

Blood and Blood Products Regulation of Bhutan 2016



DRUG REGULATORY AUTHORITY

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PREAMBLE

Blood transfusion is a unique technology that blends science with altruism. Safe transfusion not only requires the application of science and technology to blood processing and testing, but also social mobilization to promote voluntary blood donation by sufficient numbers of people who are healthy and are at low risk of infections that can be transmitted to the recipients of their blood.

In the exercise of powers conferred to the Bhutan Medicines Board under the Section 5.14 and within the meaning of medicinal products under 34(xxi) of Medicines Act of the Kingdom of Bhutan 2003, human blood and blood products shall be declared as medicinal products.

As per the Section 5.2 of the Act, Blood and Blood Products Regulation of Bhutan 2016 is adopted to ensure universal access to safe blood and blood products through the strategy of self-sufficiency, based on voluntary, non-remunerated blood donors as the sole source of blood in the country through appropriate control of premises, facilities, equipments and processes as per the national standards.

This Regulation acknowledges that blood transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the blood transfusion services.

This Regulation shall be revised as and when required.

CHAPTER I
PRELIMINARY

SHORT TITLE

1. This Regulation shall be called BLOOD AND BLOOD PRODUCTS REGULATION OF BHUTAN 2016.

SCOPE AND EXTENT

2. This Regulation shall apply to all the blood centers and blood storage centers involved in collection, preparation, storage, dispatch, quality control and quality assurance of blood and blood products or matters connected therewith.

However, this Regulation shall not apply to blood and plasma when collected for sole purpose as starting material for manufacture of medicinal products industrially.

COMMENCEMENT

3. This Regulation shall come into force on the 9th day of the fifth month of the Fire Male Monkey Year of the Bhutanese calendar corresponding to 14 June 2016.

RULE OF CONSTRUCTION

4. In this Regulation, unless the context indicates otherwise, the singular shall include the plural and masculine shall include the feminine.

REPEAL

5. Upon commencement of this Regulation, any policies or standards on blood and blood products contradicting to this Regulation shall be repealed.
6. Notwithstanding the repeal in Section 5 of this Regulation, anything done or action taken before coming into force of this Regulation shall be deemed to have been done or taken under National Blood Policy 2007 and National Standards for Blood Transfusion Service 2013.

CHAPTER II

BHUTAN MEDICINES BOARD, BLOOD TECHNICAL ADVISORY COMMITTEE, DRUG REGULATORY AUTHORITY AND REFERENCE LABORATORIES

PROCEDURES FOR THE BOARD

7. The Board shall ensure the establishment of an effective national blood system integrated within the national health system.
8. The Board shall constitute Blood Technical Advisory Committee to advise the Board on technical matters related to enforcement of this Regulation and carry out other functions assigned by the Board.
9. The Board shall ensure that Authority is provided with adequate number of technical personnel with appropriate qualifications and experience to carry out the functions as deemed necessary.
10. The Board shall ensure that the Royal Government of Bhutan allocates adequate resources to carry out the functions under this Regulation.
11. The Board shall exercise the powers and functions stated under Section 5 and 6 of the Act which includes, but not limited to the following:
 - a. The Board may delegate the Authority to carry out the functions of the Board prescribed under the provisions of the Act.
 - b. The Board shall prescribe and approve the revision of the fees from time to time.
 - c. The Chairperson of the Board, at any time, on disciplinary grounds and abuse of power, may suspend or terminate any member of the committee(s) constituted under this Regulation and shall appoint another appropriate person to replace the member for the remaining term;

BLOOD TECHNICAL ADVISORY COMMITTEE

12. The Blood Technical Advisory Committee shall regulate its own procedures as follows;
 - a. The Committee shall advise the Board on all technical matters related towards ensuring safe and effective blood and blood products.
 - b. The Committee shall constitute of the following members nominated by Ministry of Health;
 - i. Transfusion Medicine Specialist
 - ii. Chief Laboratory Officer, Public Health Laboratory
 - iii. Microbiologist

- iv. Gynecologist
- v. Emergency Physician
- vi. Program Officer, Blood Safety Program
- vii. Medical Officer
- viii. Clinical Nurse

13. The Chairperson and the Member Secretary of the Committee shall be rotated among the members every two years and the nomination shall be based on the majority decision.
14. The Committee members shall hold office for a period of five years from the date of his appointment, unless he earlier vacates office by resignation, death or removal, and shall be eligible for reappointment for one more term.
15. The members shall attend the meeting in person. If a member fails to attend three consecutive meetings, he shall forfeit the membership unless otherwise a valid explanation is submitted to the Board. The Board shall appoint appropriate replacement for such members.
16. The Authority shall co-ordinate and organize the Committee meetings and shall maintain records of the meetings, which shall be retained for a period of ten years and other important documents may also be stored in an electronic form.
17. The meeting shall convene only with a quorum of two third of the members.
18. The Committee shall meet twice in a year and as and when required.

TERMS OF REFERENCE OF THE BLOOD TECHNICAL ADVISORY COMMITTEE

19. The Committee shall;
 - a. Provide technical advice to the Board on matters related to blood and blood products Regulation and recommend the Board for institution of subcommittee(s) as and when required.
 - b. Provide technical advice to the Authority on all technical matters related to implementation of this Regulation.
 - c. Review and recommend on the technical issues related to national standards and guidelines for National Blood Transfusion Service, and any other technical matters related to blood and blood products as and when required by the Ministry of Health.
 - d. Function as a National Hemovigilance Committee.

- e. Maintain the confidentiality of the proceedings and shall not disclose any important decisions of the meetings unless approved by the Authority.
- f. Declare the conflict of interest in the form I-CI of this Regulation and abstain oneself from the particular meeting in case of any conflict of interest.
- g. Avail remuneration for attending the Committee meetings as per the existing government rules and Regulations.
- h. Also carry out any other responsibilities as assigned by the Board.

FUNCTIONS OF DRUG REGULATORY AUTHORITY

20. The Authority established under Section 10 of the Act shall carry out the functions as delegated by the Board as under;
- a. Control and regulate processes of collection, testing, preparation, storage and distribution or delivery of blood and blood products as per the written procedures.
 - b. Register test kits and reagents for screening TTIs and blood transfusion related devices as per the written procedures of the Authority.
 - c. Register Competent Person(s) for blood centers.
 - d. Issue technical clearance and technical authorization for blood centers and blood storage centers.
 - e. Inspect premises for collection, testing, preparation, storage and distribution or delivery of blood and blood products.
 - f. Obtain and receive any information and evidences to examine all such person(s) involved in the contravention of the provisions of the Act.
 - g. Identify reference and appellate laboratories outside the country on recommendation by the Blood Technical Advisory Committee and on approval by the Board.
 - h. Control and regulate advertisement of blood and blood products.
 - i. Promote, educate and create awareness on the Regulation and notifications passed there under.
 - j. Notify on the safety and product performance status in the country as deemed required.

- k. Liaise with other relevant agencies to carry out the functions assigned by the Board and
- l. Carry out any other responsibilities assigned by the Board.

PUBLIC HEALTH LABORATORY

- 21. The Board shall delegate Public Health Laboratory as the National Reference Laboratory to carry out the functions entrusted by this Regulation as under;
 - a. Conduct analysis of test kits for screening of TTIs and blood transfusion related devices.
 - b. Furnish assessment reports to the Authority.
 - c. Develop standard sampling procedures for the laboratory.
 - d. Conduct any other tests deemed necessary by the Authority based on routine inspection or complaints received from any health centers related to blood transfusion related devices.

APPELLATE LABORATORY

- 22. In the event, where the test report provided by the reference laboratories is challenged by the aggrieved, the test report from the appellate laboratory shall be final.
- 23. Where the test report of the appellate laboratory under Section 22 of this Regulation is in favor of party who is not the Authority, the Authority shall bear the cost of such appellate laboratory test and vice versa.

CHAPTER III
QUALITY MANAGEMENT SYSTEM

24. The blood centers shall have documented quality manual with defined scope of services and procedures but not limited to the following;
- a. **Organization and Management structure**
 - i. The blood centers and blood storage centers shall have an organization chart, clearly defining the reporting structures and hierarchies of the management and the human resource as per the existing NSBTS and/or standards set by the Authority.
 - b. **Personnel**
 - i. There shall be adequate number of professionals available to carry out activities related to blood and blood products.
 - ii. All professionals in the blood centers and storage centers shall have up to date job descriptions with defined tasks and responsibilities. Each blood centers shall have designated personnel for quality assurance who shall function independent of routine functions of that center.
 - iii. All personnel in the blood centers and blood storage centers shall receive initial and continued training appropriate to their specific tasks.
 - iv. Periodic competency assessment shall be carried out on all personnel and assessment records documented. Training plan shall be in place and training records maintained.
 - c. **Premises**
 - i. The standard requirement for premises shall be in accordance with the existing NSBTS and/or standards set by the Authority.
 - ii. Each blood storage center shall have a dedicated space which will function as blood storage area.
 - iii. If the blood and blood products are stored in the health centers other than blood centers and blood storage centers, such products shall be stored as per the existing National Standards for Blood Transfusion Services and/or standards set by the Authority.

d. Equipment and Reagents

- i. There shall be appropriate and dedicated equipments for different processes in the blood centers and blood storage centers which shall be in accordance with the existing NSBTS.
- ii. There shall be an audible and/or visible alarm system in place to indicate when the equipment storage temperature is outside the acceptable limits.
- iii. There shall be documented validations for the critical equipments having direct impact to the quality of blood and blood products.
- iv. There shall be a clear planned preventive maintenance and operating instructions for the equipment in accordance with the existing NSBTS.
- v. All TTI test kits used for screening donated blood shall be registered with Authority.
- vi. All the test kits and reagents shall be registered as per the guidelines laid down by the Authority.
- vii. Only the test kits and reagents registered with the Authority shall be imported.

e. Quality Assurance

- i. There shall be written procedures for product quality review, product risk management, change control, deviation evaluation, internal audit and CAPA.

f. Defect Reporting System

- i. There shall be written procedures to ensure that complaints, all types of product defects are documented, investigated where necessary followed by implementation of corrective and preventive action.
- ii. The designated person shall inform Authority in case of critical complaints on product non conformities.

CHAPTER IV

DONOR SCREENING, SELECTION, BLOOD COLLECTION, TESTING, STORAGE, RELEASE, TRANSPORTATION AND DISCARD

25. The minimum requirements for routine functioning of blood centers in the country shall be in accordance with existing NSBTS and other standards set by the Authority.
26. Ministry of Health shall ensure all blood donations are from voluntary, non-remunerated and regular blood donors from low-risk population.
27. Ministry of Health shall develop information, education and communication materials for the general public information.

DONOR SCREENING AND SELECTION

28. Donor education, counseling and selection shall be conducted by a qualified person or any person authorized by the in-charge of the blood center in accordance with the existing NSBTS.

The process shall include but not limited to the following;

- a. All the prospective blood donors shall be provided with pre donation counseling and relevant information.
- b. All the prospective blood donors shall provide accurate and true information regarding his medical, lifestyle and vaccination history.
- c. All the prospective blood donors shall be evaluated through an interview, physical and laboratory examination.
- d. Eligibility criteria for blood donor shall be ensured.
- e. Where a donor is not suitable for donation, the deferral guidelines shall apply.
- f. Records of the results of donor evaluations shall be maintained and any relevant abnormal findings from the evaluations shall be informed to the donor.

BLOOD COLLECTION

29. The blood centers shall ensure that all the requirements of blood collection are in accordance with the existing NSBTS.

30. All the mobile blood donations shall be carried out based on the guidelines set by the Ministry of Health.
31. Premises used for mobile blood donations shall be of appropriate size with proper ventilation and sanitation facilities for the safety during the donation process.
32. Other relevant sections of this Regulation shall be applicable to any off-site premises for donation.

LABELLING

33. The blood center shall ensure that the label on each unit of blood and blood products bear the details in accordance with the existing NSBTS.

LABORATORY TESTING

34. The blood centers and blood storage centers shall ensure the following requirements in accordance with the existing NSBTS but not limited to;
 - a. The testing of blood for ABO and Rh blood groups and TTIs.
 - b. Pre transfusion compatibility testing on blood recipients.
 - c. Quality control tests for reagents and blood and blood products.

STORAGE, RELEASE AND TRANSPORTATION

35. There shall be proper storage conditions for the blood and blood products during testing, storage and transportation until it is issued for clinical transfusion purpose.
36. There shall be designated area and physical separation for quarantined and expired blood and blood products.
37. Only authorized personnel shall have access to blood storage areas.
38. The blood and blood products shall be released only upon approval by authorized personnel based on a standard procedure.
39. There shall be a validated temperature controlled transfer from collection site to processing or storage site and from site of issue to the site where transfusion shall take place.
40. There shall be a written procedure and established inspection criteria to accept the returned blood and blood products into the inventory for re-use.

DISCARD OF BLOOD PRODUCTS

41. The blood products shall be discarded in accordance with the existing NSBTS.
42. All the waste generated from the blood centers and blood storage centers shall be managed in accordance with the existing Waste Prevention and Management Regulation.

DOCUMENTATION AND RECORDS

43. Every activity that affects the quality of blood and blood products shall be documented. The documentation shall be designed to ensure that the work performed is standardized and that there is traceability of all steps in the process.
44. All the documents related to blood and blood products shall be maintained for a period of five years.
45. Ministry of Health shall have all the data collected from the blood centers and blood storage centers.

CHAPTER V

COMPETENT PERSON AT BLOOD CENTERS AND BLOOD STORAGE CENTERS

46. In accordance to section 19 of the Act, all the personnel at the blood centers shall be Competent Persons.

QUALIFICATION FOR COMPETENT PERSON AT THE BLOOD CENTERS

47. The blood centers shall be operated under the supervision of at least one person in any of the sub-categories under 'a' or 'b'.

a. Medical Officer (MBBS) with;

- i. Post graduate degree (MD Pathology or MD Transfusion Medicine), OR
- ii. Post graduate Diploma in Transfusion Medicine, OR
- iii. Minimum of one year working experience in a blood center.

b. Health Laboratory professional possessing one of the following qualification;

- i. Degree in Medical Laboratory Technology with minimum of six months experience in laboratory testing of blood and quality management, OR
- ii. Diploma in blood banking and clinical transfusion with two years experience in laboratory testing of blood and quality management, OR
- iii. Diploma in Medical Laboratory Technology with minimum of five years experience in blood center.

48. All the blood center and blood storage center professionals handling blood and blood products must possess a minimum qualification of certificate in general Medical Laboratory Technology and shall have a minimum of six months field attachment in the blood centers.

49. Only those personnel with qualification mentioned in section 47 or 48 shall be deemed recognized by Authority.

50. The in-charge of the laboratory services shall be the head of the blood storage center and focal point to the authority.

51. Delegation of the supervisory work shall be given in written to the appropriately qualified and authorized individuals.

PROCEDURES FOR REGISTRATION AS A COMPETENT PERSON

52. The professionals in the blood centers and blood storage centers in the government settings are exempted from registration with the Authority provided they are registered

with the Council and fulfill minimum required qualifications as in section 47 or 48 of this Regulation.

53. Any person who wishes to be employed in a private blood center shall be registered with the Council and fulfill the required qualification in section 47 or 48 of this Regulation and register as competent person with the Authority.
54. The procedure for registration and renewal shall be as per the Bhutan Medicines Rules and Regulation wherever applicable.

CHAPTER VI

TECHNICAL CLEARANCE FOR GOVERNMENT BLOOD CENTERS AND BLOOD STORAGE CENTERS

55. Blood centers and blood storage centers shall obtain technical clearance from the Authority by using application form II-TC and III-TC respectively.
56. The technical clearance shall be issued by the Authority in a prescribed format upon verification of the application.
57. Upon receipt of the application for the new government blood centers and blood storage centers, the Authority shall assess the application and affect inspection to verify the suitability of the site before issuance of technical clearance.
58. In case the blood centers and blood storage centers are found deficient; the Authority shall provide reasons in writing including the grounds for refusal and advice for improvements as the case may be.

PROVISIONAL AUTHORIZATION FOR PRIVATE BLOOD CENTERS

59. Any person intending to set up private blood centers shall apply to the Authority in application form IV-PA along with a provisional authorization fee as prescribed by the Authority and shall submit the following but not limited to;
 - a. Location of the proposed site with the sketch map of the proposed blood center.
 - b. List of proposed activities and products.
 - c. List of equipments.
 - d. List of personnel with qualifications.
60. Upon receipt of the application, the Authority shall assess the application in consultation with Blood Technical Advisory Committee and verify the suitability of the proposed blood center. If the Authority is satisfied, the technical report shall be forwarded to the Board for approval.
61. In case of application considered deficient, the Authority shall provide reasons in writing including the grounds for refusal and advice for improvements as the case may be.

62. The provisional authorization shall be issued in a prescribed format specifying the next date of inspection.
63. The provisional authorization shall be valid for two years from the date of issue or on an earlier date where the applicant applies for final approval for authorization.
64. The provisional authorization shall be subjected to renewal upon submission of the same application form accompanied by the prescribed fees.

TECHNICAL AUTHORIZATION FOR BLOOD CENTERS

65. Once the blood center is ready for operation, the applicant shall apply to the Authority for technical authorization using application form V-TA with the prescribed fees and the Authority shall cause inspection to verify the suitability of blood center.
66. In case of non compliance to the conditions of the application, the Authority shall provide reasons in writing including the grounds for refusal and advice for improvements as the case may be.
67. The Board shall approve the application based on the inspection report of the Authority and recommendation of the Blood Technical Advisory Committee.
68. Upon approval by the Board, the Authority shall issue technical authorization for blood centers.
69. If the changes proposed are not in line with the provisional authorization, a new application shall be required.
70. The technical authorization shall be a pre-requisite for issuance of trade license from the Ministry of Economic Affairs.

RENEWAL OF TECHNICAL AUTHORIZATION AND TECHNICAL CLEARANCE

71. The technical clearance and technical authorization shall be valid for two years unless suspended or revoked.
72. Application for renewal of technical clearance and technical authorization shall be submitted using the same form used for obtaining technical clearance and technical authorization respectively at least thirty days before its expiry date.
73. The grace period of one month shall be given after expiry to renew the technical clearance and technical authorization.

74. After the grace period, the technical clearance certificate and technical authorization shall be revoked and services shall be suspended till such time that new technical clearance/authorization is obtained.
75. The blood center shall not make any substantial changes in the services which it undertakes without the prior written approval of the Authority.

CHAPTER VII
INSPECTION OF BLOOD CENTERS AND BLOOD STORAGE CENTERS

76. The Authority shall conduct inspection of blood centers and blood storage centers as per the standards set by the Authority.
77. The powers of the inspectors shall be in accordance with the Section 15 of the Act.
78. Any individual or premise is subject to inspection or search if there is reasonable evidence or information that an offence is being committed or there is any contravention to the provisions of the Act and this Regulation in accordance with Civil and Criminal Procedure Code.
79. The inspector shall possess a minimum qualification of bachelor's degree in relevant field to conduct inspection of blood centers.
80. The inspector shall possess a minimum qualification of certificate in relevant field to conduct inspection of blood storage centers.

CHAPTER VIII
ADVERSE TRANSFUSION REACTION/EVENT AND HEMOVIGILANCE

81. All the blood centers and blood storage centers shall have written procedures for reporting and investigation of all adverse reactions and events.
82. Each blood center shall act as a hemovigilance center and shall receive reports from the storage centers and upon evaluation of the reports, only serious adverse reactions and events shall be reported through a defined procedure to the National Hemovigilance Center using form VI-ATR.
83. The Board shall establish a National Hemovigilance Center at the Authority and shall have the following responsibilities:
 - a. To receive reports of all serious adverse reactions and events and maintain records of all the serious adverse reactions and events.
 - b. To coordinate and organize the National Hemovigilance Committee meetings.
 - c. To provide feedback to the hemovigilance centers.
 - d. To take regulatory measures and issue public notifications based on the severity of reactions and events and such other matters related to it.
 - e. To liaise or collaborate with other international or regional hemovigilance agencies.
84. Blood Technical Advisory Committee shall function as the National Hemovigilance Committee as per the Section 19 (d) of this Regulation and shall be responsible to perform causality assessment and make recommendations for regulatory actions.
85. The National Hemovigilance Committee shall meet as and when required to review the reports received from the hemovigilance centers.

CHAPTER IX ENFORCEMENT MEASURES

86. The enforcement measures shall be applicable only for the functions of the blood centers and blood storage centers.
87. The non-compliances to the provisions of this Regulation shall be categorized into critical and major based on the degree of risk to either the blood donors or the blood recipients.

CRITICAL NON COMPLIANCES

88. Critical non compliances may consist of the following but not limited to;
- a. Any government blood centers and blood storage centers involved in the sale of blood or any blood products.
 - b. Any payment made in cash for blood donation.
 - c. Fraudulent practices (ex. Use of poor quality test kits, reagents and unsafe blood transfusion related devices) which may have serious impact on the health of the donors, recipients and/or general public.
89. Blood Technical Advisory Committee may recommend the Board to issue notification for any other critical non compliance.
90. For all critical non-compliances by the blood centers and blood storage centers, the Authority shall suspend or revoke the technical clearance or technical authorization whichever is applicable.
91. Critical non compliances by the professionals working in the blood centers and blood storage centers shall be dealt as per the laws of the Council.

MAJOR NON COMPLIANCES

92. Major non-compliances include;
- a. Any deviations from the standards by an individual that may have affect on the quality and safety of blood and blood products.
 - b. Blood centers and blood storage centers failing to have Quality Management System and other standards as required under this Regulation.

93. For major non-compliances, the Authority shall issue a written warning on the first and second incidence for the same non conformities.
94. Any licensee or person for major non compliances shall be punishable with a fine equivalent to the minimum daily wage of three months on third offence and suspension of technical authorization on the subsequent offence.
95. If the government blood centers and blood storage centers fail to comply with the regulatory requirements following the first and second incidence, the Authority shall write to the management to take appropriate administrative actions as per the Civil Service Rules and Regulation or any other governing laws of the country.
96. Among others, the administrative order shall specify actions the violator must undertake to come into compliance, set deadline within which compliance must be undertaken, including immediate compliance and provide for administrative sanctions for failure to comply with the order.
97. The imposition of the administrative action under section 95 of this Regulation, or imposition of fines and penalties on anyone whether the centers for contravening the provision of the Regulation, does not excuse any criminal liability under the Act or any other laws of the country.

SUSPENSION AND REVOCATION OF TECHNICAL CLEARANCE/AUTHORIZATION

98. The Authority shall suspend technical clearance or authorization during the investigation period.
99. The blood centers and blood storage centers whose technical clearance or authorization has been suspended shall close the service and during such suspension.
100. Any clearance or authorization which is revoked under this Regulation shall cease the service and may not apply for any such clearance for the period of two years from the date of revocation.
101. The Authority shall share the order of revocation to the Ministry of Economic Affairs in case of private centers for cancellation of trade license.

CHAPTER X APPEAL

PROCEDURES FOR APPEAL

102. Any individual aggrieved by any decision made by the Authority shall submit a written petition to the Board within ten working days from date of issue of the decision or notification.
103. The Board may constitute a committee who shall investigate the issues of the petition in consultation with relevant agencies. The committee shall submit the written report of the investigation to the Board.
104. The decision of the Board shall be final and binding.

MISCELLANEOUS PROVISIONS

LOSS OR DAMAGE OF DOCUMENTS

105. The applicant shall inform the Authority within fifteen days in case of loss or damage of any relevant documents with proper verification.

EXCEPTIONS

106. This Regulation may not be applicable when the blood and blood products are transported in or outside the country for following conditions or circumstances but not limited to;
 - a. National disaster and public health emergencies.
 - b. Requirement of blood and blood products for rare blood groups
 - c. For research and studies by institutions and universities
 - d. Any other conditions deemed necessary by the Board

EMERGENCY SITUATION AT BLOOD STORAGE CENTERS

107. Situations wherein available blood stocks are exhausted and an additional blood is needed as a life saving intervention, the supervisor of the blood storage center:
 - a. May carry out blood donation process to meet the urgent demand.
 - b. The blood donors of age 16 and 17 years could be accepted for donor suitability provided the other selection criteria for weight, medical history and risk factors are met.

- c. Pre-donation testing of donor's blood sample shall be carried out which include:
 - i. Haemoglobin estimation of donor using available test method at the laboratory
 - ii. ABO and RhD grouping
 - iii. Blood screening tests for HIV, HBV, HCV and syphilis using rapid tests
- d. Only those potential donors who test negative for all TTI tests and meet all other criteria of donor suitability set in the National Standards shall be selected for blood donations.
- e. In the event that the time between the pre-donation TTI testing and the donation exceeds 48 hours then the above TTI tests should be repeated at the time of donation.
- f. The Blood Safety Program shall develop a check list of all essential items required during such emergency donor selection, blood collection, and testing and ensure that all items are made available to all blood storage centers.
- g. All such decisions, procedures carried out shall be documented.

DEFINITIONS

108. In this Regulation, unless the context otherwise requires;

1. **Act** refers to the Medicines Act of the Kingdom of Bhutan 2003.
2. **Authority** refers to Drug Regulatory Authority.
3. **Blood** refers to human blood drawn from the donor and mixed with anti-coagulant.
4. **Blood Center** refers to a structure or a facility that is responsible for any aspect of donor recruitment, donor screening and selection, blood collection, testing, processing, storage, release and/or distribution of human blood or blood products when intended for transfusion to a recipient. It is also responsible for pre-transfusion tests on patient blood samples and issue of blood and blood products for clinical transfusion as well as investigating and reporting adverse transfusion reactions.
5. **Blood Cold Chain** refers storage and transportation of blood and blood products at appropriate temperature and conditions from the point of collection to the point of use.
6. **Blood Collection** refers to a procedure whereby a single donation of blood is collected in an anticoagulant solution.
7. **Blood Donor** refers to a person who gives whole blood or one of its products.
8. **Blood Products** refers to any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma and cryoprecipitate). It does not include plasma derived medicinal products (e.g. albumin and Factor VIII).
9. **Blood Storage Centre** refers to a center that is involved only in the functions of receiving and storing screened blood and blood products from an authorized blood center, performing pre-transfusion tests on patient blood samples and issue blood for clinical transfusion as well as investigating and reporting adverse transfusion reactions.

10. **Blood Transfusion Related Devices** refers to devices having direct impact on the quality and safety of blood and blood products (e.g. blood bags, blood infusion sets, blood warmers, immuno-hematological reagents, etc.).
11. **Board** refers to Bhutan Medicines Board established under the Section 4.2 of the Act.
12. **CAPA** refers to Corrective and Preventive Action.
13. **Council** refers to Bhutan Medical and Health Council.
14. **Corrective Action** refers to any activity performed to eliminate the cause of an existing nonconformance or other undesirable situation in order to prevent recurrence.
15. **Critical** refers to a condition that may have direct adverse impact the quality and safety of blood and blood products.
16. **Change control** refers to a process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner.
17. **Deviation** refers to any departure from the required standards and procedures.
18. **Distribution** refers to delivery of screened blood and blood products from one blood center to other blood center or a blood storage center maintaining a blood cold chain. It does not include the issuing of blood or blood components for transfusion.
19. **Document** refers to written or electronically generated information and work instructions. Examples of documents include quality manuals, policies, procedures, or forms.
20. **Evaluation** refers to specific selection process to determine the suitability of a procedure or material (reagent, equipment or assay).
21. **Expiry** refers to the last day on which blood or blood product is considered suitable for transfusion.
22. **Health Centers** refers to hospitals and clinics where clinical transfusion takes place.

23. **Hemovigilance** refers to a set of surveillance procedures for monitoring, reporting and investigation of adverse events (reactions and incidents) covering the whole transfusion, from the collection of blood and blood products from donors to follow-up of blood recipients, intended to collect and assess information on unexpected or undesirable effects and prevent their recurrence.
24. **Incidents** refers to events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on clients, groups, staff, or the organization.
25. **Job Description** refers to description of the duties, responsibilities and organizational relationships that constitute a given job or position.
26. **Mobile Site** refers to a unit or site used for collection of blood, operating temporarily or at movable locations off-site from a permanent collection site, under the responsibility of a blood center.
27. **Non-conformance** refers to deficiencies or failure to meet regulatory requirements.
28. **NBTS** refers to National Blood Transfusion Service.
29. **Plasma** refers to liquid portion of the blood in which the cells are suspended.
30. **Platelet** refers to recovered, single unit' means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.
31. **Preventive Action** refers to an action taken to reduce the potential for an error to occur.
32. **Processing of Blood** refers to any steps in the preparation of blood product that is carried out between the collection of blood and the issuing of a blood product.
33. **Product Quality Review** refers to regular periodic or rolling quality reviews of blood and blood products with the objective of verifying the consistency of the existing process, the appropriateness of current specifications to highlight any trends and to identify product and process improvements.
34. **Provisional authorization** refers to the authorization issued for setting up a blood center before it becomes fully operational.

35. **Quality** refers to the total set of characteristics of an entity that bear on its ability to satisfy stated and implied needs, consistent and reliable performance of services or products in conformity with specified requirements.
36. **Quality Assurance** refers to all the activities from blood collection to distribution made with the object of ensuring that blood and blood products are of the quality required for their intended use.
37. **Quality Management System** refers to coordinated activities to direct and control an organization with regard to quality at all levels within the blood centers and a quality system for blood transfusion service embraces the principles of quality management, quality assurance, and continuous quality improvement, and shall include personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, non-conformance and self-inspection, quality control, blood product recall, and external and internal auditing.
38. **Quarantine** refers to isolating nonconforming blood, blood products or materials.
39. **Reactions** refers to a suspected or proven, unexpected response to a blood transfusion, manifested by signs and/or symptoms in reference to transfusion.
40. **Reagent** refers to a substance used to perform an analytical procedure. A substance used (in detecting or measuring a product and preparing a product) because of which biological or chemical activity.
41. **Recipient** refers to someone who has been transfused with blood or blood products.
42. **Red Cell** refers to the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.
43. **Reference Laboratories** refers to the testing laboratories of the Public Health Laboratory and the reference laboratory outside as identified by the Board.
44. **Repeat Blood Donor** refers to a blood donor who has donated blood at least three times previously and has donated blood minimum once during last year.
45. **Regular Blood Donor** refers to blood donor who donates blood in accordance with the minimum time interval set under the NSBTS.

46. **Replacement/family Donation** refers to the donation given by an individual who gives blood when it is required by a member of the patient family or community. This may involve a hidden paid donation system in which the donor is paid by the patient's family.
47. **Quality Risk Management** refers to a systemic process for the assessment, control, communication and review of risks to the quality of the blood and blood product.
48. **Serious Adverse Events** refers to a case where the patient is transfused with a blood product that did not meet all the requirements for a suitable transfusion for that patient or was intended for another patient and that might have lead to death or a life –threatening, disability or incapacitating condition or which results in or prolongs hospitalization or morbidity. It may be due to transfusion error or due to deviations from standard operating procedures or hospital policies that have lead to mis-transfusion. It may or may not lead to a serious adverse transfusion reaction.
49. **Serious Adverse Reactions** refers to an undesirable response or effect in a patient associated with administration of blood or blood products that is fatal, life – threatening, disability or incapacitating condition or which results in or prolongs hospitalization or morbidity.
50. **Specification** refers to the description of the criteria that must be fulfilled in order to achieve the required quality standards.
51. **Technical Authorization** refers to authorization issued for blood centers.
52. **Technical Clearance** refers to clearance issued for blood centers and blood storage centers.
53. **Traceability** refers to the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa.
54. **TTI refers to Transfusion Transmitted Infection**, an infection that is potentially capable of being transmitted by blood transfusion.
55. **Unit** refers to a defined quantity of blood or blood products in one container as prescribed by clinician.

56. **Validation** refers to an action of proving that any operational procedure, process, activity or system leads to the expected results. The validation work is normally performed in advance according to a defined and approved protocol laying out tests and acceptance criteria.
57. **Voluntary Non-remunerated Donation** refers to donation given by an altruistic donor who gives blood freely and voluntarily without receiving money or any other form of payment.
58. **Whole Blood** refers to a single blood collection, collected in an anticoagulant solution with or without additives.
59. **Window Period** refers to time period between the on-set of infection till the detection of the antibodies.
60. **Written Procedures** refers to controlled documents that describe how specified operations are to be carried out.

Form: I- CI
Regulation Section: 19(f)

CONFLICT OF INTEREST DECLARATION

1. Do you or your partner have any financial or other interest in the subject-matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest?

Yes: No: If yes, please give details in the box below.

2. Do you have, or have you had during the past 5 years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of medicinal products, or directly representing the interest of any such entity?

Yes: No: If yes, please give details in the box below.

Type of interest, e.g. patent, shares, employment, association, payment, (including details on any compound, work, family relation etc.)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

3. Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me.

Name & Signature ,

Date :

Place :

Form: II-TC
Regulation Section: 55 & 72

APPLICATION/RENEWAL OF TECHNICAL CLEARANCE FOR BLOOD CENTER

I on behalf of hereby apply for grant/renewal of technical clearance for a blood center.

- i. Name of the blood center:
- ii. Location:
- iii. List of blood products
 - a)
 - b)
 - c)
 - d)
- iv. List of blood storage centers to which it intends to supply:
 - a)
 - b)
 - c)
 - d)
- v. Name of the Supervisor:
- vi. BMHC Registration Number:

Declaration (please tick the boxes):

- I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- If my application is granted, I shall abide by the Medicines Act and Bhutan Blood Regulation 2014 and any other standards set by the Authority.

Signature:
Name of Applicant:
Address:
Telephone No:

Date:

APPLICATION/RENEWAL OF TECHNICAL CLEARANCE FOR BLOOD STORAGE CENTER

I on behalf of hereby apply for grant/renewal of technical clearance for a blood storage center.

vii. Name of the blood storage center:

viii. Location:

ix. List of blood products to be received from the blood center(s)

e)

f)

g)

h)

x. Name of the blood center(s) from where the above blood and blood products are to be received

a)

b)

c)

d)

xi. Name of the supervisor:

xii. BMHC Registration Number:

Declaration (please tick the boxes):

I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

If my application is granted, I shall abide by the Medicines Act and Bhutan Blood Regulation 2014 and any other standards set by the Authority.

Signature:

Name of applicant:

Address:

Telephone No.:

Date:

Form: IV-PA
Regulation Section: 59 & 64

APPLICATION/RENEWAL OF PROVISIONAL AUTHORIZATION FOR BLOOD CENTER

I/Weof..... hereby apply for the grant/renewal of a provisional authorization to set up a Blood Center and I have attached the following documents;

- a) Location of the proposed site with the sketch map of the blood center.
- b) List of proposed activities and products.
- c) List of equipments.
- d) List of personnel with qualifications.

The Blood Center is expected to be in operation with effect from.....

Application fee has been deposited to the Royal Government of Bhutan vide Revenue Receipt no (*Attach copy*)

Declaration (please tick the boxes):

I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

If my application is granted, I shall abide by the Medicines Act and Medicines Regulations and any other standards set by the Authority.

Signature:
Name of Applicant:
Address:
Telephone No:

Date:

Form: V-TA
Regulation Section: 65 & 71

APPLICATION/RENEWAL OF TECHNICAL AUTHORIZATION FOR BLOOD CENTER

I/We hereby apply for grant/renewal of technical clearance for a blood center.

xiii. Name of the blood center:

xiv. Location:

xv. List of blood products

i)

j)

k)

l)

xvi. List the Competent Person(s):

xvii. BMHC Registration Number:

Application fee has been deposited to the Royal Government of Bhutan vide Revenue Receipt no (*Attach copy*)

Declaration (please tick the boxes):

I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

If my application is granted, I shall abide by the Medicines Act and Bhutan Blood Regulation 2014 and any other standards set by the Authority.

Signature:

Name of Applicant:

Address:

Telephone No:

Date:

Form: VI-ATR

Regulation Section: 82

**SERIOUS ADVERSE REACTION/EVENTS IN PATIENT/DONOR REPORTING FORM
(CONFIDENTIAL)**

(Report identification No. _____)

If you are suspicious that adverse reaction/events may be related to blood donation/transfusion of a blood or a blood products, PLEASE COMPLETE THIS FORM

A. PATIENT/DONOR DETAILS

Patient/Donor name:
Age/Sex:
CID No:
Patient's Diagnosis:

B. SUSPECTED BLOOD UNIT (for blood transfusion reaction)

Type of the blood product(s)	Unit no. & exp date	Volume transfused (ml)	Reason(s) for Transfusion	Date and Time of start of transfusion	Date and Time of stopping transfusion

C. DETAILS OF SUSPECTED ADERSE REACTION/EVENTS

Description of the reaction/events & any treatment given	Date & time of reaction : _____
	Outcome(tick only one) <input type="checkbox"/> Patient/donor recovered with no damage to body function <input type="checkbox"/> Serious sequelae/significant disability directly attributable to reaction/event <input type="checkbox"/> Patient/donor died due to reaction/event

D. TYPES OF SERIOUS ADVERSE TRANSFUSION REACTION/EVENTS (tick the appropriate box)

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody
- Non-immunological haemolysis (causes: IV drug or fluid, mechanical pressure to unit, freezing or heating the unit)
- Anaphylaxis/hypersensitivity
- Transfusion related acute lung injury
- Transfusion-transmitted bacterial infection
- Transfusion-transmitted viral/parasitic infection (Hepatitis B, Hepatitis C, HIV-1/2, Malaria or any other specify)
- Post-transfusion purpura
- Transfusion related Graft versus host disease
- Transfusion Associated Cardiac overload
- Other serious reaction(s) (*specify*): _____

E. IMPUTABILITY LEVELS: Excluded/Unlikely/Possible/ Probable/ Definite (Tick the appropriate one)

F. HISTORY OF PREVIOUS TRANSFUSION REACTION/EVENTS: YES NO

IF YES, GIVE DETAILS: _____

G. TYPES OF SERIOUS REACTION/EVENT IN BLOOD DONOR (tick appropriate box)

- Injury to artery
- Injury to nerve
- Injury to tendon
- Convulsions
- Other (Please specify):

H. ANY OTHER RELEVANT INFORMATION

I. DETAILS OF THE REPORTING HEMOVIGILNACE CENTER:

Name of the center: _____

Technical Clearance /Technical Authorization No. of the center: _____

Name of the reporter: _____

Designation: _____

Address: _____

Signature: _____

Please attach any other relevant information if required.

SEND THIS FORM TO:

NATIONAL HEMOVIGILANCE CENTER

DRUG REGULATORY AUTHORITY

THIMPHU, BHUTAN

TEL: 337074/75 EMAIL: dra@dra.gov.bt

Imputability level means the likelihood that as serious adverse reaction in a recipient can be attributed to the blood or blood product transfused. The imputability levels are given below;

Definite (Certain) means when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.

Probable (Likely) means when the evidence is clearly in favour of attributing the adverse event to the transfusion.

Possible means when the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.

Unlikely (Doubtful) means when the evidence is clearly in favour of attributing the adverse event can to causes other than the transfusion.

Excluded means when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.



DRUG REGULATORY AUTHORITY

Towards ensuring quality, safety and efficacy of blood and blood products

Designed and Printed at Lhazeen Press