

## **Blood Banking Service Regulations FAQ**

### **General**

#### **1. Who is required to hold a blood banking licence under the Healthcare Services Act (HCSA)?**

- Any person or business conducting **any one, any combination or all** of the five of the following activities in relation to blood and/or blood components for the purpose of therapeutic transfusion is required to hold a blood banking service licence:
  - (a) Collection
  - (b) Testing
  - (c) Processing
  - (d) Storage
  - (e) Distribution.
- The following licensees are **exempted** from the need to hold a license, if they fall within the scenarios described below:
  - (a) A HCSA clinical laboratory service licensee providing the transfusion medicine discipline and carrying out the collection, processing or distribution of blood or blood components;
  - (b) A private hospital licensee under the PHMCA providing acute hospital services (i.e. licensed as a “medical hospital” or “surgical hospital”)
    - carrying out the collection or distribution of blood or blood components; or,
    - carrying out blood banking activities for the purposes of autologous or directed transfusion;
  - (c) A medical clinic licensee under the PHMCA carrying out the collection of blood or blood components on behalf of a blood banking licensee.

### **Clinical Governance Officer**

#### **2. Can I appoint a doctor who has only worked/studied overseas as my Clinical Governance Officer (CGO)?**

- A CGO that has only worked/studied overseas **may not be** appointed as CGO until he/she fulfils the following conditions.
- He/she must be:
  - (a) A fully registered doctor with the Singapore Medical Council (SMC); and
  - (b) registered as a specialist either
    - in the specialty of haematology, or
    - in the specialty of pathology **and** trained in transfusion medicine.
- In addition, the CGO must have at least 5 years’ of relevant work experience in Singapore with either:
  - (a) an acute hospital licenced under the HCSA or PHMCA which provides the transfusion medicine laboratory discipline; or
  - (b) a blood banking licensee.

**3. I am a clinical laboratory / acute hospital service licensee providing one or more blood banking service activities. Which part of the blood banking service Regulations apply to me? Do I need to fulfil the CGO qualifications and experience requirements in the blood banking service Regulations?**

- There is no need for the following licensee to hold a blood banking licence, if they meet the respective conditions:
  - (a) A HCSA clinical laboratory service licensee providing transfusion medicine laboratory discipline.
  - (b) A private hospital licensee under the PHMCA who is providing acute hospital services, and carrying out any one or any combination, but not all, of the blood banking activities.
- Nonetheless, these activities by the licensees will be subject to regulatory requirements under the relevant service regulations or PHMC regulations (including requirements related to blood services).

### **Committees appointed by licensees**

**4. Am I required to appoint specific committees for blood banking services?**

- Yes, blood banking service licensees are required to appoint at least one Serious Reportable Event Quality Assurance Committee, under Regulation 20 of the Healthcare Services (General) Regulations.

### **Personnel**

**5. What are the requirements for supervising staff at blood donation site?**

Requirements of supervising staff

- The operations of blood donation site must be supervised by either:
  - (a) a registered medical practitioner, or
  - (b) a Clinical Nurse Leader (CNL):
    - 1) who has been a registered nurse with the Singapore Nursing Board for at least 5 years, and
    - 2) who has at least 5 years' relevant working experience in an institution licensed or approved to provide blood banking services under HCSA and PHMCA respectively.
    - 3) For the CNL, there must also be adequate arrangements in place for prompt activation and provision of medical care by a medical practitioner.
- While supervision is required, the supervising registered medical practitioner need not be on-site at all times to provide the supervision. Nonetheless, he/she must always remain contactable while the service is being provided, to oversee the service at the blood donation site and for staff to seek directions and advice from. He must also ensure that prompt medical care can be provided to donors when needed.

- However, if the site is supervised by a CNL, the CNL is required to be on-site **at all times**, with adequate and appropriate arrangements put in place for the prompt activation and provision of medical care by a registered doctor.

Competency of supervising staff

- The supervising medical practitioner or CNL must be trained and assessed to be competent in the following:
  - (a) The screening, selection and counselling of donors;
  - (b) The appropriate and timely monitoring and management of donors at the blood donation site to ensure their safety;
  - (c) The clinical assessment of donors before, during and after their donation of blood; and
  - (d) The escalation of incidents affecting donors and staff for appropriate clinical management.

## Recruitment and evaluation of donors

### **6. How should a BB licensee check that the donor is donating blood voluntarily?**

- Before blood collection, licensees should ensure through self-declaration that the donor is not remunerated for the blood or blood component that he/she is intending to donate. The self-declaration should be documented.
- Licensees must also not give or offer any valuable consideration to the donor.
- Licensees are, however, allowed to issue to the donor a token of appreciation that is commensurate with the act of volunteerism (e.g. food vouchers).

### **7. What are the donor eligibility criteria?**

- The donor eligibility criteria should include risk to the donor in donating blood, based on the donor's medical history, physical condition (e.g. body weight, blood pressure), haemoglobin content, etc.
- The donor should also be evaluated for whether his/her blood is suitable for use in therapeutic transfusion, including whether the donor has any common infectious disease, such as human immunodeficiency virus (HIV), Hepatitis B, Hepatitis C and syphilis.
- There should be a written policy for the review of donor and blood unit testing results, as part of the assessment of the suitability of the donated blood for use in therapeutic transfusion.
- Donors who do not meet the blood donation criteria should be appropriately managed via an effective deferral system.

### **8. Can I outsource donor evaluation activities to businesses or individuals that are not blood banking service licensees under HCSA? Who is liable if there is any mishap?**

- Yes, licensees may outsource the following to other businesses not licensed under HCSA:
  - pre-donation counselling and donor evaluation activities; and,
  - the collection of blood or blood components from donors

- However, the licensee is expected to retain oversight of any outsourced services and remains ultimately responsible for ensuring that the outsource provider is competent for the tasks delegated and compliant with the relevant Regulations and ensuring donor safety and welfare, as well as the safety and quality of the blood that will be collected.
- The licensee is also responsible for ensuring that every personnel conducting pre-donation counselling, donor evaluation, and/or blood collection, have received relevant in-house training and been assessed to be competent, e.g. based on the licensee's internal criteria in providing pre-donation counselling, donor evaluation, and/or blood collection, respectively.