First published in the Government *Gazette*, Electronic Edition, on 30 December 2021 at 7 pm.

No. S 1038

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES (BLOOD BANKING SERVICE) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

Regulation

Regulation

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Healthcare Services (Blood Banking Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2.—(1) In these Regulations, unless the context otherwise requires —

[*Deleted by S 388/2023 wef 26/06/2023*]

"acute hospital service", "blood banking service", "simple in vitro diagnostic test" and "specified person" have the meanings given by paragraph 2 of the First Schedule to the Act;

[S 388/2023 wef 26/06/2023]

"blood" means whole human blood;

"blood component" includes plasma, red blood cells, white blood cells, platelets and cryoprecipitate;

"blood donation site" means any premises or conveyance that is occupied or used by a licensee for the collection of blood or blood components and the storage of blood or blood components incidental to their collection;

[S 388/2023 wef 26/06/2023]

"Clinical Governance Officer" means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;

"donor" means an individual who donates blood or any blood component;

"licensee" means a person who holds a licence to provide a blood banking service;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing a blood banking service;

"specified infectious disease" means an infectious disease specified in the First Schedule.

[S 388/2023 wef 26/06/2023]

[*Deleted by S 388/2023 wef 26/06/2023*]

(2) In these Regulations, blood or a blood component is treated as suitable for clinical use if —

(*a*) the blood or blood component, as the case may be —

(i) has undergone all of the tests specified in Part 1 of the Second Schedule; and

(ii) in relation to an infectious disease specified in the first column of Part 2 of the Second Schedule, has undergone all of the tests specified opposite that infectious disease in the second column of Part 2 of that Schedule and is determined to not be infected with that infectious disease; and

(*b*) every test mentioned in sub-paragraph (*a*) is carried out using appropriate test kits that have been validated for the purpose of donor testing.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations —

(*a*) the provisions of these Regulations apply in addition to the provisions of the Healthcare Services (General)

Regulations (G.N. No. S 1035/2021) (called in these Regulations the General Regulations); and

(*b*) the provisions of these Regulations prevail to the extent that any provision of these Regulations is inconsistent with the provisions of the General Regulations.

Blood donation sites

3A. Where a licensee is approved to provide a blood banking service using one or more approved conveyances or at any premises other than permanent premises, the licensee must not use those conveyances or those premises for any purpose other than as a blood donation site.

[S 388/2023 wef 26/06/2023]

Activities at approved permanent premises

4.—(1) For the purposes of section 11A(2)(*e*) of the Act, an application for approval of any permanent premises for the provision of a blood banking service must specify every activity that the applicant intends to carry out at those premises.

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(2) Where a licensee intends, at any time during the term of the licence granted to the licensee, to carry out at any approved permanent premises an activity not specified in the application for approval mentioned in paragraph (1), the licensee must notify the Director-General no later than 2 months before commencing that activity at the approved permanent premises.

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(3) In this regulation, "activity", in relation to an applicant or a licensee, means any of the following:

(*a*) the collection of blood or blood components from donors;

(*b*) the testing of blood or blood components;

(*c*) the processing of blood or blood components;

(*d*) the distribution of blood or blood components;

(*e*) the storage of blood or blood components incidental to any activity mentioned in sub-paragraphs (*a*) to (*d*).

[S 388/2023 wef 26/06/2023]

Qualifications, skills and competencies of Clinical Governance Officer

5.—(1) For the purposes of section 24(3)(*b*) of the Act, a licensee must appoint as a Clinical Governance Officer of a blood banking service a fully registered medical practitioner with —

(*a*) either of the following qualifications, skills and competencies:

(i) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of haematology;

(ii) both of the following:

(A) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of pathology;

(B) training in transfusion medicine; and

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(*b*) at least 5 years of work experience in Singapore in —

(i) transfusion medicine —

(A) in relation to the provision of an acute hospital service by a person authorised by a licence to do; or

(B) in any private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 before 26 June 2023, where the private hospital was licensed as a medical hospital, a surgical hospital or both; or

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(ii) any other area relevant to the provision of a blood banking service with any licensee.

(2) In paragraph (1), "fully registered medical practitioner" has the meaning given by section 2 of the Medical Registration Act 1997.

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Disqualifications for Clinical Governance Officer

6. A licensee must not appoint as a Clinical Governance Officer any individual who has been subject to a decision or an order made under Part 7 of the Medical Registration Act 1997 by a Disciplinary Tribunal appointed under that Act in the 3 years preceding the individual's appointment.

Duties and responsibilities of Clinical Governance Officer

7.—(1) A Clinical Governance Officer of a blood banking service must oversee —

(*a*) the conduct and provision, in relation to the provision of the blood banking service by the licensee, of all assessments of donors and blood and blood components; and

(*b*) the methods and procedures for those assessments.

(2) In addition to regulation 15(1) of the General Regulations, the Clinical Governance Officer's duties in relation to the blood banking service provided by the licensee include —

(*a*) the implementation of a risk management system to detect and address, in a timely manner, clinical or quality risks that affect —

(i) the safety and welfare of donors; or

(ii) the safety and quality of blood and blood components distributed by the licensee; and

(*b*) the evaluation of any new process for the provision of the blood banking service before its implementation by the licensee, to ensure that the process will consistently produce the results expected for that process.

Quality management system

8.—(1) A licensee must —

(*a*) establish and maintain an effective quality management system for all aspects of the blood banking service relating to —

(i) the safety and welfare of donors; and

(ii) the safety and quality of blood and blood components distributed by the licensee;

(*b*) conduct regular reviews of the quality management system; and

(*c*) make and maintain accurate reports of all reviews mentioned in sub-paragraph (*b*) to ensure the continuing suitability and effectiveness of the quality management system.

(2) A second or subsequent review of the quality management system must be conducted during the twelfth month after the month in which the applicable licensee conducted the immediately preceding review.

(3) Without limiting paragraph (1)(*a*), the quality management system must provide for all of the following:

(*a*) the implementation of appropriate and effective measures to ensure the safety and quality of blood and blood components in respect of —

(i) the recruitment of donors; and

(ii) the collection, testing, processing, storage and distribution of blood and blood components;

(*b*) the implementation of appropriate and effective measures to ensure the safety or health of donors in relation to the collection of blood and blood components, including —

(i) the detection and management of any finding or observation that has or may have an adverse effect on the safety or health of donors; and

(ii) the management of donors whose safety or health are or have been adversely affected by the collection of blood and blood components;

(*c*) the implementation of an effective, efficient and verifiable system for the following:

(i) where the licensee becomes aware that any blood or blood component that the licensee distributed to a specified person is unsafe or poses a risk of harm to any recipient of the blood or blood component (as the case may be) — the notification of the specified person;

(ii) where any blood or blood component is found to be infected by a specified infectious disease or any other infectious disease that is likely to adversely affect the health or welfare of the donor of the blood or blood component —

(A) the notification of the donor; and

(B) the provision of appropriate information to the donor relating to the donor's health or welfare and the necessary clinical follow-up in relation to the infectious disease which the blood or blood component (as the case may be) is found to be infected by;

(*d*) the implementation of an effective, efficient and verifiable system for the recall and safe disposal of any blood or blood component that is unsafe or poses a risk to any recipient of the blood or blood component, as the case may be;

(*e*) the regular review of the licensee's policies, processes and procedures for the provision of the blood banking service and, where necessary, the updating or revision of those policies, processes and procedures;

(*f*) the communication, in a timely manner, to all personnel involved in providing the blood banking service of the outcome of any review mentioned in sub-paragraph (*e*) and

any updated or revised policies, processes or procedures for the provision of the blood banking service;

(*g*) the training of all personnel in, and assessment of their competence to implement, any updated or revised policies, processes or procedures for the provision of the blood banking service;

(*h*) a system to ensure the appropriate and adequate documentation of the licensee's policies, processes, procedures and systems for the provision of the blood banking service, including —

(i) creating, reviewing and updating documentation for the licensee's quality assurance measures and the compliance of all personnel with those measures; and

(ii) ensuring proper document control of all such documentation;

(*i*) quality control measures for equipment used in the provision of the blood banking service, including acceptance testing, quality control tests and regular monitoring of equipment performance;

(*j*) the implementation of a system for appropriate accountability, roles and responsibilities of and continuing education programmes for all personnel;

(*k*) the identification, monitoring and evaluation of key performance indicators for assessing the performance outcomes of the blood banking service, including mechanisms for periodic monitoring and evaluation of those indicators;

(*l*) the investigation of any finding, observation, occurrence or complaint that discloses or may disclose any weakness or inadequacy affecting the quality of the blood banking service;

(*m*) the identification and implementation of appropriate and effective actions to address and prevent the recurrence of

any weakness or inadequacy mentioned in sub-paragraph (*l*);

(*n*) the conduct of regular risk assessments of every activity conducted as part of the provision of the blood banking service and, where necessary, the implementation of appropriate measures to mitigate or manage the risks identified in those assessments.

Personnel involved in evaluating donors and collecting blood and blood components

9.—(1) A licensee must ensure that the collection of blood or blood components from donors is supervised by a medical practitioner, or a Clinical Nurse Leader, who is physically present at all times while the collection is taking place.

(2) Where the collection of blood or blood components from donors is supervised by a Clinical Nurse Leader, the licensee must additionally ensure that adequate arrangements are made for the prompt activation and provision of medical care.

(3) The licensee must ensure that the medical practitioner or Clinical Nurse Leader (as the case may be) mentioned in paragraph (1) is competent in respect of all of the following matters:

(*a*) the screening, selection and counselling of donors;

(*b*) the appropriate and timely monitoring and management of donors during the collection of blood and blood components so as to ensure the donors' safety and welfare;

(*c*) the clinical assessment of donors before, during and after the donation of blood and blood components;

(*d*) the escalation for appropriate clinical management of incidents adversely affecting donors or any personnel involved in the recruitment and evaluation of donors or the collection of blood and blood components.

(4) In this regulation —

"Clinical Nurse Leader" means an individual who —

(*a*) has been a registered nurse for at least 5 years; and

(*b*) has at least 5 years of work experience in Singapore in —

(i) transfusion medicine —

(A) in relation to the provision of an acute hospital service by a person authorised by a licence to do; or

(B) in any private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 before 26 June 2023, where the private hospital was licensed as a medical hospital, a surgical hospital or both; or

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(ii) any other area relevant to the provision of a blood banking service with a licensee;

"registered nurse" has the meaning given by section 2 of the Nurses and Midwives Act 1999.

Facilities, equipment, supplies and processes — general

10.—(1) A licensee must ensure that all facilities for the following activities are safe, secure, adequate and appropriate for the purposes for which the facilities are used:

(*a*) the screening of donors prior to their donation of blood and blood components;

(*b*) the collection of blood and blood components from donors;

(*c*) the testing, processing, storage and distribution of blood and blood components.

(2) The licensee must ensure that all operational processes and workflows for the activities mentioned in paragraph (1) are appropriate and effective in ensuring all of the following:

(*a*) the safety and quality of blood and blood components;

(*b*) the conduct of the activities mentioned in paragraph (1) in a safe and timely manner;

(*c*) the timely resolution of any issue affecting the matters in sub-paragraph (*a*) or (*b*).

(3) The licensee must ensure that all equipment and supplies used in or in relation to the provision of the blood banking service are effective in ensuring —

(*a*) the safety of donors; and

(*b*) the safety of blood and blood components.

(4) Without limiting paragraph (3), the licensee must ensure that —

(*a*) all equipment —

(i) is properly installed, tested, calibrated and maintained in accordance with the manufacturer's specifications; and

(ii) is repaired or replaced in a timely manner when necessary;

(*b*) any equipment which is pending repair or replacement is not used in or in relation to the provision of the blood banking service;

(*c*) all reagents and other supplies used in or in relation to the provision of the blood banking service are validated to ensure their suitability for their intended use;

(*d*) all supplies that will come into contact with blood or blood components when used in the course of the provision of the blood banking service are single-use, sterile and free of pyrogens;

(*e*) all supplies that may be used in or in relation to the provision of the blood banking service are stored and used in accordance with the manufacturer's specifications; and

(*f*) appropriate and comprehensive policies and procedures for the evaluation, selection and regular review of the following are implemented and complied with:

(i) the equipment, reagents and other supplies for use in or in relation to the provision of the blood banking service;

(ii) the licensee's suppliers of the equipment, reagents and other supplies mentioned in sub-paragraph (i).

Facilities, equipment, supplies and processes — collection of blood and blood components

11.—(1) A licensee must ensure that every blood donation site is set up to ensure —

(*a*) the proper, safe and hygienic collection of blood and blood components from donors; and

(*b*) the privacy of donors.

(2) Without limiting paragraph (1), the licensee must ensure that every blood donation site satisfies all of the following:

(*a*) any part of the blood donation site that is to be used —

(i) for the collection, storage or disposal of biohazardous waste; or

(ii) as a sluice,

must be segregated from the rest of the blood donation site;

(*b*) the phlebotomy area of the blood donation site must be segregated from the rest of the blood donation site, and access to the phlebotomy area is restricted to individuals who have been screened and determined to be eligible to donate blood or blood components and any authorised personnel;

(*c*) the furniture, flooring and walls of the blood donation site are non-absorbent;

(*d*) the furniture, flooring and walls of, and equipment at, the blood donation site allow for effective cleaning using appropriate disinfectants;

(*e*) security measures must be implemented to prevent unauthorised access to any part of the blood donation site that is used for —

(i) the screening of donors;

(ii) the storage of blood and blood components collected from donors; or

(iii) the storage of medical supplies and equipment;

(*f*) there is ready access to clean running water;

(*g*) there are adequate quantities of appropriate medical supplies and equipment for the safe management of donors, including emergency medication, medical supplies and equipment.

(3) Without affecting regulation 10(2), the licensee must implement operational processes and workflows to ensure that all screenings of donors are carried out accurately and in a safe and timely manner.

(4) [*Deleted by S 388/2023 wef 26/06/2023*]

Safety programme

11A.—(1) For every approved permanent premises, a licensee must develop and implement a safety programme setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident and reduce any hazard at the approved permanent premises.

(2) Without limiting paragraph (1), a safety programme must contain appropriate and effective measures for —

(*a*) electrical safety and safety of water supply and outlets;

(*b*) the handling and disposal of sharp apparatus and objects that can readily puncture or cut human skin when encountered;

(*c*) the safety of all donors and personnel during the conduct of any test;

(*d*) waste management;

(*e*) spills management;

(*f*) ensuring that there is adequate space, ventilation and lighting for every personnel to perform work safely;

(*g*) ensuring that all safety or emergency equipment is kept in good working order and there is an adequate stock of

materials required for the handling of any medical emergency or adverse incident; and

(*h*) ensuring the cleanliness of the approved permanent premises.

(3) The licensee must keep up-to-date documentation of the policies and processes of the safety programme mentioned in paragraph (1) and make the documentation available to every personnel.

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Licensee must ensure personnel comply with safety programme

11B. A licensee must ensure that every personnel complies with the measures set out in the safety programme mentioned in regulation 11A.

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Personal protective equipment must be provided

11C. A licensee must provide every personnel performing any work with personal protective equipment appropriate for the work performed.

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Recruitment and evaluation of donors

12.—(1) A licensee must, before collecting any blood or blood component from a potential donor (*P*), ensure that *P* —

(*a*) is donating the blood or blood component voluntarily; and

(*b*) is not donating the blood or blood component in contravention of any written law.

(2) The licensee —

(*a*) must provide or arrange for the provision of pre-donation counselling to *P* by a qualified, trained and competent person in a manner that respects *P*'s privacy; and

(*b*) must conduct or arrange for the conduct of adequate and appropriate assessment of *P*'s suitability to donate blood or

blood components by a qualified, trained and competent person.

(3) The licensee must provide accurate and relevant information on all of the following matters to *P* in the course of the pre-donation counselling and assessment of *P*'s suitability mentioned in paragraph (2):

(*a*) the nature and use of blood and blood components and the importance of maintaining a healthy lifestyle as a blood donor;

(*b*) the importance of the donation of blood and blood components being voluntary and not being remunerated;

(*c*) the purpose of the donor questionnaire administered to and pre-donation health assessment of *P*, and the importance of *P* providing truthful responses and cooperating with the licensee's measures to ensure the safety of all blood and blood components collected;

(*d*) that *P* —

(i) may withdraw from or defer the donation of blood or blood components at any time; and

(ii) should inform the licensee if any blood or blood component that *P* donated is not safe for therapeutic transfusion to another individual for any reason;

(*e*) the steps by which —

(i) *P* may withdraw from or defer the donation of blood or blood components; and

(ii) where *P* has donated blood or blood components — *P* may subsequently inform the licensee not to use any blood or blood component donated by *P* for therapeutic transfusion to another individual;

(*f*) the donation process and possible adverse reactions (such as fainting and haematomas) that donors may encounter;

(*g*) information on infectious diseases that are transmissible by the transfusion of blood and blood components, including —

(i) the risk factors associated with all specified infectious diseases; and

(ii) voluntary counselling and testing services (whether provided by the licensee or another person) that *P* may use to ascertain whether he or she has contracted any specified infectious disease;

(*h*) that *P* should not donate blood or blood components for the sole or primary purpose of testing *P*'s blood for any infectious disease mentioned in sub-paragraph (*g*);

(*i*) the steps that the licensee may take in the event that any blood or blood component donated by *P* is found or suspected to be infected with any infectious disease mentioned in sub-paragraph (*g*).

(4) The licensee must ensure that the assessment of *P*'s suitability to donate blood or blood components mentioned in paragraph (2)(*b*) is clearly and accurately documented by the licensee.

(5) The licensee must not prevent or dissuade *P* from withdrawing from or deferring the donation of blood or blood components in any manner that is intended to embarrass or humiliate *P* or coerce or pressure *P* to change his or her mind.

(6) The licensee must implement and maintain a system —

(*a*) to manage the deferral of the donation of blood and blood components by any potential donor who is assessed not to be suitable to donate blood or blood components; and

(*b*) where any donor is unwell or for any other reason is of the opinion that the blood or blood component donated by the donor should not be used for therapeutic transfusion to another individual — to allow the donor to inform the licensee not to use the blood or blood component donated by the donor.

Collection of blood and blood components

13.—(1) A licensee must ensure that the collection of blood and blood components is conducted by or under the supervision of one or more qualified, trained and competent personnel.

(2) The licensee must ensure that the collection of blood and blood components is carried out in a manner that ensures the traceability, safety and suitability for use of the blood or blood components collected.

(3) Without limiting paragraph (2), the licensee must —

(*a*) before collecting any blood or blood component from a donor, verify the identity of the donor and match that identity to the record relating to that donor made and maintained by the licensee in accordance with these Regulations;

(*b*) ensure that each unit of blood or blood component collected from the donor is labelled with the correct donation identification number at all times; and

(*c*) ensure that aseptic techniques are used during the collection of blood or blood components from the donor.

(4) The licensee must, in relation to each donor, ensure that —

(*a*) the collection of blood or blood components from the donor is carried out in a manner that is safe and causes minimal discomfort to the donor; and

(*b*) the donor is adequately monitored and managed by one or more personnel after the collection of blood or blood components, and is discharged only when it is safe for the donor.

(5) The licensee must ensure that appropriate processes are implemented to ensure a swift and appropriate response to any injury sustained by any donor, or any incident affecting the safety or health of any donor or any personnel that occurs, in the course of the collection of blood and blood components, including the rapid activation of emergency medical services.

(6) Where any blood or blood component is found to be infected by a specified infectious disease or any other infectious disease that is likely to adversely affect the health of the donor of the blood or blood component, the licensee —

(*a*) must inform the donor of that fact in a timely manner, and provide the donor with appropriate information relating to the clinical follow-up for that infectious disease; and

(*b*) maintain accurate and complete records of all such donors.

Traceability of blood and blood components

14.—(1) A licensee must ensure the traceability of every unit of blood or blood component collected from a donor, starting from the time the blood or blood component is collected from the donor and ending at the time the blood or blood component is delivered to a specified person or is otherwise disposed of.

(2) Without limiting paragraph (1), the licensee must ensure that accurate and complete labelling of each unit of blood or blood component collected, tested, processed, stored, distributed or otherwise disposed of is made and maintained.

Inventory system for blood and blood components

15. A licensee must —

(*a*) implement and maintain a proper inventory system for all blood and blood components in the possession or under the control of, or distributed by, the licensee;

(*b*) ensure that all blood and blood components mentioned in paragraph (*a*) are accurately recorded and accounted for in the licensee's inventory system; and

(*c*) periodically audit the inventory system to ensure its accuracy.

Processing and testing of blood and blood components

16.—(1) A licensee must —

(*a*) ensure that all tests conducted on blood and blood components by the licensee are appropriate, accurate and up-to-date;

(*b*) before providing any test or implementing any test method, evaluate whether the test or test method produces accurate results;

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(*c*) regularly evaluate and validate the effectiveness and performance of the tests mentioned in sub-paragraph (*a*) by participating in an appropriate external quality assurance programme; and

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(*d*) ensure that a Clinical Governance Officer, or such other suitably qualified personnel designated by a Clinical Governance Officer —

(i) reviews the results of the external quality assurance programme mentioned in sub-paragraph (*c*); and

(ii) implements appropriate and effective actions to address any weakness or inadequacy in the provision of any test mentioned in sub-paragraph (*a*).

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(2) For the purposes of paragraph (1)(*b*), the licensee must —

(*a*) evaluate the performance of the test or test method against the manufacturer's specifications for that test or test method; or

(*b*) establish the performance of the test or test method to ensure acceptable reproducibility, accuracy, sensitivity, specificity and precision in relation to the expected use of the test or test method.

(3) The licensee must implement and maintain an effective system for determining the suitability of all blood and blood components for clinical use.

(4) The licensee must implement appropriate and effective processes and protocols to prevent the contamination of blood and blood components during processing.

Requirements relating to storage, quarantine, distribution, etc., of blood and blood components

17.—(1) The licensee must have in place proper and appropriate equipment and processes for the secure storage of blood and blood components, starting from the time the blood or blood component is collected from a donor and ending at the time the blood or blood component is delivered to a specified person or is otherwise disposed of.

(2) Without limiting paragraph (1), the licensee must implement and maintain a quarantine and storage system that segregates blood and blood components that have not been tested for their suitability for clinical use from any other blood and blood components in the possession or under the control of the licensee.

(3) The licensee must ensure that all blood and blood components are handled, stored and transported in a manner that preserves their integrity and quality for safe and effective clinical use.

(4) Without limiting paragraph (3), the licensee must take all reasonable steps to ensure —

(*a*) the cold chain for the transportation of the blood or blood component is maintained at all times; and

(*b*) any person engaged by the licensee to transport the blood or blood component is trained and competent to handle biohazardous substances.

(5) The licensee must implement and maintain appropriate processes for the purposes of compliance with the requirements under this regulation.

Distribution of blood and blood components to specified persons

18.—(1) Subject to this regulation, a licensee must ensure that only blood and blood components that are suitable for clinical use are distributed to a specified person.

(2) Where any blood or blood component is found not to be suitable for clinical use, the licensee must ensure that the blood or blood component, as the case may be —

(*a*) is clearly labelled and segregated from any other blood or blood component intended for distribution; and

(*b*) is not used and is disposed of safely.

(3) Subject to paragraph (4), a Clinical Governance Officer may approve the distribution of any blood or blood component that is found not to be suitable for clinical use to a specified person for therapeutic transfusion to any individual.

(4) Paragraph (3) does not apply to any blood or blood component that is infected with any specified infectious disease.

(5) Where a Clinical Governance Officer approves the distribution of any blood or blood component in accordance with paragraph (3) —

(*a*) the blood or blood component (as the case may be) is deemed to be suitable for clinical use for the purposes of paragraph (1); and

(*b*) the licensee must ensure that that blood or blood component (as the case may be) is clearly labelled and segregated from any other blood or blood component that is intended for distribution.

Donor testing

19.—(1) A licensee must —

(*a*) ensure that all tests conducted on donors by the licensee are appropriate, accurate and up-to-date;

(*b*) before providing any test or implementing any test method, evaluate whether the test or test method produces accurate results;

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(*c*) regularly evaluate and validate the effectiveness and performance of the tests mentioned in sub-paragraph (*a*) by participating in a relevant external quality assurance programme; and

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(*d*) ensure that a Clinical Governance Officer, or such other suitably qualified personnel designated by a Clinical Governance Officer —

(i) reviews the results of the external quality assurance programme mentioned in sub-paragraph (*c*); and

(ii) implements appropriate and effective actions to address any weakness or inadequacy in the provision of any test mentioned in sub-paragraph (*a*).

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(2) For the purposes of paragraph (1)(*b*), the licensee must —

(*a*) evaluate the test or test method against the specifications provided by the manufacturer of that test or test method; or

(*b*) establish the performance of the test or test method to ensure acceptable reproducibility, accuracy, sensitivity, specificity and precision in relation to the expected use of the test or test method.

Simple in vitro diagnostic tests

19A.—(1) This regulation applies to and in relation to the conduct of any simple in vitro diagnostic test that is incidental to the provision of a blood banking service by a licensee.

(2) The licensee must ensure that any simple in vitro diagnostic test on a specimen or an individual must be conducted —

(*a*) using testing material, where —

(i) the earlier of the following dates has not passed:

(A) the expiry date of the testing material;

(B) the shelf life of the testing material; and

(ii) the personnel who administers the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and

(*b*) in accordance with the instructions specified by the manufacturer of the testing material.

(3) The licensee must ensure that any testing material that may be used to conduct any simple in vitro diagnostic test is stored under the conditions, and handled in the manner, specified by the manufacturer of the testing material so as to lower the risk of contamination, unnecessary exposure of the testing material to the environment and early deterioration of the testing material.

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Documentation relating to donors and blood and blood components

20.—(1) A licensee must, in respect of each donor of blood or blood component, maintain accurate records of all of the following:

(*a*) information about the donor's suitability to donate (such as the donor's haemoglobin level at the time of donation), including the criteria used to assess the donor's suitability and the outcome of the applicable licensee's assessment of the donor in relation to each criterion used;

(*b*) the donor's express written consent for the donation of blood or blood component, as the case may be;

(*c*) the occurrence and clinical management of any adverse reaction affecting or reported by the donor;

(*d*) the occurrence and particulars of —

(i) any event that adversely affects the safety and health of the donor or the safety or traceability of any blood or blood component collected from the donor; or

(ii) any finding or observation that has or may have an adverse effect on the safety or health of the donor;

(*e*) the measures taken by the licensee to address and prevent the recurrence of the event, finding or observation mentioned in sub-paragraph (*d*);

(*f*) where any blood or blood component collected from the donor is found not to be suitable for clinical use — the distribution of that blood or blood component in accordance with regulation 18.

(2) The licensee must, in respect of every unit of blood or blood component in the possession or under the control of the licensee, maintain accurate records of the following:

(*a*) information identifying, and relating to the characteristics, source and use of, the unit of blood or blood component, as the case may be;

(*b*) information relating to the collection, testing, processing, storage, transportation and delivery or disposal of the unit of blood or blood component, as the case may be.

(3) The licensee must keep every record mentioned in paragraph (1) confidential and ensure that —

(*a*) the confidentiality, integrity and security of every such record are maintained at all times; and

(*b*) every personnel handling any such record is aware of his or her role and responsibility in maintaining the confidentiality, integrity and security of the record.

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(4) In addition, where any information in a record mentioned in paragraph (1) is in the form of an extract or aggregated compilation, the licensee must ensure that the confidentiality, integrity and security

of the information in the extract or aggregated compilation are maintained at all times.

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(5) The licensee must —

(*a*) implement adequate safeguards and appropriate protocols and processes to protect all applicable records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification;

(*b*) periodically monitor and evaluate the safeguards, protocols and processes mentioned in sub-paragraph (*a*) to ensure that they are effective and being complied with by the staff involved in handling the applicable records; and

(*c*) take reasonable care in the disposal or destruction of the applicable records so as to prevent unauthorised access to the records.

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(6) In paragraph (5), "applicable record" means any record mentioned in paragraph (1) or (2).

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Records

21.—(1) A licensee must, in relation to the provision of the blood banking service, maintain complete and accurate records of the following:

(*a*) in respect of each personnel involved in providing the blood banking service or any activity that is part of or incidental to the blood banking service —

(i) the personnel's role and duties; and

(ii) the personnel's qualifications and competencies;

(*b*) the validation of any equipment or supplies used.

(2) The licensee must ensure that all records maintained under paragraph (1) are kept secure and are readily accessible when required.

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(3) The licensee must ensure proper document control of all documents relating to the blood banking service.

Outsourcing

22.—(1) Except as provided in this regulation, a licensee must not appoint any person to provide, on the licensee's behalf, a blood banking service or any aspect of the blood banking service.

(2) A licensee may appoint any person to conduct any of the following activities on the licensee's behalf:

(*a*) the pre-donation counselling, or assessment of the suitability, of any potential donor of blood or blood components;

(*b*) the collection of blood or blood components from any donor;

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(*c*) the distribution of blood or blood components.

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(3) To avoid doubt, a licensee who appoints another person to provide, on the licensee's behalf, any activity under paragraph (2) remains responsible to comply with the licence conditions imposed on and the duties of a licensee under the Act, these Regulations and any other regulations made under the Act.

Price transparency

23. A licensee must, at the request of any person (*P*) who uses or intends to use any aspect of the blood banking service provided by the licensee, inform *P* of the applicable charges (including administrative charges) for that aspect of the blood banking service.

Offence

24.—(1) Any person that contravenes regulation 3A, 8(1) or (2), 10, 11(1) or (3), 11A(1), 11B, 12, 13(2), (4), (5) or (6), 14(1), 15,

16(1), (3) or (4), 17(1), (3) or (5), 18(1), (2) or (5), 19(1), 20(1), (2), (3), (4) or (5), 21 or 22(1) shall be guilty of an offence.

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(2) A person who is guilty of an offence under paragraph (1) shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding $1,000 for every day or part of a day during which the offence continues after conviction.

FIRST SCHEDULE

Regulation 2(1)

SPECIFIED INFECTIOUS DISEASES

1. Hepatitis B infection
2. Hepatitis C infection
3. Human immunodeficiency virus (HIV) infection
4. Syphilis

SECOND SCHEDULE

Regulation 2(2)

TESTS TO DETERMINE SUITABILITY OF BLOOD AND BLOOD COMPONENTS

PART 1

1. ABO group
2. Rh D
3. Red cell antibody

PART 2

First column	*Second column*
1. Human immunodeficiency virus (HIV) infection	(*a*) serology (*b*) nucleic acid test
2. Hepatitis B infection	(*a*) serology (*b*) nucleic acid test
3. Hepatitis C infection	(*a*) serology

SECOND SCHEDULE — *continued*

	(*b*) nucleic acid test
4. Syphilis	(*a*) serology

Made on 24 December 2021.

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[MH 78:44/1; AG/LEGIS/SL/122E/2020/10 Vol. 1]