Service Support Specification

Version Control			
Revision	Date	Status	Comment
1.1	09/19/12	FINAL published version.	Version used for original Eurobloodpack collaborative purchasing project/ tender.
1.2	18/03/15	DRAFT published for consultation purposes.	

Purpose

This document details the service support requirements related to the supply of Whole Blood Collection Systems and Ancillary Processing Systems.

Grey text provides instructions for Suppliers as to what information MUST be submitted in support of their compliance statement; where no Grey text is detailed and either:

- A response of "Compliant" is chosen, no further information is required; or
- A response of "Non-Compliant" is chosen, information confirming the nature/ extent of the non-compliance MUST be submitted.

Glossary

Where capitalised terms are not defined below their definition should be contained in the Framework Agreement Terms and Conditions.

Term	Definition
"Authority":	means a blood establishment entitled to place Orders under the Framework Agreement.
"Authority Personnel":	means all persons directly employed by the Authority or an individual authorised to act on behalf of the Authority for a specific purpose.
"Batch":	means a defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous.
"Framework" or "Framework Agreement":	means the framework agreement entitled "*Whole Blood Collection Systems and Ancillary Processing Systems*" to be entered into by NHS Blood and Transplant and the successful supplier(s).
"Goods":	means all goods, materials or articles that the Supplier is required to supply under the Framework.
"Specification":	means the requirements of the Authority as set out in: • The service support specification version 1.2 (i.e. this document) • The technical specification version 4.4; and • The Framework Agreement and any Orders placed there under.
"Material Sub-Contractor":	means any third party engaged by the Supplier that would be material to the manufacture of the Goods and/ or bring capabilities or experience that the Supplier is seeking to rely on for the provision of the Goods which meet the Specification.
"MUST" or "MUST NOT":	means a mandatory requirement.
"Outer Packaging Unit":	means packaging that combines several over-wrap packages into one delivery unit (i.e. Shipping Box).
"Over-wrap packaging":	means packaging that contains only one article (e.g. a Blood Collection system).
"Personnel":	means all persons directly employed by the Authority or an individual authorised to act on behalf of the Authority for a specific purpose.
"Premises":	means the location where the Authority collects donations and/ or where the Goods will be stored by the Authority.
"Supplier":	means the suppliers (including the Supplier) appointed under the Framework Agreement.
"SHOULD" or "SHOULD NOT":	means an optional or non-mandatory requirement.

1. Customer Service

1.1. The Supplier MUST identify key personnel who will be responsible for support and management of the Goods and act as points of contact for the Authority for the duration of the Framework Agreement.

1.2. The Supplier MUST provide a helpdesk facility, Monday through Friday from 0900hrs to 1700hrs.

The Supplier MUST provide details of:

- *a. Its customer support structure*
- *b. The number of customer support (e.g. helpdesk) staff currently employed.*
- *c. The location of customer support call centres.*
- *d. The call logging, routing (including priority setting and escalation) and closure procedures.*

1.3. The Supplier MUST ensure that key personnel speak in the local languages and understand local culture and customs appropriate to the Authority personnel.

2. Traceability

2.1. The Supplier MUST warrant, at least according to the applicable regulations, the identification and traceability of Goods from raw material through to finished product.

The Supplier MUST provide for each product code tendered (and where applicable):

- *a. Their definition of a 'Batch of filters'.*
- *b. Their definition of a 'Batch of Whole Blood Collection Systems'*
- *c. The minimum/ maximum Batch size for each of the following:*
  - *Welded (separate) bags*
  - *Needles*
  - *Canulae*
  - *Sample site couplers*
  - *Leucocyte depletion filter (if applicable)*
  - *Anticoagulant (if applicable)*
  - *Saline (if applicable)*

2.2. The Supplier MUST be able to detail information on any specific component of the Goods within three (3) working days in case of defects.

3. Complaint/ Defect Reporting

3.1. The Supplier MUST have a complaints and defect reporting system.

The Supplier MUST provide details of their system.

3.2. For all Type 1 defects (defined in Appendix A) the Supplier MUST ensure key personnel are available at all times (irrespective of public holidays and weekends) to investigate and address the impact of defects.

3.3. For any Goods, which are supplied to the Authority, the Supplier MUST report details where critical defects from other customers are reported to be above the level given above. These defects/ faults MUST be communicated to the nominated Authority representative within twenty-four (24) hours of becoming aware or could with reasonable diligence have become aware of the issue.

4. Delivery

4.1. Frequency and timings of deliveries MUST be managed by the Supplier, ensuring the Authority always has the required quantity of Goods at the Authority Premises, to allow the Authority to meet its collection targets.

The Supplier MUST confirm:

- *a. The details of their demand and forecast planning process.*

b. The lead time, from raw material to release and delivery to the Authority, for creating an entirely new batch of Goods. Note: This SHOULD NOT exceed ten (10) weeks and MUST NOT depend on other items (e.g. production capacity, production schemes etc.).

d. The quantity (expressed in calendar days) and Supplier storage locations of Goods to be held at each location.

4.2. Where Goods are to be held on the Authority Premises the Supplier MUST indicate the storage, delivery and handling requirements.

The Supplier MUST provide:

a. The footprint dimensions (expressed in cms) of the Outer Packaging Unit.

b. The environmental storage conditions of the Goods.

c. Details of permissible deviations (temperature and duration) from the recommended storage conditions for Goods transported between and stored at the Authority's Premises, where there has been a failure of temperature control.

4.3. The Supplier MUST ensure that all Goods are in compliance with their recommended storage conditions up to point of delivery to the Authority. If non-compliant the Supplier MUST inform the Authority as soon as they become aware. In these instances the Authority will have the right to reject the delivery and treat this as a non-delivery. In this circumstance the Supplier MUST re-deliver within forty-eight (48) hours.

The Supplier MUST provide evidence of how this will be achieved (e.g. Periodic temperature mapping and validation of the supply chain or temperature sensitive label is considered acceptable for transportation purposes only).

4.4. For all deliveries the Supplier MUST ensure certificates of conformance/ compliance and analysis for each Batch are included. These certificates MUST state that each Batch:

a. Conforms to CE marking requirements

b. Conforms to the Specification

c. Has been manufactured according to the requirements of Good Manufacturing Practice.

Certificates of conformance SHOULD be supplied via a secure website that the Authority can access.

The Supplier MUST provide an example certificate. Note: If certificates are able to be provided via a secure website, the Supplier MUST detail the website address and the procedure for requesting access.

4.5. Delivery times for urgent orders SHOULD be one (1) working day subject to a request being placed by the Authority by 1200 hours the previous day.

4.6. Delivery of Goods by the Supplier MUST be Delivered Duty Paid [Incoterms 2010].

4.7. The Supplier MUST ensure that all Goods being shipped are properly and adequately protected and packed for safe arrival at their destination.

4.8. The Outer Packaging Unit MUST be of a size that is suitable for safe lifting by one person and MUST comply with the EC Directive on Manual Handling: Council Directive of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (90/269/EEC).

4.9. The Outer Packaging Unit MUST:

a. display the Supplier defined product code/REF and LOT/batch in barcode and eye readable format which MUST be prominently and separately displayed in ISBT 128 format (as referenced in the technical specification). Note: Additional internationally accepted barcode formats may also be reproduced on the box provided that they are clearly identified as such and displayed less prominently than the ISBT 128 coded information.

b. display barcodes in the same format and order as those on the base label for each product code.
c. display the number of Outer Packaging Unit which can be safely stacked.
d. display the storage temperature for the unopened Outer Packaging Unit.

4.10. All deliveries MUST be consigned on euro-pallets, specifically EUR or EUR 1 pallet type.

4.11. When palletised, the Outer Packaging Units MUST be stacked in such a way that the label on each can be read without unloading the pallet.

4.12. The vehicles the Supplier uses for delivering Goods to the Authority MUST be fitted with a tail-lift where required to allow ease of delivery and minimise manual handling risks. In instances when a delivery arrives and the vehicle is not fitted with a tail lift (where required), the Authority will have the right to reject the delivery and treat this as a non-delivery. In this circumstance the Supplier MUST re-deliver within forty-eight (48) hours.

5. Recall

5.1. The Supplier MUST have a recall procedure for all Goods offered which MUST be compatible with any national and local recall procedures of the Authority.

Supplier MUST provide full details of their procedure.

5.2. If any batch or lot is recalled, either by the Supplier or the Authority's notified body/ competent authority, the Supplier MUST immediately inform the Authority and replace all recalled Goods with Goods that meet the Specification and the requirements of the notified body/ competent authority within forty-eight (48) hours or as otherwise agreed with the Authority.

5.3. At any time, on request and within twenty-four (24) hours, the Supplier MUST be able to provide details of all Goods (e.g. type, batch/ lot numbers, quantity and location) affected by a particular defect or configuration related problem. Note: The Authority secures the right to initiate 'mock' recall exercises to assess the Suppliers ability to meet this requirement.

6. Replacement Goods

6.1. Upon notification by the Supplier or the Authority that the Goods are defective or have been rejected due to not complying with the Specification they shall immediately become the responsibility and at the risk of the Supplier. Note: The Authority will:

a. Make available defective Goods for inspection by the Supplier within one (1) week, where safe to do so.
b. Retain unused defective goods for collection and replacement by the Supplier for a maximum period of one (1) month although this retention period is at the discretion of the Authority.

6.2. In the event that the Supplier requests the return of recalled, defective or rejected Goods to a nominated address, the Supplier MUST, at their own expense, arrange for collection from the relevant Authority Premises. Alternatively, the Authority will agree to return Goods to the Supplier's nominated address via its nominated courier/ postal service. However, the Supplier MUST provide suitable transport containers which comply with current national regulations relating to the transport of pathological material. The Authority will, wherever possible, supply a test certificate in order to permit the Supplier to handle, transport and analyse the used defective Goods.

6.3. The Supplier MUST replace defective or rejected Goods with Goods that meet the Specification, at no additional cost to the Authority and within forty-eight (48) hours or as otherwise agreed.

7. Compensation for Loss of Components

7.1. If Goods provided by the Supplier have been used by the Authority but as a result of a recall, defect, damage or are otherwise not in accordance with the Framework, have not subsequently

been transfused into a patient, the Supplier MUST compensate the Authority for all costs attributed to the lost donation. However, where the Supplier can show beyond reasonable doubt that it is not their fault but an Authority error, then no compensation will be due to the Authority. Note: The Authority reserves the right to increase or reduce the compensation amount at any time during the Framework duration.

7.2. The templates below MUST be used for recording responsibility and for the purposes of processing the compensation payment.


Compensation Form.doc


Compensation Claim letter.doc

8. Contract Management

8.1. The Supplier MUST attend meetings to review performance of the Supplier and the Goods as follows:

Supplier Liaison Meetings (SLM)

- Frequency: Every two (2) months unless agreed otherwise.
- Location: At a nominated Authority Premises.
- Purpose:
  - To review Key Performance Indicators (see 8.2).
  - To agree and monitor status of actions to resolve any quality, technical, change control or contractual issues.
  - To identify topics/ areas to feed into the continuous improvement programme.

Framework Review Meetings (FRM):

- Frequency: Every four (4) months unless agreed otherwise.
- Location: At a nominated Authority Premises.
- Purpose:
  - To review Key Performance Indicators based on consolidated data from all Authorities purchasing from the Framework Agreement.
  - To agree and monitor status of actions to resolve any quality, technical, change control or contractual issues, escalated by individual SLMs.
  - To monitor purchase volumes to ensure volume/ price bands set are on target to be achieved.

8.2. Key performance indicators (KPIs) MUST be agreed with the Supplier to monitor performance of various aspects of the Specification (see KPIs embedded below) within two (2) months after entry into force of the Framework. As such the Supplier MUST cooperate in good faith with the Authority to develop the indicators and processes for monitoring and reporting performance on a bi-monthly basis, including financial recompense for failure to meet agreed performance levels.

The Supplier MUST provide:

a. Feedback on the wording and measurement of the proposed KPIs (below).

b. Details (as per format below) of KPIs they believe should be measured.


Key Performance Indicators.doc

8.3. The Supplier MUST provide accurate management information to the Authority, including but not limited to:

a. A monthly contingency stock level report.

b. Complaint and defect data, within forty-eight (48) hours of the Authority requesting such data; indicating but not limited to the following:
   - Date of complaint/ defect
   - Nature of the complaint/ defect
   - Category of the complaint/ defect
   - Actions that have been taken
   - Result of the actions
   - Runtime of the actions
   - Trend reports
   - List of actions/ results yet to be completed/ reported.

c. Other data/ information required to monitor performance in accordance with 8.2 above.

d. Material Sub-Contractors (including location of manufacture) for all components/ sub-assemblies/ materials used to manufacture the Goods.

e. Annotated technical diagrams naming the components and significant areas of the Goods.

The Supplier MUST provide:

- *examples of the documents to be submitted for bullets a. and b.*
- *an up-to-date list for bullet d.;*
- *up-to-date diagrams for bullet e.*

9. Change Control

9.1. The Supplier MUST raise a change control (using the template embedded below) where:

a. New Goods or changes to existing Goods (in terms of manufacturing specifications, processes, premises, materials and/ or Material Sub-Contractor) are proposed. Note: These MUST NOT be implemented without the prior written agreement of the Authority.

b. Manufacturing changes such as routine replacement of moulds or dies and any equipment maintenance or software upgrades are proposed which require the Supplier to re-validate the manufacturing process. Note: These MUST be notified to the Authority where first lot numbers of affected batches MUST be provided to allow monitoring by the Authority.

Note: The Authority reserves the right to mandate any changes to materials in the event of either changes to regulatory requirements or evidence of improvements to donor and/or patient safety, or component quality.

FRM39.DOC

9.2. The Supplier MUST have a documented change management procedure and ensure that any Material Sub-Contractor also has similar procedures, with an obligation to inform the Supplier in a timely manner of changes, of the type detailed in 9.1.

The Supplier MUST provide evidence confirming how they will communicate and enforce this requirement upon their personnel and Material Sub-Contractors.

10. Contingency Stock levels

10.1. Contingency stock for the Goods MUST include two (2) batches that will contain a Batch of integrated filters (if applicable) which differs from the other batches of integrated filters in the contingency stock of Goods and from the batches of integrated filters used by the Authority.

10.2. The Supplier MUST comply with one of the four contingency stock options detailed in Table 1 (overleaf) and the corresponding volume of Goods MUST be made available within two (2) months after entry into force of the Framework. Note:

- The Authority accepts full financial responsibility for purchasing any Goods held by the Supplier as contingency stock (as per table 1) which have been manufactured in accordance with their demand and forecast planning process.
- Any stock held by the Authority will not contribute to the contingency stock volumes to be held by the Supplier.

10.3. The Supplier MUST guarantee that as of the time of any delivery from the contingency stock, the contingency stock will be replenished to the predefined levels, as soon as possible but MUST be within ten (10) weeks.

Option Description	Contingency Stock
1. Production of Goods on two equivalent (i.e. Authority audited and Supplier licensed) locations. On the date of entry into force of the Framework, the Supplier has divided the production of the Goods on two equivalent production locations and (where applicable) assembly locations. These locations are similar (also with regard to processes, procedures, materials and quality systems) in order to be capable to exchange the production and/ or assembly from one location to the other in case of emergencies and the Supplier guarantees the Goods are identical in all respects. **AND** The Authority has determined there is sufficient evidence to warrant a seamless/ complete switch of production, taking into consideration the Suppliers response to the questionnaire in 15.3 below.	Six (6) weeks.
2. Production of Goods on two equivalent (i.e. Authority audited and Supplier licensed) locations. On the date of entry into force of the Framework, the Supplier has divided the production of the Goods on two equivalent production locations and (where applicable) assembly locations. These locations are similar (also with regard to processes, procedures, materials and quality systems) in order to be capable to exchange the production and/ or assembly from one location to the other in case of emergencies and the Supplier guarantees the Goods are identical in all respects. **BUT** The Authority has determined there is not sufficient evidence to warrant a seamless/ complete switch of production, taking into consideration the Suppliers response to the questionnaire in 15.3 below.	Twelve (12) weeks.
3. Production of Goods not on two equivalent production locations. On the date of entry into force of the Framework, the Supplier is capable to produce and/ or assemble the Goods at two locations but only uses one location to produce and/ or assemble the Goods. **AND** The Authority has determined there is sufficient evidence to warrant robust manufacturing arrangements, taking into consideration the Suppliers response to the questionnaire in 15.3 below.	Twelve (12) weeks.

Option Description	Contingency Stock
4. Production of Goods at one location. On the date of entry into force of the Framework, the Supplier only has one location or the Supplier is capable to produce and/ or assemble the Goods at two locations but only uses one location to produce and/ or assemble the Goods. **BUT** The Authority has determined there is not sufficient evidence to warrant robust manufacturing arrangements, taking into consideration the Suppliers response to the questionnaire in 15.3 below.	Twenty-four (24) weeks.

Table 1: Contingency stock scenarios

The Supplier MUST confirm which option is applicable.

11. Good Manufacturing Practice (GMP) and Business Continuity (BC) audits

11.1. The Supplier MUST permit or procure permission for the Authority or its authorised representative during normal business hours having given advance notice, access to any premises and facilities, books and records reasonably required to audit the Supplier's compliance with its obligations under the Framework Agreement. Should the Supplier subcontract any of its obligations, the Authority shall also have the right to audit and inspect such Material Sub-Contractor.

11.2. The procedure governing GMP audits is set out in MPD556 (embedded below). If any:

a. Critical non-compliance (i.e. any non-compliance in a process or written procedure which directly affects the safety of a donor or patient) is found during the GMP audit, the Authority will need to perform a further risk assessment in respect of the critical non-compliance. The Authority may at its discretion, choose to accept the risk associated with the critical non-compliance, subject to a requirement where the Supplier MUST take certain steps to mitigate the risk, or class the result of the audit as a fail.

b. Other non-compliance is found during the GMP audit, the Authority will issue an action plan for improvement and proposed time frames for completion of such improvements, where the Supplier MUST complete their actions in a timely manner,

MPD556.doc

11.3. As part of a BC audit, the Supplier will be assessed on their responses to the Authority's Business Continuity Questionnaire (embedded below) and a site visit conducted. The result will only be classed as a fail if there is deemed to be a limited assurance of BC that would be considered a significant risk to the Authority. For all other risk classifications, the Authority will (where applicable) agree a business continuity plan for improvement to minimise any risks to the Authority, where the Supplier MUST complete their actions in a timely manner to mitigate the risks.

Business Continuity Questionnaire High Ri

The Supplier MUST submit a duly completed questionnaire

12. Training

12.1. The Supplier MUST train and/ or provide training materials to Authority Personnel on the proper use of the Goods and provide refresher training, tailored wherever appropriate to meet the

Authority's specific requirements. Additional ad hoc training and/ or training materials MUST be provided where an amendment is implemented by the Supplier and/ or as a result of new Authority Personnel being employed. Note: If filters require any special packing by Authority personnel prior to centrifugation, this MUST be clearly identified by the Supplier to Authority personnel along with recommendations for filter holders/supports.

The Supplier MUST provide:

a. *Information on proposed training sessions, including duration and location where the sessions would be held.*
b. *Example training content materials for the Goods, appropriate for all Authority Personnel.*

12.2. All training provided by the Supplier MUST minimise impact on the Authority's ability to meet its collection targets.

12.3. The Supplier MUST provide certification of competency for all Authority Personnel, confirming successful completion of each training session attended.

The Supplier MUST provide examples of types of certification it provides for training sessions.

12.4. An e-learning facility SHOULD be provided by the Supplier. Where e-learning is claimed then it MUST be maintained/ refreshed and be available to Authority staff during the life of the Framework.

If available, the Supplier MUST provide details of the e-learning facility.

13. Quality/ Regulatory

13.1. The Supplier MUST meet the requirements of an internationally recognised standard for quality management (i.e. ISO9001 or another comparable National or International standard).

The Supplier MUST provide:

a. *A copy of the certificate or the certificate number for verification with the issuing body.*
b. *Evidence that the certification covers the supply of the products or services to which this tendering process applies.*

Note: If certificates are able to be provided via a secure website, the Supplier MUST detail the website address and the procedure for requesting access.

13.2. The Supplier MUST manufacture Goods that meet recommended standards for Good Manufacturing Practice.

13.3. The Supplier MUST provide to the nominated Authority location an agreed number of Goods forming a Quality Assurance (QA) batch, for each new batch of all Goods to be delivered.

13.4. The Supplier MUST minimise the QA activities to be performed by the Authority.

13.5. If QA batches are required by the Authority, they MUST be delivered at least two (2) weeks in advance of the main delivery of each new batch.

13.6. The Goods MUST not pose a safety or health risk to Authority personnel; where any residual risks associated with the use of the Goods exist (when used in accordance with the Instructions for Use), the Supplier MUST inform the Authority.

The Supplier MUST provide evidence to support this which MUST include hazards that have been eliminated or controlled by design. Where residual risks exist these MUST be stated in addition to actions that MUST be implemented to reduce risk to an acceptable level.

14. Sustainability

14.1. Goods SHOULD be designed to limit the environmental impact of their consumption and production.

The Supplier MUST provide details of the environmental impacts of all Goods offered, including the initiatives they have in place to mitigate these impacts.

15. Continuous Improvement

15.1. It is recognised that over the life of the Framework Agreement new developments/ innovations may become available and the Authority may wish to take advantage of these. The Supplier MUST notify the Authority of any such new developments which are relevant to the System offered - in accordance with 9.1 above - and where mutually agreed, work with the Authority to develop and implement the new developments.

15.2. The Supplier MUST work with the Authority to develop and deliver a continuous improvement programme covering all elements of the Goods offered and other obligations detailed in the Framework.

Requirements that could potentially be incorporated into this specification:

10. Contingency stock

10.1 Possible amendment to business continuity stock (clause 10), to ensure stock has been verified as performing satisfactorily before being used, this could be achieved through blood establishments performing pre-batch acceptance testing for all new lots/ batches.

Appendix A - Defect Warning and Action Levels

The defect level guidelines for critical (Type 1) and other (Type 2) defects (expressed in defects per million) are given below:

Defect type	Target level	Action level
Type 1	0	800 (0.08%)
Type 2	<1,300 (0.13%)	2,000 (0.20%)

These levels are intended to be guidelines for the absolute levels for the review of defect rates. In practice the Authority will also use statistical process control principles and current performance. The Authority expects to raise issues for investigation by the Supplier, based on defect rates being either outside of control limits, demonstrating an upward trend or being worse than previously achieved levels of performance, where previously achieved levels of performance means the current sustainable defect rate.

- Type 1 defects are serious defects that can or have resulted in the pack contents or sterile fluid pathway becoming microbially contaminated or could otherwise compromise donor or patient safety and include holes, tears, joint failures, contamination/ soiling etc.
- Type 2 defects include all other defects that are unlikely to compromise patient safety and include label adhesion problems (winging or creasing), sub-optimal design (e.g. needle guard not retracting smoothly), kinked lines, bent needles, broken/ damaged or missing parts, moulding errors and cosmetic defects (e.g. printing blemishes on label surface).