requirements for EI/RI have been met including all criteria identified in the Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). The Medicines and Healthcare products Regulatory Agency (MHRA) have published guidance on EI and this should be referred to (MHRA 2010). |
| 8.12 | The system MUST prevent EI in the following cases:   * where the patient group or antibody screening results have not been transferred electronically from automation to the LIMS; * with units that have not been entered into blood bank stock electronically * where automated results have been manually edited * Where there is only one group and screen record present * Where there is a discrepancy in the historic and current blood groups * Where the sample timing is not valid * Where a flag has been made on a specific patient (eg bone marrow/solid organ transplant) * Where the patient has a current or historic positive antibody screen * Red cell units are ABO incompatible with patient |
| 8.13 | The LIMS must support EI and RI including electronic selection of suitable blood in accordance with BCSH and MHRA requirements and including:   * Age and gender rules * Antigen negative requirements * Special requirements (eg irradiated, CMV negative) * At least 2 blood group and antibody screen results in LIMS * Current group and save results transmitted automatically from the analytical system to the LIMS * Current group and save sample results must not be manually edited * Current group and save sample <72 hours old * Historic blood group matches current blood group * Antibody screen results must be negative for the current and historic samples * Patient must not have received a bone marrow transplant or other exclusion * Red cell units must have been entered into the stock system electronically |
| 8.14 | There will be occasions where it is necessary to release blood for transfusion without performing/completing pre transfusion testing or crossmatching. In these circumstances the LIMS must allow emergency issue as identified in the Guidelines for Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). |
| 8.15 | In all cases entry of retrospective testing e.g. compatibility results, should be possible with full audit trail of entries and amendments available |
| 8.16 | If patient information is not available at the time of issue later reconciliation should be possible once the full patient record has been established. The LIMS must retain the information associated with the initial issue of the blood components. |
| 8.17 | The LIMS should be capable of accepting patient information transmitted from the BloodTrack system associated with emergency blood issue and reconciling the unit details with the patient details within the LIMS system |
| 8.18 | The LIMS should enable selection of fractionated blood products based on clinical algorithms. The LIMS SHOULD provide a comprehensive suite of rule to enable the building of clinical algorithms to facilitate prompt accurate and/or timely selection of the right product (e.g. management of anti-D immunoglobulin, issue of IVIg in accordance with ideal body weight dosing). |
| 8.19 | The LIMS system should include a user configurable flags or logic rules to prevent inappropriate issue of batch/blood products, e.g., issue of anti-D Ig to an RhD positive patient  Please state which rules are covered for management of anti-D Ig |
| 8.20 | The LIMS must provide an outstanding requests/orders list for blood components and batch products, including:   * Urgency * Location * Component/product type * Number required * Sample status (eg, no sample required, sample in lab, sample to be taken) * Patient details * Date/time required   List generated in chronological order |
| 8.21 | The LIMS must provide an outstanding requests/orders list for tests, including:   * Test type * Patient details * Urgency * Sample status (eg, sample in lab, sample to be taken) * Sample accession number * Sample date/time |
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| 9 | Component labelling and Issue |
| 9.1 | All labels for a single patient’s authorised component/product issue should be printed as a single batch |
| 9.2 | The system should be able to be configured to print all necessary (as per 9.4) data items on the chosen laboratory label (Example specimen label to be provided) |
| 9.3 | The system should provide a process to verify that the correct label has been attached to the correct unit |
| 9.4 | The compatibility tag should be printed out once the units have been authorised as compatible or suitable for issue. The information required to be printed onto each label is identified in Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). The system must include the following information on the compatibility tag when available:  i. last name;  ii. first name;  iii. date of birth;  iv. unique patient identification number  v. patient ABO and D group;  vi. donation number (ideally in both eye-readable and barcode format);  vii. component/product type;  vii. statement indicating whether the component/product is compatible or suitable;  ix. (should include) date by which the component/product must be transfused or de-reserved (taking into account the change in expiry date and time when thawing frozen plasma component/products). |
| 9.5 | It should be possible to print a comment on the compatibility tag, e.g. to highlight where the blood group of the unit and the patient are compatible but not identical. |
| 9.6 | The system must support the requirement for unique identifying barcodes for use with the electronic tracking system for collection and administration of all blood components and batch products |
| 9.7 | There must be a specific process step to ensure the correct label has been attached to the correct component. Ideally this verification should be by automated means using electronically readable information (this process may be provided by the BloodTrack system, but the LIMS must support label printing via the BloodTrack system).  This verification step must include:  ● check to ensure donation number on component is identical to the donation number on the compatibility tag;  ● check to ensure the component type on the compatibility tag is correct |
| 9.8 | Where automated support for verification of the donation number is employed this will require printing of the barcoded donation number on the compatibility tag. The automated system should be designed to ensure that the donation numbers from both the component and the compatibility tag have been compared, (i.e. duplicate entry of one barcode would be detected as an error). |
| 9.9 | Remote Electronic Issue: Components in remote issue locations should be managed by the transfusion laboratory and procedures in place to ensure that at all times only suitable components are available. The current location of all blood and components, including thawed FFP, MUST be available in the laboratory LIMS. Records must be kept in the LIMS of all movements of components |
| 9.10 | Remote issue of red cells must only be used for patients who have been determined by the LIMS rule base as eligible for EI. The LIMS must be capable of controlling all aspects of EI |
| 9.11 | Remote electronic issue via the BloodTrack haemobanks must be rigorously controlled through use of standard operating procedures, trained and competent staff and validation of the system in use. The following controls within the LIMS must apply to all remote electronic issue systems:  ● the identification of the patient and the request for components must follow the same rules as electronic issue  ● request information must be transferred to the LIMS either through electronic requesting or direct from the electronic tracking system.  ● the LIMS must verify the patient request and authorise the issue of compatible components  ● the LIMS must take into account any special requirements (including irradiated, CMV negative, antigen negative) that apply to the patient and ensure that these are met at remote allocation in BloodTrack |
| 9.12 | Records stored should include:  ● identity of individuals undertaking any step in the process;  ● identification of the patient;  ● donation numbers of the units placed into stock or issued;  ● component type(s);  ● date and time of placement and issue |
| 9.13 | There should be an alarmed electronic override feature as this is essential for use in emergencies i.e. release of emergency group O blood. All events should be logged and investigated retrospectively |
| 9.14 | There must be a process to reconcile units issued as emergency (eg O RhD negative red cells, PCC) to unnamed patients with the patient record once the transfusion has occurred. This process must be automated within the LIMS, taking the patient information from the electronic blood tracking system |
| 9.15 | All blood that has been recalled or removed from the remote issue system for longer than the specified time (depending on user configurable storage conditions) must be quarantined so that it cannot be dispensed |
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| 10 | Post Analytical Reporting |
| 10.1 | The system must support the availability of both printed report and electronic reports |
| 10.2 | Reports should be clearly presented and contain terminology that is clear and unambiguous with any added comments conforming to those identified in BCSH guidelines. |
| 10.3 | Reports should be designed to give all information required for full identification of the patient and essential user information as laid down by UKAS ISO15189 standards. |
| 10.4 | The printed report should state the number of pages containing the full report (eg page 1 of 2) |
| 10.5 | The report should be able to draw the users attention to the date of final authorisation and advise the user when the sample is no longer valid for red cell issue |
| 10.6 | There should be options to generate printed reports by:  ● type of test;  ● consultant/requestor;  ● location;  ● blood component/product;  ● others as defined by local specification. |
| 10.7 | Test reports should state whether they are:  ● final - released following authorisation;  ● interim - released prior to authorisation but clearly marked as unauthorised or incomplete. |
| 10.8 | An audit trail must be in place to show when the electronic report was viewed and by whom |
| 10.9 | The system must support transfer of information to and from other IT systems, including EPR, GP systems, NPEx. Such transfer should comply with applicable healthcare communication standards applied within the organisation. Dispatch of the reports must be to a recognised system and must meet the security and information governance recommendations |
| 10.10 | The system must provide an option to send a report of any transfusions to the patient’s GP location. |
| 10.11 | The system should support the production of amended reports where required and provide a full audit trail of this activity |
| 10.12 | The system should provide a facility for the generation of reports for monitoring laboratory performance  Please state how this is achieved and any details of any standard reports available |
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| 11 | Cold Chain |
| 11.1 | The system must support compliance with the cold chain as detailed in the Blood Safety and Quality Regulations (2005) and the BCSH The administration of blood components (2017). |
| 11.2 | The system should prevent automatic issue of blood components and batch products that do not have a laboratory compliant cold chain audit trail |
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| 12 | Training |
| 12.1 | The supplier should detail the training requirements for the system including duration of any training courses normally included in the supply of the system. |
| 12.2 | The supplier should provide advanced training for at least two members of staff for the system |
| 12.3 | The supplier should provide on-site training for all system operators |
| 12.4 | The supplier should give details of any user groups.  If a cost is attached to attendance of these meetings it SHOULD be shown here. |
| 12.5 | On-going training should be provided as required following significant changes to software or hardware or laboratory staff. |
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| 13 | Installation & Operation Qualification |
| 13.1 | The supplier should provide a detailed implementation and installation project plan with timescales. |
| 13.2 | The supplier should perform the installation and operational qualification validation steps for the system |
| 13.3 | The supplier should support the laboratory performance qualification/verification as defined by the laboratory, to meet the standards required by ISO 15189, BCSH and MHRA |
| 13.4 | The system should operate for its lifetime in accordance with ISO 15189 BCSH and MHRA standards or equivalent |
| 13.5 | The supplier should provide an installation and an operational risk assessment for the use of their system. |
| 13.6 | The supplier should ensure full service provision is maintained during implementation/works.  Details of how this will be achieved MUST be included in the tender response |
| 13.7 | A fully competent company representative should be available until the installation is complete and system is functioning satisfactorily. |
| 13.8 | All software upgrades and their subsequent validation/verification to meet ISO 15189, BCSH and MHRA, or equivalent should be fully supported by the supplier and be free of charge |
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| 14 | Operation and Maintenance |
| 14.1 | Supplier should guarantee a maximum response time by an engineer/ application specialist of 30 minutes from reporting a fault during 9 to 5.30 (core hours). |
| 14.2 | Supplier should guarantee a maximum response time from fault reporting to escalation of 8 working hours |
| 14.3 | Supplier SHOULD provide 24/7 support for breakdowns. |

# Example KPI’s

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| **Service  Level** | **Measure** | **Consequence** |
| Transfusions LIMS System Uptime | 99.7% availability of service delivered to domain boundary under supplier’s control (a technical architecture diagram will be used to define the domain boundary)  Except for Planned Outages agreed between the supplier and the purchasing organisation. | The supplier will reimburse the purchasing organisation £1000 per whole hour that the system or part thereof is down.   The supplier to provide an incident report detailing the cause, resolution and next steps to ensure the fault does not occur again. |
| Planned Outages | Agreed planned outages should take place on the agreed date and with the arranged timescales. | Should the planned maintenance not take place on the agreed date or takes longer than the agreed timescales then a fixed penalty of £250 is applied.   If more than two repeated breaches per year take place a review and lessons learnt process should take place between the parties to minimise future breaches. |
| Telephony Support | All helpdesk calls to be logged within 15mins of initial call and a helpdesk ticket number issued to the reporting individual by email    All helpdesk calls will be assigned a severity as per the Service Level Agreement   100% call back by the supplier engineers within an hour of the initial call being received / logged (during agree helpdesk support working hours) required | Re-call rate to be routinely monitored. Quarterly review of helpdesk figures if all within expected KPI levels, when the KPIs are not being met than an agreed action plan and more frequent review meetings until KPIs back in control.   For any delay beyond the first hour of the initial call being received / logged a £250 penalty charge will be applied. |
| System Updates | supplier led system updates or fixes should be made available and deployed in a timely manner within the agreed planned outages / maintenance schedule.   Customer led system updates or enhancements should be made available within the timescales set out in the request and agreed by the supplier and the purchasing organisation. | Should the supplier not make available system updates or fixes within the agreed maintenance schedule then this will incur a [1]% reduction in the annual contract fee . Similarly if the purchasing organisation do not help facilitate the supplier to apply the system updates / fixes within a timely manner then purchasing organisation can expect delayed fixes / responsiveness from the supplier. |
| National Datasets Compliance / standards | If there are any changes to the National Dataset or Compliance Standards, the purchasing organisation will agree in a timely manner with the supplier on how best to implement these changes.   Within two months of the purchasing organisation notifying the supplier of any changes required for the National Dataset or Compliance Standards it is expected that the supplier will notify The Trust of the planned implementation date and costings (if any) of the proposed solution, such date to be no longer than one calendar month from the date of notification. | If after two months of the purchasing organisation notifying the supplier of any changes required for the National Dataset or Compliance Standards and no solution or costing have been proposed the supplier should provide a report detailing the cause of delay, a project plan to resolution and next steps to ensure the delay does not occur again. |
| Implementation | Key milestones to be met as per the implementation plan submitted | Charge of £X per week delay in reaching each key milestone except where the delay can be demonstrated to be beyond the control of the supplier. |
| Reporting | KPI’s to be collated monthly and reported quarterly to the purchasing organisation within 10 days of the end of the quarter | £250 per missed day reporting |
| Quarterly Service Reviews | Quarterly Monthly reviews in the first year then annually |  |
| Upgrades | To be defined |  |