Updated as at 5 Apr 2021

Blood Banking Service Regulations FAQ

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General

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

- Any person or business conducting **all** five of the following activities in relation to blood, blood components and/or blood products 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.

- Licensees performing selected blood banking activities only will nonetheless be required to comply with the relevant blood banking service standards. This is to ensure the safety and quality of blood, as well as donor safety and welfare, where such licensees are involved in blood banking activities. However, they need not apply for the blood banking licence.

Clinical Governance Officer

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

- Yes. However, the CGO must either be

  (a) registered with the Specialist Accreditation Board (SAB) in the specialty of haematology, or

  (b) registered with the SAB in any other specialty (e.g. pathology), but with relevant higher qualification and training in transfusion medicine acceptable to DMS.

- In addition, the CGO must have at least 5 years' of relevant work experience, in an institution licensed or approved to provide blood banking or blood transfusion services under the HCSA, Private Hospitals and Medical Clinics Act (PHMCA) or overseas regulatory standards equivalent to HCSA as determined by DMS.

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?

- Non-blood banking service licensees are only required to meet the standards which are relevant to the blood banking activities that they perform.

- For example, standards pertaining to the blood donation site, or on blood donor recruitment and evaluation and blood collection, are only applicable to licensees performing blood collection.
- In addition, non-blood banking service licensees do not need to meet the CGO requirements in the blood banking service Regulations.
- While non-blood banking licensees are not required to meet the CGO requirements for blood banking, these licensees remain subject to the CGO requirements where these are prescribed for the other licences they hold (e.g. clinical laboratory).

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 17 of the draft Healthcare Services (General) Regulations.

Personnel

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

- Medical screening, pre-donation counselling and blood collection shall be conducted safely by an appropriately qualified, trained and competent personnel to safeguard the safety of the donor, and the safety and quality of the blood or blood components collected.
- The operations of blood donation site must be supervised by either a registered medical practitioner on-site, or a Clinical Nurse Leader (CNL) who has been a registered nurse with the Singapore Nursing Board for at least 3 years and who has at least 3 years' relevant working experience in an institution licensed or approved to provide blood banking services under HCSA and PHMCA respectively on-site. For the latter, there must also be adequate arrangements in place for prompt activation and provision of medical care by a medical practitioner.
- The supervising medical practitioner or CNL must 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.

- Personnel who have not been certified competent must be supervised by a competent personnel.

6. Must the supervising medical practitioner be physically present at the blood donation site at all times?

- 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, the CNL is required to be on-site with adequate and appropriate arrangements for prompt activation and provision of medical care by a registered doctor.

Recruitment and evaluation of donors

7. What level of check is required to confirm if the donor is donating blood voluntarily?

- Before blood collection, licensees should ensure through self-declaration that the donor is not remunerated for the blood 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.

8. What are the donor eligibility criteria?

- The donor eligibility criteria include whether there is 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 transfusion-transmissible infection, 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 on the suitability of the donated blood for use in transfusions.

- Donors who do not meet the blood donation criteria should be appropriately managed via an effective deferral system.

9. 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?

- Every personnel conducting pre-donation counselling and donor evaluation should have received relevant in-house training and be assessed to be competent, e.g. based on the licensee's internal criteria in providing pre-donation counselling or donor screening respectively.
- These personnel do not need to be employees of the licensee.
- Nevertheless, the licensee is expected to retain oversight of any outsourced services and remains ultimately responsible for compliance 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 same applies for any other services that are outsourced, such as blood collection and distribution.

Blood collection

10. Am I expected to follow-up with a donor found to be infected by a transfusion-transmissible infection?

- The licensee is required to provide the relevant information to donors who are found on testing to be infected by a transfusion-transmissible infection, such as a letter explaining the donor's condition, and for the donor to seek appropriate medical attention at an appropriate healthcare institution.
- Blood, blood components and blood products collected / derived from infected donors should be disposed safely and there are effective measures to prevent inadvertent use.

Traceability of blood, blood components and blood products

11. What must be included in the label for blood, blood component or blood product?

- Every blood donation and the blood components processed from the donation should be assigned and labelled with a unique identification number which is used as an identifier for traceability purpose.

- The licensee should keep a record of the donor's name and identification, his/her blood donation and the blood components processed from the donation so that each blood donation and its blood components can be traceable to its donor.
- The licensee is also required to maintain donor records on the following:

  (a) Contact information such as telephone number and address;

  (b) Health questionnaire;

  (c) Physical assessment;

  (d) Screening tests;

  (e) Written consent.

Storage, quarantine and distribution of blood, blood components and blood products

12. Can I use blood that does not meet all the donor blood tests, under exceptional circumstances, e.g. where the blood group is rare and the supply is expected to be insufficient for all patients who will require it?

- Blood units that are confirmed to be infected should not be used under any circumstance.
- For other non-conformities, the use of non-conforming units should be limited to exceptional cases, e.g. where the benefits are assessed to outweigh the risks, and where it does not compromise the recipient's safety. Use of non-conforming units needs to be approved by the CGO and the decision should be documented clearly.[1]

[1] For example, minor non-conformance such as where the post-thaw haematocrit is slightly low but is clinically insignificant, for frozen red cells for uncommon blood groups.