Standard Summary Project Fiche for the Transition Facility

1. Basic Information

1.1 CRIS Number: 2004/16762.01.03.
   Twinning ‘light’: MT04-IB-OT-04

1.2 Title: Upgrading the National Blood Transfusion Service to quality standards as specified in Directive 2002/98/EC

1.3 Sector: Internal market

1.4 Location: Malta

2. Objectives

2.1 Overall Objective:

To ensure the provision of a safer supply of blood and blood components for Malta, thereby assisting Malta to comply with EU requirements in this area.

2.2 Project Purpose

To support the Department of Institutional Health in guaranteeing a safer, more efficient National Blood Transfusion Service, in compliance with quality standards as specified in EU Directive 2002/98/EC on ‘Setting Standards of Quality and Safety for the collection, testing, processing, storage and distribution of human blood and blood components’.

2.3 Justification

Under EU Directive 2002/98/EC on ‘Setting standards of quality and safety for the collection, testing, processing, storing and distribution of human blood and blood components’, the Processing Unit at the National Blood Transfusion Centre should operate up to the required quality standards. On Malta’s accession to the EU, this Processing Unit will require a licence to be able to operate. Whether this licence is awarded or not will depend on the achievement of satisfactory quality standards.

Although the Directive 2002/98/EC does not specify the required standards of quality for blood transfusion as ‘Good Manufacturing Practice’ per se, reference is made to the Feasibility Study (page 4) for this project carried out Dr William Murphy (Annex 7):

“Blood transfusion Services in Member States are therefore required to achieve and maintain a quality standard in their operations that is defined and detailed by a “Quality System” that meets the norms of “Good Practice”, and in particular meets the technical specifications of such a quality system as laid out and kept up to date by the provisions of Article 29(h). Such a quality system will comply with the norms of good manufacturing practice, good laboratory practice, and good distribution practice as appropriate in the processes and procedures of the Blood Transfusion Service.”
The Community Standards and specifications required under Article 29(h) have not yet been defined under the procedure detailed in Article 28; however it is apparent from several sources, including direct communication with the Commission, that they will be based largely on the provisions of the Rules for Good Manufacturing Practice in the EU, with reference to the relevant ISO guidelines. The role of GMP is quite clearly indicated both in the reference to Good Practice above, and in the requirements of the specifications agreed in the technical specifications required under Article 29 (b), (c), (d), (e), (f) & (g)."

3. Description

3.1 Background and justification:

The National Blood Transfusion Centre is divided into three units:

- the Donation/collection area,
- the Processing Unit, and
- the hospital blood bank.

At present these are all housed in the same building, but the premises are old and too small to house all three units. The Government of Malta, through the Ministry of Health, is committing itself to finding new premises for the donation and collection area (Unit 1), a process that has already started with a final site being earmarked and evaluated for the said purpose. The hospital blood bank (Unit 3) will be transferred to the new state hospital, Mater Dei, when this is opened towards the end of 2006; in the interim period this Hospital Blood Bank (Unit 3) will be housed temporarily in another area in Saint Luke’s Hospital.

This Project will directly affect the ProcessingUnit (Unit 2). The Government has committed itself to undertake refurbishment of the ProcessingUnit premises prior to installation / upgrading of equipment. This refurbishment will be carried out one floor at a time, with lab areas being decanted from one floor to the other temporarily. This will reduce costs, as the Blood ProcessingUnit will not have to be relocated elsewhere while the works are being carried out. All alterations required to be able to house Quality systems and equipment will be implemented, including laying of modern floor and wall surfaces, and the installation of a dedicated electrical supply and lift.

The current technical blood banking equipment is in good working order and up to date and will therefore continue to be utilized (this will remain the responsibility of the Department of Health as per capital investment forecasts in Section 11.3 of Fiche). However, equipment which will ensure quality and safety of product and staff needs to be procured and installed. This includes:

- upgrading of the existing IT and communication systems,
- climate control systems,
- flow cytometer,
- laboratory work stations and other ‘furniture’ and
- surveillance and security systems.

It is worth pointing out at this stage that the Blood Processing Facility can carry on using the general laboratory workstations and equipment that it is currently using, but this will
hinder the Facility from achieving the required Quality standards. This equipment is necessary in order to achieve the required standards, ensure quality assurance of blood and blood components, and in order to maintain compliance with EU standards on this issue. The following is a detailed explanation that provides a direct link between equipment requirements and the quality standards to be achieved.

**Upgrading of the existing IT and communication systems**

The Blood Processing Facility has an adequate IT system in terms of standard IT equipment such as PC’s, laptops, printers, etc. However, the Progesa system being used (Version 4.4d) requires upgrading to Version 4.4g if the Facility is to ensure traceability of blood as specified in the Directive. This will require a new server and the costs of this upgrade are specified below:

*Progesa upgrade and Patient Module project cost estimate*

The following are the costs involved broken down by each phase:

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
<th>Cost €</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Server consisting of an Alpha Server DS25</td>
<td>42,265</td>
</tr>
<tr>
<td>2</td>
<td>Progesa 4.4g Patient Module</td>
<td>11,500</td>
</tr>
<tr>
<td>3</td>
<td>Progesa V4.4g Patient Module Training</td>
<td>8,000</td>
</tr>
<tr>
<td>4</td>
<td>Parameter set-up assistance via phone and modem</td>
<td>4,000</td>
</tr>
<tr>
<td>5</td>
<td>Update and go-live Patient Module 5 days</td>
<td>5,000</td>
</tr>
<tr>
<td>6</td>
<td>On-site training, remote assistance, go live assistance</td>
<td>6,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>76,765</strong></td>
</tr>
</tbody>
</table>

**Climate control systems**

Several elements play an important role in ensuring the safe storage and transportation of blood from the donation process through to transfusion. An essential element of this “blood cold chain”, in accordance with the required quality standards as laid down in the Directive, is rigorous climate control.

Selection and procurement of the necessary equipment and temperature monitoring devices is required to achieve the required quality standards.

The elements of the blood cold chain are:
- Equipment for storage and transportation
- Temperature monitoring devices
- Back up systems
- Well-trained personnel
- Standard operating procedures
- Measurements to monitor process control

This is a very fragile chain as one weak link can have very serious, even fatal consequences for the particular patient. The following key equipment is required for the cold chain to be successful: blood bank refrigerators, plasma freezers, platelet agitators,
plasma thawing equipment, blood transport boxes and coolants, temperature monitoring devices, accessories to the blood cold chain equipment including voltage regulators and standby generators. Some of this equipment is already functioning well in the Processing Unit but the chain is not complete. The following are estimated costs of the items required:

<table>
<thead>
<tr>
<th>Item</th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk in fridge/freezer</td>
<td>85,000</td>
</tr>
<tr>
<td>Quarantine blood bank refrigerators / freezers</td>
<td>19,000</td>
</tr>
<tr>
<td>Centralised temperature monitoring system including installation and hardware</td>
<td>40,000</td>
</tr>
<tr>
<td>Plasma thawing equipment</td>
<td>10,000</td>
</tr>
<tr>
<td>Blood transport boxes</td>
<td>2,000</td>
</tr>
<tr>
<td>Blood temperature monitoring devices (during transport)</td>
<td>2,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>158,000</strong></td>
</tr>
</tbody>
</table>

**Laboratory workstations and other equipment**

The essential considerations for procurement of laboratory workstations and other equipment according to the required quality standards are the following:

Choice of material for work surfaces depends on whether it needs to be resistant to chemicals, disinfectants, detergents, high and low temperatures, abrasion and impact, as well as cleaning and disinfection. The surface should be sufficiently durable to withstand heavy use.

Under-bench units or cabinets may be floor-standing, fitted with castors, suspended or cantilevered from the bench frame. The furniture design should permit easy floor cleaning and decontamination beneath the units and facilitate the interchange of units to give flexibility for activity needs.

The work surface and frames of benches and tables should be sufficiently strong and stable to carry the equipment load.

Furniture including that in computer areas should be ergonomically designed with respect to the height and reach of the average operator and whether they are seated or standing: the relative positioning of furniture and equipment should reflect activities which are related to one another.

Shelves and over bench cupboards should be low enough for their contents to be easily reached.

The colour and surface texture of furniture should be chosen to reduce glare and reflection and to enhance environmental comfort (where possible neutral colours should be chosen).

Large pieces of furniture should be placed where they do not compromise the circulation and emergency routes, disturb air-flow to ventilated enclosures, or cast shadows on work surfaces.
Any joints in work surfaces must be made preferably using epoxy resin grout to give a surface which will not crack, retain dirt or foreign matter and will not promote or sustain the growth of harmful or pathogenic agents.

Edges to work surfaces, doors and drawer fronts must be resistant to wear and tear, impacts and liquids in normal use.

The ideal surface material for NBTC Laboratory work-stations would be cast epoxy resin which is highly resistant to all dry, wet and chemical uses and may be cast into work surfaces with integral sinks, etc. It is extremely hard wearing and the surface can be easily cleaned and reinstated.

As recommended by the foreign technical expert in the feasibility study, a flow cytometer for the Quality Control lab is also required for monitoring of quality control.

Estimated cost for laboratory workstations and equipment:

<table>
<thead>
<tr>
<th></th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>Screening Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>QC Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>Products Lab</td>
<td>54,000</td>
</tr>
<tr>
<td>Flow cytometer (QC lab)</td>
<td>115,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>259,000</strong></td>
</tr>
</tbody>
</table>

**Security systems**

Access to the Blood Transfusion Laboratories is to be limited to their staff and others such as cleaners and maintenance workers who are permitted entry if supervised by a trained member of laboratory staff. Casual visitors will be actively discouraged by a combination of physical barriers (including surveillance systems) and clear notices. Hospital porters, messengers or others delivering specimens or collecting blood products, should be admitted to a waiting room separated from the laboratory. A hatchway will be useful for the delivery of specimens and blood collection.

Doors shall be kept closed when the laboratory is occupied and locked when it is vacated. Double key systems, security locks and electronic personal signature devices will provide protection against unauthorised entry but arrangements should be made so that fire or emergency services can gain access if the laboratory is unoccupied.

Doorways should be wide enough to accommodate the largest items of equipment and provide for the unimpeded escape of occupants in the event of fire. Where the door opens into a circulation or fire protected escape route it must be of fire resistant material and self-closing. All exits and escape routes should be clearly sign-posted.

Unauthorised or forced entry into the laboratories can be counteracted by:

- Reducing the number of entrance doorways into the building,
- Providing surveillance devices (including CCTV),
- Fitting alarms to fire exit doors,
- Reducing the number and size of windows (if possible),
- Fitting locks or grilles

**Estimated cost**

To cover the above items including CCTV, security locks, fire alarms, and fire prevention, security at all levels of the blood chain from donation to issuing (limited access with full access traceability)

<table>
<thead>
<tr>
<th></th>
<th>€</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security access systems</td>
<td>25,000</td>
</tr>
<tr>
<td>CCTV systems</td>
<td>15,000</td>
</tr>
<tr>
<td>Digital security locks</td>
<td>8,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>48,000</strong></td>
</tr>
</tbody>
</table>

**Technical training** of staff at the Processing Unit is satisfactory and specific training has so far been provided by the suppliers of equipment to the blood bank. However, EU Directive 2002/98/EC also stipulates that personnel involved in the processing of blood and blood components are provided with “…timely, relevant and regularly updated training…” vis-à-vis good manufacturing practice requirements. This Unit urgently requires funding for its personnel to build staff capacity and ensure achievement of the required standards in compliance with EU requirements.

The health service in Malta, both public and private, is fully dependent on the provision of blood and blood components through the national blood transfusion service. Failure to achieve the standards required by the European Union could potentially jeopardise the running of this essential service, with consequent detriment to safe health care delivery in Malta.

**3.2 Linked Activities:**

There have been no past pre-accession funds allocated for this area. There has been no bilateral assistance in this field to date.

The National Blood Transfusion Service is wholly funded by the government through the Health Department. The government is committed to provide a safe and sustainable blood supply.

With regards to this project, the Maltese Government is committing itself to:
- Relocating the donation area to a more suitable premises,
- Relocating the hospital blood bank area on completion of Mater Dei Hospital,
- Providing the site/premises for housing the Processing Unit and carrying out the required structural works prior to installation of equipment.

Upon completion of this project, certification (Accreditation) by an external auditing body shall follow. This will be the ultimate verifiable tangible result of the project. There is no authority in Malta that has the competence required to audit the Blood Processing
Unit and therefore establishing links with an external (foreign) auditing body will be necessary.

### 3.3 Results

The Department of Institutional Health is aiming at the following results:

1. An organisational set-up with staff well acquainted with quality standards and implementation.
2. Staff trained in maintaining the required standards.
3. A Blood Processing Facility that is compliant with accepted standards required for Quality Systems implementation.

### 3.4 Activities

#### Component A: Institution Building

This component shall be implemented through a Twinning ‘light’ scheme and is divided into two sub-activities:

1. Training of selected members of staff in managerial positions to become proficient in quality systems as applied to blood banking. Suitably qualified experts will travel to Malta to deliver the training and audit the NBTS quality systems and standards. The experts required should be experts in Blood Banking and quality systems as relevant to blood banking. They should have the relevant experience in the subject and preferably an experience in conducting external audits to Blood Banks.

We estimate that two experts, one of whom would preferably also have an experience on IT systems requirements for quality system certification will be required. Each expert would be required to make three visits of one week each over the duration of the Twinning ‘light’. These short-term experts shall conduct an audit and deliver training to the management team on quality system requirements.

The cost based on two experts, three visits each of 5 nights is €25,056:

\[
\begin{align*}
15 \text{ days} \times €200 &= €3,000 \\
150\% \text{ flat-rate} &= €4,500 \\
18 \text{ days} \times €196 &= €3,528 \\
3 \text{ flights} \times €500 &= €1,500 \\
\text{Total each expert} &= €12,528 \\
\text{Total} &= €25,056
\end{align*}
\]

Malta is a small country and the problem in the blood bank is insularity. We have only one blood bank and no training facilities in blood banking except from the purely technical aspect. With the exception of the Medical Director, staff are not exposed to other blood banks or indeed other blood bank experts. There is a need for exposure to the actual management of blood banks, the formulation of quality manuals, QC procedures, and to exchange ideas and knowledge or experience. Although by and large they are doing a reasonable job officials need specific training in order to ensure full compliance with Directive 2002/98/EC. In fact, one of the key elements of the directive is staff
training and education. For most areas and situations it is not possible to provide this through local sources.

The finance officer is one of the key officials. In a system where responsibilities especially in finance and procurement, are clearly defined, this person is responsible (in collaboration with the users) to issue all the specifications for all items at the blood bank. By EU standards Malta’s is a very small Blood Bank, however it has the same responsibilities as blood bank in other Member States, which have more resources. The NBTS is limited in people, finances, training opportunities, and constrained by Malta’s isolation. The NBTS aims to build on its resources, a strong motivated and altruistic donor base, a team of dedicated, motivated and competent staff at the Blood Bank who have an ambition to learn and improve.

The NBTS has a solid foundation on which to build. The aim of this project is to utilise these resources and build up a system which can attain the Quality Standards as specified in the Directive.

2. Attachment of local staff to centres of excellence in other European Blood Banks (Quality certified centres).

These attachments (traineeships) would be for key management personnel to visit Centres of Excellence in Quality certified centres. Personnel targeted include the QA manager, two people from the QC laboratory, two operations managers, finance and procurement officer, and the computer system administrator – seven people in all. The total number of days is expected to be around 20 days over a maximum period of ten months.

20 days @ €199’

Total (for seven people) €27,860

Grand Total (Twinning ‘light’) €52,916

Component B. Investment

Procurement of the following equipment is required:

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security and surveillance systems</td>
<td>€48,000</td>
</tr>
<tr>
<td>4 Laboratory workstations</td>
<td>€144,000</td>
</tr>
<tr>
<td>Laboratory equipment (flow cytometer)</td>
<td>€115,000</td>
</tr>
<tr>
<td>Climate control systems:</td>
<td>€259,000</td>
</tr>
<tr>
<td>Walk in fridge/freezer</td>
<td>€85,000</td>
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<td>€2,000</td>
</tr>
<tr>
<td>Blood temperature monitoring devices (during transport)</td>
<td>€2,000</td>
</tr>
</tbody>
</table>

* Member State to be selected. Figure is indicative and for budgetary purposes only.
3.5 Lessons Learned

The following key issues have been incorporated into the design of this project to ensure a successful outcome:

Adequate project management: The project manager is leading a core team of professionals qualified in the key areas of transfusion medicine and/or health management who believe in the importance of this project for Maltese health care delivery and who are committed to its successful realisation within the stipulated schedules. They are all experienced professionals in their particular fields and have been entrusted with other projects in the past.

Early issuing of tenders: The tender specifications are already being prepared in order to avoid unnecessary delays and enable adherence to tendering timeframes. The Planning Matrix has been extensively discussed with all key stakeholders to ensure that targets are as realistic as possible and that results obtained are indeed measurable and verifiable.

Links with other European centres of excellence have already been established regarding the Training component.

The Project was extensively discussed and reviewed during the Expert’s visit in February 2004. This analysis by a highly qualified professional with significant experience in quality of transfusion medicine at the European level proved to be extremely useful feedback.

4. Institutional Framework

- The National Blood Transfusion Service (NBTS) is incorporated within the Health Division, falling directly under the Department of Institutional Health. This Department has a regulatory function within the Ministry of Health, the Elderly and Community Care, and is responsible for ensuring that health care delivery in Malta is of the required standards. It is also responsible for ensuring a safe and sustainable blood supply, and for coordinating emergency and disaster preparedness.

- The Service (NBTS) includes two donation centres and a mobile unit. There is another donation centre (SMOM) in Malta but all blood collected from all centres is referred to the National Blood Bank which processes, screens and issues blood to all hospitals in Malta. Blood donation is strictly voluntary and blood is given free to all centres. The National Blood Bank is managed by a Medical Director. Key competent personnel are in place in the relevant areas of quality assurance, quality control, production management and procurement.

- The following are the current Staffing Levels in the Donation and Processing Unit:
Position | Full time equivalent
--- | ---
Nursing Officer | 1
Registered Nurse | 8.5
Enrolled Nurse | 5
Nursing Aide | 3
Ward Clerk | 1 (reception duties)
Clerk | 2 (secretarial/reception duties)

**Technical Side:**

- Principal Medical Lab Scientist (MLS) 1
- Assistant Principal MLS 2
- Serology Lab MLS 3
- Screening Lab MLS 3
- Products Lab MLS 5.5
- Quality Control Lab MLS 2*
- Finance/Procurement (Asst Principal MLS) 1

*Another 2 MLS in QC lab are on maternity leave.

- Proposed reorganisation of staff: as required by EU Directive the following positions are necessary:

1. Responsible Person / Medical Director
2. Quality Assurance Officer
3. Operations Manager/s (since work is carried out 7 days a week 24 hours a day 2 FTE are required)
4. Quality Control Officer

Each of these positions requires a specific job description in line with EU Directive requirements. At present, Blood Bank staff is still employed by the Ministry of Health, the Elderly and Community Care but the necessary administrative and structural changes have been approved at Ministerial level, and in the near future, a call for applications based on the above-mentioned job descriptions will be made. Recruitment will be on renewable contract basis. As explained above, the Processing Unit is already manned by competent key personnel, but current positions need to be formalised according to the nomenclature specified in the Directive.

The following set-up is envisaged:

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**Competent Authority**

(Regulator)
No institutional constraints are envisaged.

The National Blood Transfusion Service is a public service under the Ministry of Health, and managed directly by the Department of Institutional Health. There is no direct input from any private source of income, and the owner of all pertaining assets is the Government of Malta.

5. Detailed Budget

<table>
<thead>
<tr>
<th>Transition Facility Support</th>
<th>Investment Support</th>
<th>Institution Building</th>
<th>Total TF (=I+IB)</th>
<th>National Co-financing*</th>
<th>IFI*</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twinning ‘light’</td>
<td>-</td>
<td>53,000</td>
<td>53,000</td>
<td></td>
<td></td>
<td>53,000</td>
</tr>
<tr>
<td>Equipment</td>
<td>300,000</td>
<td>-</td>
<td>300,000</td>
<td>242,000</td>
<td></td>
<td>540,000</td>
</tr>
<tr>
<td>Total</td>
<td>300,000</td>
<td>53,000</td>
<td>353,000</td>
<td>242,000</td>
<td></td>
<td>595,000</td>
</tr>
</tbody>
</table>

* In cases of co-financing only

The amounts for co-financing indicated in the table correspond to cash co-financing. In addition, in-kind contributions from the Maltese administration for a good implementation of the Twinning ‘light’ may be developed in the terms of reference.
The cost of air tickets of Maltese officials participating in study visits will be paid for out of the Travel vote of the beneficiary.

The co-financing expenses will be monitored by the beneficiary and the NAO. For the earmarked co-finance, a clear and verifiable set of costs will be provided. The beneficiary will define which budget lines are the source for co-finance.

The beneficiary together with the NAO commits to sound financial management and financial control.

For the investment component, co-financing will be joint.

6. Implementation Arrangements

6.1 Implementing Agency

Department of Institutional Health
Health Division
15 Merchants Street
Valletta CMR 02
Malta

Project Leader:

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Fax: +356 2299 2299
E-mail: nadine.p.camilleri@gov.mt

The National Blood Transfusion Centre

Contact person:

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Consultant, National Blood Transfusion Centre
St Luke’s Hospital
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Fax: +356 21250163
E-mail: alex.aquilina@gov.mt

Contracting Authority

Department of Contracts
Notre Dame Ravelin
Floriana CMR 02
Malta

Contact person:

Mr Dennis Attard
6.2 Twinning

Twinning ‘light’ counterpart:

Dr Nadine Camilleri
Department of Institutional Health,
Health Division
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Valletta CMR 02
Malta

Tel: +356 2299 2584
Fax:+356 2299 2299
E-mail: nadine.p.camilleri@gov.mt

6.3 Non Standard Aspects

Not applicable

6.4 Contracts

One Twinning ‘light’ contract of a value of €53,000.

One supply tender is envisaged. The estimated value of the equipment required to achieve the required quality standards is €542,000.

7. Implementation Schedule

7.1 Start of Tendering / Call for proposals

September 2004

7.2 Start of Project Activity

February 2005

7.3 Project Completion

December 2005

8. Sustainability

The Department of Health will be responsible for future maintenance and operational costs. In areas where tender for procurement and installation of equipment includes after-sales servicing and maintenance, the supplier will naturally be held responsible.
9. **Conditionality and Sequencing**

The procurement of the investment component is conditional upon:
- Department of Health to finalise the relocation process of the donation and hospital blood bank areas by June 2004
- Department of Health to provide premises for Blood Processing Unit/Facility and carry out the necessary infrastructural works by December 2004. Provision of equipment is conditional upon finalisation of all renovation works in the premises of the Processing Unit.
- A further evaluation of the necessary budget (up to the maximum foreseen in the fiche) for the investment component will be carried out on the basis of the results of a needs assessment study when they are available. (Please refer to Annex 7).

**Sequencing**

External audit to verify whether the required standards have been achieved will be carried out by a recognised accredited body in January 2006.
Annex 1: Log frame Planning Matrix

<table>
<thead>
<tr>
<th>Project</th>
<th>Programme Name and Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upgrading the National Blood Transfusion Service to Quality standards</strong></td>
<td>Contracting period expires 15/12/2006 Disbursement Period expires 15/12/2007 Total budget: €595,000 TF budget: €353,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall Objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure the provision of a safer supply of blood and blood components for Malta, thereby assisting Malta to comply with EU requirements in this area.</td>
<td>Achievement of required quality standards through training of staff and installation / upgrading of equipment.</td>
<td>Final audit by accredited body Regular reporting to EU Commission.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>To support the Department of Institutional Health in guaranteeing a safer, more efficient National Blood Transfusion Service, in compliance with quality standards as specified in EU Directive 2002/98/EC on ‘Setting Standards of Quality and Safety for the collection, testing, processing, storage and distribution of human blood and blood components’.</td>
<td>1. The Blood Processing Unit achieves the desired Quality standards and is granted a licence by the Competent Authority by January 2006. 2. NBTS staff with the training and technical knowledge of how to operate at the required standards by November 2005.</td>
<td>Accreditation by a recognized body Regular reporting to EU Commission.</td>
<td>Government provides premises and carries out infrastructural works required prior to installation of equipment. Formulation and implementation of a national blood transfusion policy following WHO guidelines.</td>
</tr>
<tr>
<td>Results</td>
<td>Objectively verifiable indicators</td>
<td>Sources of verification</td>
<td>Assumptions</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------</td>
<td>------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>1. An organisational set-up with staff well acquainted with quality standards and implementation. 2. Staff trained in maintaining the required standards. 3. A Blood Processing Facility that is compliant with accepted standards required for Quality Systems implementation.</td>
<td>Quality requirements as specified in Council Directive 2002/98/EC implemented by December 2005.</td>
<td>Final audit by accredited body to include assessment of quality systems in place, staff proficiency, documentation systems, etc. Regular reporting to EU Commission STE Reports Certificates of Attachment (personnel)</td>
<td>Adequate funding for the project.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training of selected members of staff in managerial positions to become proficient in quality systems as applied to blood banking. Attachment of key NBTS personnel to European centres of excellence in the field. Procurement and installation of equipment required to reach expected quality standards.</td>
<td>Twinning ‘light’ contract Supply tender</td>
<td>Co-operation with local health authorities and the Malta Standards Authority. Availability of funds for both components of the project.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preconditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Government finalises relocation of blood donation and hospital blood bank areas and carries out the necessary infrastructural changes required in Blood Processing Unit.</td>
<td></td>
</tr>
</tbody>
</table>
Annex 2: Implementation Chart

SUMMARY DETAILED TIME IMPLEMENTATION CHART FOR THE PROJECT

**Title:** Upgrading the National Blood Transfusion Service to quality standards as specified in Directive 2002/98/EC

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>2004</th>
<th></th>
<th>2005</th>
<th></th>
<th>2006</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>J</td>
<td>A</td>
<td>S</td>
<td>O</td>
<td>N</td>
<td>D</td>
</tr>
<tr>
<td>All Components</td>
<td>D</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>I</td>
</tr>
</tbody>
</table>

D = Design  
C = Contracting  
I = Implementation  
X = Closure
Annex 3: Contracting and Disbursement Schedule

CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE

**Title:** Upgrading the National Blood Transfusion Service to quality standards as specified in Directive 2002/98/EC

<table>
<thead>
<tr>
<th></th>
<th>31/01/05</th>
<th>31/03/05</th>
<th>30/06/05</th>
<th>30/09/05</th>
<th>31/12/05</th>
<th>31/03/06</th>
<th>30/06/06</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONTRACTED</strong></td>
<td>53,000</td>
<td>595,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DISBURSED</strong></td>
<td>42,400</td>
<td>367,400</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>595,000</td>
</tr>
</tbody>
</table>

All figures in Euro
Annex 4:

This project is an investment in the quality and safety of the national blood transfusion service, and hence an investment in health care delivery in Malta.

A financial appraisal is not applicable as the benefits derived from this project are not immediately quantifiable in financial terms.

From the economic perspective, the Maltese government is committed to ensuring a safe and sustainable blood service to maintain the required standards in health care delivery. Failure to achieve the required standards in the blood production facility may have disastrous effects on the national and private health service delivery on the island, as the blood production facility will not be able to operate if it is not granted a manufacturer’s licence. Although difficult to quantify in financial terms, such measures would have a widespread negative impact, not only on the health and well being of Maltese citizens, and hence on Maltese industry in general, but also on the tourism industry and the country’s economy.

The project involves internal works in existing premises in the precincts of Saint Luke’s Hospital. The current Blood Processing Unit will not require relocation as works can be carried out in one floor at a time, shifting equipment and lab areas as necessary. No new buildings will be erected and there will not be a negative impact on the environment. Care will be taken to keep noise and traffic disturbance to a minimum, more so as the premises will be housing a functional Blood Processing Unit at any time.
Annex 5: Relevant Laws and Regulations

EU Directive 2002/98/EC

Although this Directive has not yet been transposed into Maltese law, it will come into force, together with Annexes, in February 2005. No derogations are envisaged.

Malta will become a Member of the EU in May 2004, and should be in line with this Directive when it comes into force.
Annex 6: List of Equipment with Indicative Prices

Progesa upgrade and Patient Module project cost estimate

<table>
<thead>
<tr>
<th>Task</th>
<th>Cost €</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Server consisting of an Alpha Server DS25</td>
<td>42,265</td>
</tr>
<tr>
<td>2 Progesa 4.4g Patient Module</td>
<td>11,500</td>
</tr>
<tr>
<td>3 Progesa V4.4g Patient Module Training</td>
<td>8,000</td>
</tr>
<tr>
<td>4 Parameter set-up assistance via phone and modem</td>
<td>4,000</td>
</tr>
<tr>
<td>5 Update and go-live Patient Module 5 days</td>
<td>5,000</td>
</tr>
<tr>
<td>6 On-site training, remote assistance, go live assistance</td>
<td>6,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>76,765</strong></td>
</tr>
</tbody>
</table>

Blood cold chain – climate control

<table>
<thead>
<tr>
<th>Task</th>
<th>Cost €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk in fridge/freezer</td>
<td>85,000</td>
</tr>
<tr>
<td>Quarantine blood bank refrigerators / freezers</td>
<td>19,000</td>
</tr>
<tr>
<td>Centralised temperature monitoring system including installation and hardware</td>
<td>40,000</td>
</tr>
<tr>
<td>Plasma thawing equipment</td>
<td>10,000</td>
</tr>
<tr>
<td>Blood transport boxes</td>
<td>2,000</td>
</tr>
<tr>
<td>Blood temperature monitoring devices (during transport)</td>
<td>2,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>158,000</strong></td>
</tr>
</tbody>
</table>

Laboratory workstations and equipment

<table>
<thead>
<tr>
<th>Task</th>
<th>Cost €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>Screening Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>QC Lab</td>
<td>30,000</td>
</tr>
<tr>
<td>Products Lab</td>
<td>54,000</td>
</tr>
<tr>
<td>Flow cytometer (QC lab)</td>
<td>115,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>259,000</strong></td>
</tr>
</tbody>
</table>

Security system

<table>
<thead>
<tr>
<th>Task</th>
<th>Cost €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security access systems</td>
<td>25,000</td>
</tr>
<tr>
<td>CCTV systems</td>
<td>15,000</td>
</tr>
<tr>
<td>Digital security locks</td>
<td>8,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>48,000</strong></td>
</tr>
</tbody>
</table>
Annex 7 - Feasibility Study for the Investment component of the Project ‘Upgrading the National Blood Transfusion Service to quality standards as specified in Directive 2002/98/EC’

Date of Report: 05 March 2004

Feasibility study performed by:
Dr William G. Murphy MD, FRCPEdin, FRCPath,
National Medical Director, Irish Blood Transfusion Service

Study performed February 2004.

Visit of expert to BTS, Malta, 16 – 19th February 2004.
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Conclusions................................................................. Page 10
Profile of the Expert...................................................... Page 11
1. Introduction

The provisions of Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33/39, 8.2.2003) come into force in Member States in 8 February 2005. Upon accession to the European Union, Malta will be required to ensure that the Blood Transfusion Service is well placed to meet these requirements in time.

2002/98/EC places a number or requirements on Governments, Blood Establishments\(^1\), and on Hospital Blood Banks\(^2\).

Broadly

Members States are required to enact the provisions, and each shall designate a body called the Competent Authority to inspect, accredit or licence, and regularly re-inspect and re-accredit Blood Establishments in its territory.

Blood establishments are required to conform to certain provisions governing quality of staff, documentation, processes, premises, equipment, storage, distribution and transport. They will be licensed or accredited by the Competent Authority in accordance with their conformance with these provisions, and may not deviate from their approved activities without prior permission of the Competent Authority.

Specific and more limited provisions apply to Hospital Blood Banks. The Directive does not specify how the member states must achieve and monitor compliance in the case of hospital blood banks and does not require them to inspect and accredit the banks as such. Nevertheless, these facilities are required to reach appropriate standards of training of personnel and of documentation, and to store blood and blood components in an appropriate manner; in addition the hospital blood banks must have a comprehensive system both for ensuring traceability of every blood component transfused in their hospitals, for capturing the occurrence of adverse events attributable to blood transfusion, and for reporting them to the competent authority.

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\(^1\) "Blood establishment shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks."

\(^2\) "Hospital blood bank shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital transfusion activities."
2. Blood Establishments and Quality

Article 11 states, in relation to “Quality System for blood establishments”:

1. Member States shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice.
2. The Commission shall establish the Community standards and specifications referred to in Article 29(h) for the activities relating to a quality system to be carried out by a blood establishment.

Article 29 of 2002/98/EC in turn specifies:

"The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):
(a) traceability requirements;
(b) information to be provided to donors;
(c) information to be obtained from donors including the identification, health history, and the signature of the donor;
(d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including
   — permanent deferral criteria and possible exemption thereto
   — temporary deferral criteria;
(e) storage, transport and distribution requirements;
(f) quality and safety requirements for blood and blood components;
(g) requirements applicable to autologous transfusions;
(h) Community standards and specifications relating to a quality system for blood establishments;
(i) Community procedure for notifying serious adverse reactions and events and notification format."

Blood transfusion Services in Member States are therefore required to achieve and maintain a quality standard in their operations that is defined and detailed by a “Quality System” that meets the norms of “Good Practice”, and in particular meets the technical specifications of such a quality system as laid out and kept up to date by the provisions of Article 29(h). Such a quality system will comply with the norms of good manufacturing practice, good laboratory practice, and good distribution practice as appropriate in the processes and procedures of the Blood Transfusion Service.

The Community Standards and specifications required under Article 29(h) have not yet been defined under the procedure detailed in Article 28; however it is apparent from several sources, including direct communication with the Commission, that they will be based largely on the provisions of the Rules for Good Manufacturing Practice in the EU, with reference to the relevant ISO guidelines. The role of GMP is quite clearly indicated both in the reference to Good Practice above, and in the requirements of the specifications agreed in the technical specifications required under Article 29 (b), (c), (d), (e), (f) & (g).

The requirements of Good Practice, and in particular GMP, apply to several core elements of a manufacturing facility, as a Blood Centre should be considered for the purposes of the Core Directive 2002/98/EC and of the Technical Directives: Quality Management, Quality Control, Premises, Equipment, Personnel and Training, Production, Complaints and Recall, and Documentation.
3. Visit to the Blood Transfusion Service, Malta.

The Blood Transfusion service was visited from 16 to 19 February 2004. Meetings took place with the Medical Director/Chief executive officer, and with all heads of Departments. The main premises at St Luke’s Hospital and the mobile collection unit were visited. The premises and equipment, including plans for upgrading, were assessed for suitability for purpose, and the quality system and documentation were also assessed. The proposed programme for upgrading was analysed in relation to this assessment.

In addition, a meeting took place in the Department of Health with Dr R Busuttil, Director General, on 19 February 2004, and with Dr John Cachia, Director, Institutional Health, and Dr Nadine Camilleri, Department of Institutional Health.

Findings.

The BTS collects and processes approximately 20,000 units of blood per year. The blood is collected at fixed and mobile sites, and all testing, processing and distribution is performed at the Blood Centre. In general, the practices and procedures in place in relation to collection, processing and testing are of a good standard. Quality control is generally adequate, and the quality assurance system in place, while in need of some upgrading, is well established. The technical training of staff was not assessed in great detail, but staff appeared proficient, and staff numbers did not give rise to concern. Equipment was generally adequate and provisions for maintenance were satisfactory.

Premises and equipment. The current building has long passed the time when it was adequate for the purpose it now serves.

There is insufficient space to allow proper flows of stores, products, materials, personnel and waste. Well-designed, smooth, uncluttered and non-crossing process and material flows are a key element of GMP, and will be difficult to achieve in the present building.

There is insufficient space for product and stores receipt and dispatch. The entrance of donors, staff, incoming blood and stores through the same uncontrolled and unsecured entrance, and the dispatch of much of the product and waste along with the passage of donors, visitors and staff through the same route is far short of ideal.

Stores space is very limited, and would require considerable upgrading in volume and design to meet good practice requirements.

The general finish requires upgrading. It is a major principle in current blood component manufacturing, as in general pharmaceutical manufacturing, that processes take place in environments that are not only clean and seen to be clean, but in places that are designed to be easily cleaned and easily kept clean.

There is insufficient space for expansion as requirements change in the future – it is inevitable that nucleic acid testing will become established as a normal test in transfusion centre processes; bacterial screening of the product and the environment will be required in time; flow cytometry in quality control, extended product storage requirements, and requirements for additional product lines such as neonatal products will all further stress the capacity of the premises in the coming years.
Staff numbers will inevitably rise to cope with the additional requirements of the Directives in the future – adequate premises to house staff are essential if they are to perform their tasks in accordance with GMP. Furthermore increased document retention and sample archiving will be required under the provisions of 2003/98/EC.

The proposal to move the donor centre to another site, and the removal of the crossmatch laboratory to the new hospital site will free up much needed space; adequate redesign of the building along GMP process flow lines will alleviate much of the constraints now present in achieving compliance with good practice, but the layout of the space and flows over several floors, the immovability of several structural walls that cramp space and restrict flows and the inevitable pressures caused by technological advances and compliance requirements mean that the lifetime of the usefulness of the current building, even when upgraded as proposed, will be in the order of 5 to 7 years at most.

**Quality Management, Quality Control, and Documentation.** The current staffing structure of responsible person, quality manager and quality control technologists is adequate. However more extensive validation and quality monitoring, including environmental monitoring, will be required. In addition the requirements for documentation, document control, and change control, will increase considerably above the current level. Therefore increased space provision for the quality function is required, including document storage space, quality control laboratory space, and staff office space. The technical directives require validated quality control methodology and processes, and statistical process control to ensure that process are in conformity with design and intended result – this will require additional quality resources in terms of staff, skills, and space.

At present standard operating procedures are contained in large comprehensive documents that are more akin to laboratory procedure manuals than SOPs, and that will not lend themselves to the rigours of document review and updating, change control, and GMP training in processes, SOPs, and changes and upgrades. In addition the range of practices and procedures not covered by SOPs appears sizeable at this point. Extensive GMP training is a requirement for every Blood Centre and Transfusion Service in Europe, and Malta is no exception to this.

**Personnel and Training.** As in any Blood Transfusion Service, skilled, trained and motivated staff are the most precious resource. Good practice requires that staff are trained in the procedures that they perform, and that training is updated as required, and adequately documented. General understanding of and familiarity with the principle of the quality system are required for all staff. Most competent authorities will identify a requirement for a distinct training office in the blood centre, functioning usually, but not essentially, as part of the quality assurance function. Alternatives are to provide and assure training at individual department level, or as part of the human resources function. Personnel numbers must be adequate for the procedures performed.
4. Analysis of the Investment Component of the Project

Activity A: GMP training for staff.

The proposal is for a programme of visits by outside experts to provide GMP training to staff at the Malta BTS, along with an audit component to be provided by the experts. A total of six weeks experts’ time at the BTS is costed.

This is to be supplemented by seven key members of staff spending approximately 20 working days each at overseas facilities over a period of approximately ten months.

Comment: This is well thought out, and reflects the overall requirement and the current state of knowledge in the Centre. There is no compelling reason to specify the number of outside experts as two; it could as easily be one, three or four. It might be easier to divide the task among more than two, but in any event the total amount of expert time is a reasonable estimate. There will be a requirement, at some time in the future, to consider whether a member of the quality team should undertake a formal course to become a certified Qualified Person. This is the norm in the pharmaceutical industry, and may extend in part at least into the blood centres in Europe; however this is not standard practice as yet in the EU, and the decision need not form part of the current plans or proposal.

Activity B: Investment in Premises

It is proposed to invest in upgrading of the Blood Centre to bring it up to the standards required of GMP with regard to

Security, environmental control, and laboratory refurbishment – general finish and integrated workspaces.

Comment: Achieving the required standards in the current building requires, as detailed above, rehousing the donor area and the hospital blood bank in separate facilities, remodelling of the current building, and addition of several improvements not currently provided:

General security of the GMP flows and production and storage areas are an essential requirement.

In addition storage conditions of product at all stages of manufacture and storage are specified under the terms of 2002/98/EC, and compliance will require adequate environmental control and monitoring as indicated in the project proposal.

Within the project to upgrade the physical facilities at the Blood Centre general laboratory remodelling to facilitate environmental integrity and product flow is also required as proposed in the project.

The proposal for funding of the security and climate control system components and the laboratory upgrade component as presented is generally reasonable in terms of requirement and cost. Detailed product flow diagrams of products, stores, personnel, materials and waste have not been signed off, and should be reviewed from a GMP point of view before the tenders for environmental controls and security are placed.

Information Technology Upgrade.
The requirements for full traceability of every unit of blood from donor to patient envisaged in 2002/98/EU will require a IT modification scoped to track blood following distribution. Because of the relatively confined nature of hospital practice in Malta, the fairly modest cost envisaged in the project proposal for this is probably sufficient; however validation costs for this extension have not been included, and will need to be budgeted for; an additional 15% of the installation cost should be included for this purpose.
5. Conclusions

BTS Malta is well placed to achieve the standards required for compliance with 2002/98/EU once investment in training, premises and equipment has been undertaken. There is a clear understanding of the steps to be implemented and of the modifications required.

Refurbishment of the current building to free up considerable additional space for production, laboratory activities, quality assurance, control and management and for storage, along with installing adequate security and environmental control and laboratory upgrading is essential to bring the facility to GMP standard. However the ultimate lifespan of the current facility will be limited to 5 – 7 years at most due to the inevitable necessity of continual upgrading and expansion in production, testing, and quality management. Planning for the eventual replacement should be begun at the earliest opportunity.

The refurbishment of the building should include detailed process flow diagrams to ensure maximum effectiveness of the programme.

Government support for the Service is essential to achieve the objective; it appears manifest in the support expressed for the initiatives outlined in the project proposal, in the provision of funding for the relocation or the donor centre and the hospital blood bank.

The costings and timelines in the project proposal appears reasonable and achievable.
6. Profile of the Expert

Dr William G. Murphy, MD, FRCPEdin, FRCPth
National Medical Director, Irish Blood Transfusion Service,
National Blood Centre, James’s Street, Dublin 8, Ireland.

MB, BCh, National University of Ireland 1976; MRCP(UK) 1982; MRCPath 1989; MD (NUI) 1990.

Senior Lecturer in Medicine, University of Edinburgh 1991 to 1996.

National Medical Director IBTS 1996 to date.


Member of the Board, European Blood Alliance.

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