

## REGULATION ON BLOOD AND BLOOD PRODUCTS

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### **SECTION ONE Objective, Scope, Legal Basis and Definitions Objective**

**ARTICLE 1 – (1)** The objective of this Regulation is to set out the establishment of transfusion centres, blood donation centres and regional blood centres, the determination of standards for equipment, materials and personnel, their relations with one another and their working procedures and principles, the procedures and principles regarding the quality assurance programmes they shall implement, the procedures and principles regarding obtaining, fees and cancellation of licences, and the working procedures and principles of the Blood and Blood Products Council. Scope

**ARTICLE 2 – (1)** This Regulation covers all public institutions and organisations, natural persons and private legal entities engaged in activities related to blood and blood components. (2) The provisions of the Medical Devices Regulation published in the Official Gazette No. 26398 dated 9/1/2007 and the Regulation on In Vitro Diagnostic Medical Devices published in the Official Gazette No. 26398 dated 9/1/2007 shall be reserved in the implementation of this Regulation. (3) Medicinal products based on blood components obtained from human blood and plasma by industrial methods by public or private institutions, including in particular products such as albumin, immunoglobulin and coagulation factors, as well as blood and stem cells, are outside the scope of this Regulation. Legal Basis

**ARTICLE 3 – (1)** This Regulation has been prepared based on Article 7 of the Law on Blood and Blood Products No. 5624 dated 11/4/2007 and Article 43 of the Decree Law No. 181 dated 13/12/1983 on the Organisation and Duties of the Ministry of Health. Definitions and abbreviations

**ARTICLE 4 – (1)** In this Regulation; a) Recipient: the person to whom blood or blood components are transfused, b) Ministry: the Ministry of Health, c) Ministry: the Ministry of Health, ç) Regional Blood Centre (RBC): the most comprehensive unit, established in the regions to be determined by the Ministry, operating in cooperation with the blood donation and transfusion centres in its own region, having the capacity to meet the blood needs of the region for which it is responsible, and where all activities and transactions related to blood banking can be carried out, d) Distribution: the supply of blood and blood components to the manufacturer or to transfusion centres (it does not include the provision of blood and blood components for transfusion purposes), e) Haemovigilance: the entirety of procedures ensuring the epidemiological follow-up of blood donors or unexpected or severe side effects or events occurring in recipients, as well as of blood donors, f) Service unit: transfusion centres, blood donation centres and regional blood centres, g) Serious adverse event (SAE): an unintended event arising in relation to the collection, testing, processing, storage or distribution of blood or blood components, which, as a result of the transfusion of the blood or blood components affected thereby, may lead to death or life-threatening conditions, permanent or significant disability or incapacity, hospitalisation or prolongation of hospitalisation in patients, ğ) Serious adverse reaction (SAR): an unintended reaction arising in relation to the collection or transfusion of blood and blood components, which may lead to death or life-threatening conditions, permanent or significant disability or incapacity, hospitalisation or prolongation of hospitalisation in donors or patients, h) Traceability: the ability to trace each unit of blood or blood component taken from a donor to its final destination and in the reverse direction, ı) Quality assurance: all activities carried out from blood collection to distribution for the purpose of guaranteeing that blood and blood components are of the required quality for their intended use, i) Quality control: the part of the quality system focused on fulfilling

quality requirements, j) Quality system: the organisational structure, responsibilities, procedures, processes and resources for the implementation of quality management, k) Quality management: the coordinated activities for directing and controlling an organisation with regard to quality at all levels within the service unit, l) Blood: whole blood taken from a donor and processed for transfusion or manufacturing purposes, m) Blood donor: the person who gives whole blood or components thereof, n) Blood donation: the act of giving whole blood or blood components, o) Blood Donation Centre (BDC): the unit that takes blood from donors and operates, in terms of its functioning, under a regional blood centre, ö) Release of a blood component: the process enabling a blood component to be removed from quarantine status through the use of systems and procedures that ensure that a prepared blood component meets the release specifications, p) Blood components: cellular blood components obtained from whole blood directly, by apheresis or by other methods, such as erythrocyte, platelet and granulocyte suspensions, as well as plasma, r) Blood products: blood components and plasma products obtained from blood, s) Law: the Law on Blood and Blood Products No. 5624 dated 11/4/2007, ş) Look-back: the investigation carried out in order to identify the suspect donor or donors, based on a report of a suspected transfusion-related adverse reaction in a recipient, t) Council: the Blood and Blood Products Council, u) Autologous transfusion: the form of transfusion in which, where the donor and the recipient are the same person, the person's own blood or blood components, collected in advance, are used, ü) Plasma products: all therapeutic products obtained by the processing of human plasma, v) Reporting establishment: the service unit reporting serious adverse reactions and/or events to the competent authority, y) Guide: the written document in which the standards and requirements concerning blood banking and transfusion practices, prepared and revised annually by the Blood and Blood Products Council, are defined, z) Deferral: the permanent or temporary suspension of the suitability of a donor of blood or blood components, aa) Release: the state in which blood or blood components have become suitable for transfusion and ready for use, and their release may be carried out, bb) Standard: the requirements needed for comparison, cc) Whole blood: human blood taken from a blood donor for transfusion or for processing in order to obtain new products, mixed with a suitable anticoagulant substance and not subjected to any separation process, çç) Facilities: hospitals, manufacturers and bio-medical research institutes to which blood or blood components may be delivered, dd) Transfusion: the transfer of whole blood or a blood component to a patient in need thereof due to a health problem, ee) Transfusion Centre (TC): the unit which, except in emergencies, is not authorised to take blood from blood donors, and which prepares blood or components obtained for use in patients by performing cross-matching and other required tests for transfusion, ff) Written procedures: controlled documents describing how the determined activities are to be carried out shall mean. SECTION TWO General Principles, the Blood and Blood Products Council Principle of voluntariness

**ARTICLE 5 –** (1) Unremunerated, voluntary and regular donation shall be the principle in the procurement of blood, blood components and products. However, practices encouraging blood donors, which do not constitute financial compensation, are exempted. (2) Provided that it is within their own authority and responsibility, service units may organise various campaigns and educational meetings, in cooperation with institutions serving the public interest and by informing the Ministry, in order to promote unremunerated, voluntary and regular donation. However, these activities shall by no means contain commercial purpose or content. Duties and responsibilities

**ARTICLE 6 –** (1) The Ministry is authorised and responsible for the planning of services relating to blood and blood products, the monitoring of their implementation, and the opening and inspection of service units. (2) The permission required for the evaluation, within the country or abroad, of plasma collected domestically for the purpose of product manufacturing, or for the import of plasma from abroad for the purpose of product manufacturing, is granted by the Ministry. (3) The Ministry establishes the Blood and Blood Products Council in order to provide the necessary scientific support for its activities concerning blood and blood products. (4) The Ministry establishes scientific and advisory commissions when necessary. The commissions determine their

own working procedures and principles. (5) It is the duty of the relevant service unit to ensure that the health of the donor and the recipient is not endangered, from the procurement of blood and blood components from the donor to their administration to the recipient, to protect them against medical risks, to perform transfusions safely, and to monitor the donor and the recipient after transfusion. (6) The collection, testing, processing, storage, preparation for use, making available, and distribution of blood and blood components, as well as the monitoring of feedback on transfusion practices, are the responsibility of the relevant service unit. (7) The activities of service units specified in the guide shall be recorded in writing or electronically and retained for 15 years. The basic test results of donors shall be retained electronically for 30 years. The contents of records subject to mandatory retention shall be arranged as specified in ANNEX-6. Donor witness samples shall be retained in the manner and for the period specified in the guide, provided that this is not less than 1 year. (8) Service units are obliged to protect donors' personal information, not to disclose it to third parties, and not to release it to the press. Each service unit shall have procedures and principles relating to data security, and the protection and/or disclosure of information shall be carried out in accordance with these procedures and principles. (9) Service units are responsible for donor information. (10) The collection of blood, blood components, and products from the donor and their transfusion to the recipient shall be performed under the responsibility and supervision of a physician. (11) Service units carry out their activities within the framework of a quality management system. (12) In states of emergency as well as martial law, mobilisation, and war, Regional Blood Centres (RBCs) organise the procurement and nationwide stockpiling of blood and blood products, and the materials required therefor, that may be needed, within the framework of the Ministry's planning. Establishment of the Council and its working procedures and principles

**ARTICLE 7 –** (1) The Blood and Blood Products Council consists of eight members in total, under the chairmanship of the head of the relevant Ministry unit; seven members are selected by the Minister from among specialist physicians who have distinguished themselves in the field of blood, blood products, blood banking, and transfusion medicine through their work, or from among persons who have completed postgraduate education in these subjects. Members are selected for a term of two years. A member whose term has expired may be re-selected. (2) The Ministry, when necessary, invites experts to the Council in order to obtain the opinions of the Turkish Armed Forces, Universities, the Turkish Red Crescent Society, and non-governmental organisations operating in the field of blood banking and transfusion medicine. (3) The membership of an elected member who, without a valid excuse, fails to attend meetings twice consecutively during the term of membership shall terminate; another member shall be selected within one month to replace the member whose membership has terminated. (4) The Council holds ordinary meetings at least four times a year. The Ministry invites the Council to meetings outside the ordinary meetings when necessary. The meeting invitation, together with the date, venue, and agenda of the meeting, is notified to the members in advance by the Ministry. (5) With the acceptance of the absolute majority of the members participating in the meeting, the Council may also deliberate and take decisions on matters outside the meeting agenda, provided that they are related to its duties. (6) The Council convenes with the participation of the absolute majority of the total number of members and takes its decisions by majority of votes. In the event of a tie in the votes, the view supported by the Chair shall be deemed adopted. The decisions of the Council are recorded in the minutes of the meeting and signed by the members attending the meeting. Those who oppose the decision sign it with an annotation. The grounds for the opposing view must be stated beneath the decision or in its annex. (7) The activity reports of the Commissions related to the subject are reviewed by the Council. (8) The secretariat services of the Council are carried out by the relevant units of the Ministry. Duties of the Council

**ARTICLE 8 –** (1) The duties of the Council are as follows: a) To formulate scientific opinions on the establishment, development, and implementation of the national blood policy and the blood programme that will ensure the implementation of this policy, b) To express opinions on the

opening, activities, and inspection of service units, and to provide scientific opinion support in controversial practices related to the field of work, c) To adopt advisory decisions for the purpose of improving the safety and quality of blood and blood components, preparing, renewing, and developing practice guides covering scientific and technical progress, ensuring the development of studies and practices on medical matters related to blood banking and transfusion, producing solutions to problems, and ensuring their reflection in legal regulations. SECTION THREE Service Units, Blood Supply and Use Regional Blood Centre

**ARTICLE 9 –** (1) The Regional Blood Centre is the most comprehensive service unit, established in the regions designated by the Ministry, working in cooperation with the blood donation and transfusion centres in its own region, having the capacity to meet the blood needs of the region for which it is responsible, where all work and procedures related to blood banking can be carried out, and it provides uninterrupted service. (2) The Ministry determines the area of responsibility of the RBC, taking into consideration the geographical, population, transportation and climate conditions of the region. (Amended second sentence: OG-4/12/2009-27422) It is essential that one RBC be established in the designated service region. However, where deemed necessary by the Ministry, more than one RBC may also be established in the same region; a) It is responsible for all activities related to blood donation organisation, and the collection, testing, preparation, storage and distribution of blood and blood components within its area of responsibility, for the evaluation of data on the follow-up of transfusions sent by transfusion centres, and for making the necessary arrangements within its own area. b) It provides blood donors by planning an active donor organisation within the defined service region. It cooperates with other RBCs to ensure the supply of sufficient blood and blood components. c) (Amended: OG-4/12/2009-27422) It opens BDCs affiliated to itself. It is responsible for the working conditions and operation of these centres. ç) The authority to open and operate a donation apheresis unit for transfusion purposes rests exclusively with it. d) It establishes a plasma apheresis unit for plasma collection for the purpose of obtaining products, with the approval of the Ministry. e) It signs the protocol outlined in the guideline with the TC. f) It is obliged to supply the blood and blood components needed by the transfusion centres within its area of responsibility, to monitor the critical stock level specified in the protocol, and to meet the demand of the TC so as not to reduce the amount of stocked blood below the critical stock level. (Repealed second sentence: OG-4/12/2009-27422) g) It is obliged to prepare the blood components requested by the TCs within its area of responsibility, the types, standards and preparation methods of which are defined in the guideline. ğ) Upon the request of the TC, it provides and applies the conditions for the collection and storage of blood from the patient before surgery for autologous transfusion. h) Where non-conformities are detected in the transfusion centres within its area of responsibility with respect to quality and protocol requirements, it notifies the Ministry of the situation. ı) It conducts research and development activities on blood and blood components. It monitors the quality control programmes of the BDCs within its area of responsibility. i) It plans the in-service training of its personnel. j) With the written approval of the Ministry, it operates as a reference laboratory in the field of blood banking and transfusion medicine. k) For martial law, mobilisation, war and natural disasters and other cases deemed necessary by the Ministry, it organises the supply, storage and distribution of blood in accordance with the Ministry's plan. Transfusion Centre

**ARTICLE 10 –** (1) The Transfusion Centre is a unit which, except in emergencies, is not authorised to collect blood from blood donors, obtains blood and components from the RBC to which it is affiliated, and performs cross-matching and other required tests for transfusion, preparing them for use in patients. (2) All inpatient treatment institutions, as well as health facilities that meet emergency intervention conditions and that the Ministry deems necessary for transfusion practice, open a TC. The TC; a) Is administratively affiliated to its own institution. b) Obtains every type of blood and blood component required from the RBC to which it is affiliated, in accordance with the protocol signed between them. c) Submits to the RBC to which it is affiliated,

during the protocol stage, the licence issued by the Ministry pursuant to the relevant articles of this Regulation. ç) Notifies the Ministry in writing of the situation where the RBC fails to fulfil its obligations.

(3) The patient's physician is responsible for the transfusion decision, its implementation, follow-up, the reporting, verification and treatment of adverse effects/events, and the preparation of the relevant forms and data defined in the guideline with respect to haemovigilance. Together with the patient's physician, the hospital transfusion committees are also responsible for the transfusion practices carried out in hospitals. The transfusion centre is responsible for the collection and evaluation of data related to the follow-up of transfusions and for their transmission to the Ministry and to the RBC to which it is affiliated. (4) In situations requiring emergency transfusion, the transfusion need reported by the attending physician is met from the transfusion centre stocks. In cases where the TC cannot meet this demand, it makes an emergency request to the RBC. Where the RBC cannot supply the suitable blood or blood component to the TC, emergency approval is obtained from the RBC through the fastest means of communication. In this case, blood is collected at the TC. The required tests are performed under emergency conditions. Responsibility for the tests performed lies with the TC. The TC is obliged to transmit the information related to this practice to the RBC. Blood Donation Centre

**ARTICLE 11 –** (1) The Blood Donation Centre is a unit that collects blood from donors and operates under the affiliation of the RBC in terms of technical and administrative functioning. It is a unit established by the RBC in places deemed necessary for the supply of safe blood, and included in the voluntary, non-remunerated and regular donor organisations arranged by the RBC. Head of the Service Unit

**ARTICLE 12 –** (1) Persons possessing the following qualifications shall obtain the necessary information and documents set out in ANNEX-1 in order to apply for a licence. After the licence is obtained, they shall be appointed by their institutions as the person in charge of the service unit. The person in charge of the Blood Centre (BKM) and the Blood Bank (KBM) shall work on a full-time basis. Additional duties may be assigned by the administration of the institution to the persons in charge of Transfusion Medicine (TM), provided that these duties do not interfere with the performance of their duties. a) Persons in charge of service units shall be specialist medical practitioners authorised to practise their profession in Türkiye, or medical practitioners holding a certificate of completion of the blood banking and transfusion medicine course issued by the Ministry, or medical practitioners holding a master's degree in blood banking and transfusion medicine. b) The person in charge of the Blood Centre (BKM) laboratory shall be a specialist medical practitioner who has received laboratory training within the curriculum of his/her own specialty and who is authorised to practise his/her profession in Türkiye. c) For the persons in charge of Blood Centre (BKM) units, it shall be required to have worked for at least 3 years in licensed blood centres. ç) (Amended: Official Gazette 4/12/2009-27422) Physicians appointed as persons in charge of Transfusion Medicine (TM) and Blood Bank (KBM) units who do not fulfil the conditions set out in paragraph (a) shall be required, within six months following their appointment to the unit, to attend the blood banking and transfusion medicine certificate course provided by the Ministry and to obtain the certificate. (2) The duties of the person in charge of the service unit are as follows: a) To obtain the necessary information and documents for the licensing of the service unit for which he/she will be in charge, and to submit the application, b) To ensure that the service unit operates efficiently and with quality, in compliance and cooperation, in line with the quality policy of the service unit, c) To ensure that all activities in the service unit are carried out in accordance with the applicable legislation, the quality standards to which it is subject and the standard operating procedures, and to inspect the activities within the stated framework, ç) To ensure the necessary coordination regarding all activities carried out in the service unit, d) To identify the needs of the service unit and the units subordinate to it and to ensure that they are met, e) To ensure that documentation and records are kept in the service unit, that traceability is ensured within the scope of haemovigilance, and that serious adverse events and reactions are

reported, f) To carry out the necessary activities for personnel training, g) To prepare the annual activity report of the service unit for the preceding year and to determine the objectives for the following year, to plan the work programme as a project and to implement it, ğ) To conduct examinations and investigations, to prepare reports and to submit opinions on matters requested to be examined by senior management, h) To monitor the personnel records, disciplinary matters and personal rights in accordance with the provisions of the relevant personnel and disciplinary regulations to which the personnel are subject, and to ensure their fulfilment, ı) To follow legislative and scientific developments, to incorporate new knowledge and techniques into the activities, and to ensure the development of the institution and the enhancement of the quality of service. Service unit personnel

**ARTICLE 13 –** (1) The service unit shall employ a sufficient number of suitably trained and experienced personnel who are directly involved in the collection, testing, processing, storage and distribution of blood and blood components, and in the keeping and evaluation of records, within the scope of the field of activity of the service unit. In each service unit, there shall be: a) A person in charge possessing the qualifications defined in Article 12, b) Personnel responsible for technical, administrative and quality matters, c) A sufficient number of technical, administrative and quality personnel in accordance with the capacity of the service unit. (2) The duties and responsibilities of the service unit personnel shall be defined in the guideline. The personnel shall possess the qualifications specified in the guideline. (3) The training of service unit personnel shall be planned by the management, the content of the training programme shall be determined and records thereof shall be kept. Personnel competence shall be assessed regularly and records thereof shall be kept. (4) Biosafety and hygiene instructions shall be applied in accordance with the Regulation on the Prevention of Risks Arising from Exposure to Biological Agents, published in the Official Gazette No. 25488 dated 10/6/2004. Service unit building, sections, equipment and materials

**ARTICLE 14 –** (1) The service unit is obliged to maintain, in accordance with the updated guideline, the sections, equipment and materials necessary for the activities of the service unit specified in ANNEX-2 "licence application form for the service unit". (2) The service unit building, including mobile areas, shall be arranged in a manner that minimises the risk of error, in a logical sequence appropriate to its operation and activities, and this shall be maintained. Effective cleaning and maintenance facilities shall be available in order to reduce the risk of contamination to a minimum level. (3) The service unit shall consist of the sections defined in the guideline. Of these sections: a) The blood collection room is a room reserved for the safe collection of blood from donors, equipped for the initial treatment of donors who experience adverse reactions, and arranged so as to ensure the safety of both the donors and the personnel in order to prevent errors during the procedure. Prior to blood collection, a separate area, distinct from other activity areas, shall be available for confidential interviews and suitability assessments. b) Testing and processing areas are laboratory areas separately arranged for carrying out all tests necessary for the preparation of safe blood and for the processing of blood and blood components, accessible only to authorised personnel. c) The storage area ensures that different blood and blood components and necessary materials are stored under appropriate conditions, safely and separately. Necessary precautions are taken against equipment failure or power cuts. ç) The medical waste storage area is an area for the safe storage of waste. (4) In the service unit, equipment and materials: a) Are selected in a manner that minimises risks to donors, personnel, blood and blood products. b) Are validated and calibrated in accordance with their intended use, and their continuity is ensured. c) Operating instructions are prepared and the necessary records are kept in accordance with the quality system. ç) Inventory records are kept and retained for at least 10 years. d) In order to ensure reliability in computerised systems, software, hardware and backup procedures are checked at the installation stage and at regular intervals. Hardware and software are protected against unauthorised use and alteration. The backup procedure prevents data loss and damage to data. Quality system

**ARTICLE 15 –** (1) The principles for the establishment and operation of the quality system in the service unit are as follows: a) All personnel in the service unit are responsible for the compliance of the operations with the quality system. b) The quality system includes quality management, quality assurance, continuous quality improvement, personnel, building and equipment, documentation, collection, testing and processing, storage, distribution, quality control, recall of blood components, financial audit, contract management, nonconformity and internal audit. c) The quality system ensures that all processes are carried out in compliance with standards and specifications. The management reviews the effectiveness of the system at regular intervals and takes corrective measures when necessary. (2) Service units support their quality assurance through a national or international system. Within this system, procedures, buildings and equipment are validated before use. (3) Tests and processes are as follows: a) Donor suitability: In order to ensure safe blood, procedures compliant with the requirements specified in Annex-4 and Annex-5 are prepared and implemented for donor selection and donor screening. The interview is conducted in a manner that ensures confidentiality. Records and assessments regarding the donor's suitability are signed by the responsible personnel.

b) Collection process of blood and blood products: The verification, recording of the donor's identity, and the establishment of a clear link between the donor and the blood, blood components and blood samples are designed accordingly. Procedures describing this process are established. The process and quality control activities are maintained as defined in the guide. c) Basic laboratory tests to be performed on the donor: 1) ABO, Rh D blood group, 2) HBsAg, 3) Anti-HCV, 4) Anti-HIV 1/2, 5) Syphilis screening, 6) Other tests envisaged by the Board in the light of scientific developments and published in the guide upon approval by the Ministry. ç) Tests are validated, data demonstrating the suitability of the standards are available, and test procedures are prepared. Algorithms related to the tests, the methods used and the modes of application are carried out as set forth in the guide. d) Validation: Equipment and materials are used in accordance with validated procedures. e) Labelling: Blood and blood products are labelled in a manner that ensures the traceability of all stages. The designations used by the service unit on the label shall be uniform. The label contains at least the following information: 1) Name of the component, 2) Measurement information (volume, weight, number, etc.) of the product in accordance with the quality requirements, 3) Numerical or alphabetical identification of the donor, 4) Name of the service unit, 5) ABO blood group, Rh D group, 6) Date of collection and expiry date, 7) Storage temperature, 8) Name, composition and volume of the anticoagulant and additional solutions. f) The service unit records and stores the information specified in ANNEX-6 in a readable manner in a suitable environment for a period of not less than 30 years in order to ensure the full traceability of blood and blood products. The service unit establishes the traceability system in accordance with the items specified in "Annex-7 Data recording for traceability" in such a way as to ensure the tracking of blood and blood products from collection to transfusion. g) Autologous blood and blood products are labelled in accordance with the guide. ğ) Blood and blood components shall not be released unless the requirements of the Regulation are fulfilled. In circumstances preventing release, the release of other components obtained from the same donation shall also be prevented. The release procedure is carried out and recorded by the authorized person or persons. The release record demonstrates that the forms, other records and test results comply with the acceptance criteria at every stage of the process. h) Released and non-released blood and blood components are kept separately, both administratively and physically, and this is indicated by labelling. A procedure is prepared whereby, following release, it is determined for each unit whether it has been transfused to the recipient and, if not, its final disposition. (4) Service units submit their activities carried out during the year to the Ministry as specified in the guide. Statistical data belonging to the service units are retained for at least 15 years. (5) The principles for the storage and distribution of blood and blood components are as follows: a) The storage and distribution of blood and blood components are carried out as specified in the guide. b) For blood and blood components collected for the purpose of manufacturing medicinal products, the quality

system of the service unit ensures compliance with the storage and distribution requirements of the Regulation on Licensing of Medicinal Products for Human Use published in the Official Gazette No. 25705 dated 19/1/2005 and the Regulation on Manufacturing Facilities of Medicinal Products for Human Use published in the Official Gazette No. 25268 dated 23/10/2003. c) In order to ensure and maintain the quality of blood and blood components during the storage period, storage and distribution procedures as defined in the guide are in place and implemented. ç) Inventory and distribution records are kept in accordance with the procedure. Blood and blood components shall not be returned to inventory unless their compliance with the quality requirements and the procedure has been determined. d) During storage, packaging and distribution, the integrity and storage temperature of blood and blood components are maintained. e) Autologous blood and blood components, as well as blood components collected and prepared for specific purposes, are stored separately in accordance with the established procedures. f) Private and public legal entities wishing to utilise plasma collected domestically for product manufacturing purposes, either domestically or abroad, or to import plasma from abroad for product manufacturing purposes, are responsible for documenting, at the time of the permit application, the compliance of the plasma in question with the provisions of this Regulation as well as with the provisions of the Regulation on Licensing of Medicinal Products for Human Use and the Regulation on Manufacturing Facilities of Medicinal Products for Human Use. (6) Nonconformity of blood and blood components: a) The release of blood and blood components that do not meet the quality and safety conditions specified in the guide is possible by a joint decision of the physician of the patient to whom the blood or blood component will be transfused and the responsible person of the Blood Centre or the Blood Bank. The decision is documented with its justification in the patient records. b) Complaints, serious undesired effects and incidents relating to released blood components are recorded. Where necessary, the recall procedure, corrective or preventive actions are determined, carried out and concluded by authorized personnel. c) In accordance with Article 17, an effective and verifiable procedure is prepared for the notification of serious undesired effects and incidents. Nonconformities are analysed at the intervals determined in the procedure. ç) In the event of a recall, if a risky situation is involved, authorized personnel notify the sources concerned. (7) Internal audit: a) An internal audit procedure is prepared for the follow-up of the processes carried out in the service unit. b) Audits are carried out by trained and authorized persons in accordance with the procedure. c) An audit report is prepared and corrective-preventive actions are monitored. Documentation

**ARTICLE 16** – (1) Documents covering specifications, procedures and records encompassing all activities carried out by the service unit shall be prepared and updated. (2) Records shall be kept legibly by handwriting or on microfilm or in electronic environment. (3) Only authorised persons may make changes to documents. In case of a change, the date shall be entered and signed, reviewed, and implemented immediately. (4) All documents shall be kept available during audits. Notification of serious adverse reactions and events

**ARTICLE 17** – (1) Service units shall keep records of serious adverse reactions and events observed before, during or after transfusion, which may be attributable to the quality and safety of blood and blood components, and shall notify the Ministry. Notification shall be made in accordance with the "Notification of serious adverse reactions and events" set out in the guide. **FOURTH CHAPTER Licensing, Inspection and Administrative Sanctions** Licensing of service units and the obligation to obtain a licence

**ARTICLE 18** – (1) Natural and legal persons who will operate within the scope of this Regulation shall be obliged to obtain a licence from the Ministry, or from the governorship if authorised by the Ministry, before commencing their activities. (2) The collection, testing, processing, storage and distribution of blood and blood components, the importation of blood and blood components other than plasma imported for the purpose of obtaining products, and the follow-up of transfusion shall be carried out only by licensed service units. (3) Service units, as RBCs, HUs and RBUs, shall apply to the provincial health directorate of the province where they are

located in order to obtain a licence, together with the information and documents defined in ANNEX-1. A separate licence application shall be made for each service unit. (4) The suitability of the application shall be evaluated by the provincial health directorate within 7 days. If there are deficiencies, they shall be notified in writing to the relevant institution. After determining that the information and documents are complete and appropriate, the provincial health directorate shall conduct an on-site inspection of the service unit applying for a licence within one month in order to determine whether it possesses the conditions laid down in the Regulation. The application file of the service unit whose suitability has been determined, together with the on-site inspection report, shall be sent by the directorate to the Ministry. The Ministry shall evaluate the application file and the inspection report and, where it deems necessary, after conducting an on-site inspection of the service unit, shall issue a licence to the service unit found suitable, within 30 days, for the activities it will carry out and for the place where it will carry out these activities. (5) In the event of a change or departure of the person responsible for the service unit, the responsibility shall be transferred to another person possessing the qualifications set out in the first paragraph of Article 12. In this case, the relevant institution shall apply to the Ministry within one month together with the documents concerning the new service unit manager. In applications whose suitability is determined as a result of the evaluation made by the Ministry, the new responsible person shall be entered in the licence. (6) (Amended first sentence: OG-4/12/2009-27422) Service units to be newly opened shall apply for a provisional licence, to be used until a licence is obtained and granted only once, by completing the documents in ANNEX-3, for a period of at most one year for RBCs and at most three months for other units. The service unit operating under a provisional licence shall continue its activities in accordance with the principles set out in the Regulation and the guide. Within this period, it shall complete the deficiencies required for a permanent licence. (7) The provisional licence application shall be made, on behalf of an HU, by the relevant hospital; on behalf of an RBU, by the RBC to which it is affiliated; and on behalf of an RBC, by the public institutions and organisations authorised by the Ministry and by the Turkish Red Crescent Society. The Ministry shall conclude the provisional licence application within 15 working days. (8) Service units may not make changes to the activities specified in the licence application without the written permission of the Ministry. (9) In the event that authority is delegated to governorships, the licensing procedures for service units other than RBCs shall be concluded by the relevant governorship. (10) The licence fee shall be determined and announced separately by the Ministry in accordance with the relevant legislation. (11) Service units are obliged to renew their licences every 5 years. Otherwise, their licences shall be revoked. (12) (Added: OG-20/11/2009-27412) The Ministry may grant the RBC licence for a limited period in the places it deems necessary, taking into account the service planning and regionalisation it will carry out. The validity of licences granted in this manner shall terminate at the end of the period granted without the need for any further procedure. Inspection

**ARTICLE 19 –** (1) Institutions and organisations operating service units shall be obliged to comply with the provisions of the Law and this Regulation and to notify administrative and technical problems arising in practice to the service unit to which they are coordinated or affiliated within 5 working days. Regional Blood Centres shall notify the Ministry of the notifications of the service units affiliated to them within 5 working days. (2) Except for extraordinary inspections, service units shall be inspected by the Ministry at least twice a year in accordance with the inspection form set out in the guide. (3) In the event of a serious adverse event or reaction, or suspicion thereof, the Ministry shall request the necessary information from the service units or conduct an extraordinary inspection regarding the matter. (4) In inspections, the physical structure of the service unit, its technical equipment, personnel status, the procurement, storage and distribution of blood, the methods used in immunohaematological and microbiological tests, and the records shall conform to the Regulation, the communiqués of the Ministry and the minimum standards set out in the guide. (5) In inspections, the inspection form shall be filled in and the inspection report shall be notified to the management and the Ministry. For the irregularities and

deficiencies identified, the provisions of Article 6 of the Law and Article 20 of this Regulation shall apply. Administrative sanctions

**ARTICLE 20 –** (1) The Ministry shall warn the relevant service unit in order to remedy the deficiencies, errors and/or non-compliances identified during inspections. If it determines that the service unit has not remedied the deficiencies, errors and/or non-compliances within the given period, or if in any inspection it determines that the service unit does not meet the requirements on which the licence is based, it shall suspend or revoke the licence of the relevant unit. (2) The Ministry shall notify the service unit that its licence has been suspended and the reasons therefor within 14 working days from the receipt of the inspection report, in which it determined that the service unit did not remedy the deficiencies, errors and/or non-compliances or did not meet the requirements on which the licence is based, by the relevant unit. The notification shall contain the following; a) The definition of the error and/or non-compliance, b) The measures to be taken and the activities to be carried out by the service unit in order to remedy the error or non-compliance, c) The period required for the realisation of these activities. (3) The Ministry shall revoke the licence of the service unit which fails to implement, within the notified period, the measures to be taken and the corrective activities to be carried out in order to remedy the error or non-compliance specified in the second paragraph, and shall make a notification within 7 working days. (4) The Ministry shall immediately revoke and notify the licence of the service unit in situations threatening public health and safety. (5) The Ministry shall revoke the provisional licence of service units that fail to complete their deficiencies within one year for RBCs and three months for other units following a provisional licence application. (6) Service units whose licences have been revoked shall, where necessary, be operated by the Ministry through the seizure thereof by the Ministry and the taking of the necessary measures. Guide

**ARTICLE 21 –** (1) All activities carried out in service units must comply with the guide to be issued by the Ministry. The guide shall be updated by the Board at least once a year in accordance with scientific developments. (2) The topics to be included in the guide are as follows: a) Donor screening form and evaluation criteria, b) Procedures and principles for blood collection, donor reactions, c) Methods for the preparation of blood components, the characteristics they must possess, and the storage and transportation conditions of blood components, ç) Basic information regarding quality control, d) The performance and evaluation of immunohaematological tests and microbiological screening tests to be carried out prior to transfusion, e) Technical equipment, physical structure, and the characteristics of the devices used, f) Biosafety measures, g) The characteristics of the record system ensuring the traceability of blood from the donor to the recipient, ğ) The methods to be followed in the distribution of blood and blood components, h) The technique for preparing standard operating procedures and the quality manual, ı) The protocol to be signed between the BRC and the Hospital Blood Bank (TM), i) Procedures related to transfusion and the alternative transfusion procedure, j) Procedures for patient and personnel safety, k) Service unit inspection form. Records to be kept by the Ministry

**ARTICLE 22 –** (1) The Ministry keeps records of all information and documents submitted to it during the licensing of service units, together with all information and documents obtained as a result of inspections and controls of these establishments, the inspection report, and notifications made to it regarding serious adverse effects and incidents, and retains them for a period of at least 15 years. Financial provisions

**ARTICLE 23 –** (1) Blood and blood components delivered by the BRC to the Hospital Blood Bank (TM) shall be invoiced by the BRC in accordance with the protocol concluded with the Hospital Blood Bank. CHAPTER FIVE Provisional and Final Provisions Preparation of the guide and the status of existing blood units PROVISIONAL ARTICLE 1 – (1) The guide referred to in Article 21 of this Regulation shall be published by the Ministry within three months from the date of entry into force of this Regulation. (2) Type A and Type B blood centres and blood stations that have been operating until the date of entry into force of the Law are obliged to remedy their deficiencies within one year from the entry into force of this Regulation and to obtain a licence in

accordance with the provisions of the Law and this Regulation. The activities of those that fail to obtain a licence within this period shall be suspended by the governorship and reported to the Ministry. Entry into force

**ARTICLE 24** – (1) This Regulation shall enter into force on the date of its publication. Enforcement

**ARTICLE 25** – (1) The Minister of Health shall execute the provisions of this Regulation.

4/12/2008 27074 Dates and Numbers of the Official Gazettes in Which the Amending Regulations Were Published 1. 4/12/2009 27422 2. 3/4/2012 28253 3.

#### **ANNEX-1 INFORMATION AND DOCUMENTS REQUIRED FOR LICENCE APPLICATION**

1 – Completion of the "Service unit licence application form" in Annex-2, 2 – Building and layout plan of the service unit, 3 – The following of the service unit responsible person: – (Amended phrase: OG-4/12/2009-27422) A certified true copy of the diploma approved by the Provincial Health Directorate or the original of the photo-bearing discharge certificate, – Other documents demonstrating that he/she has experience, – 2 passport-size photographs, – Republic of Türkiye Identity Number 4 – (Amended phrase: OG-4/12/2009-27422) The original of the bank receipt indicating that the licence fee determined by the Ministry has been paid (The payment receipt is not requested at the application stage; it is submitted to the Directorate upon delivery of the licence. The bank account number to which the payment is to be made is notified by the Ministry.), 5 – A quality manual or computer documentation containing master files of a nature that meets the requirements relating to the quality system, together with: – Job descriptions, – Organisational chart, – Number and qualifications of personnel, – Hygiene conditions, – Building and equipment, – List of Standard Operating Procedures (relating to the selection, rejection-acceptance criteria of donors, the preparation, testing, distribution and disposal of blood and blood components, and the recording and reporting of serious unwanted effects and incidents).

#### **ANNEX-2 LICENCE APPLICATION FORM FOR SERVICE UNITS RBF-REV 00 LICENCE APPLICATION FORM FOR SERVICE UNITS**

##### **(1) Previous Information**

Licence Number If a licence has previously been obtained from the Ministry of Health, please indicate below.

Licence No:

Date/Number:

##### **(2) Information on the Applicant**

Type of Service Unit Name of the Service Unit Applicant Title of the Institution Republic of Türkiye Identity No: Postal code Telephone Mobile tel Fax E-mail Address

If you are a consultant or representative on behalf of the licence applicant, please tick here and complete the contact details below.

Contact Details (Consultant/representative) Contact person's name and surname Company name Address

##### **(3) Service Unit Information**

###### **(a) Activities**

ACTIVITIES OF THE UNIT YES NO Evaluation of donor suitability Donor screening Testing of donor samples Donor examination Collection of blood Whole blood collection Apheresis Autologous blood collection Mobile blood collection Donor organisation Testing of blood Immunohaematological tests Microbiological screening tests Confirmatory tests Separation of blood into components Preparation of products Erythrocyte suspension Fresh frozen plasma Platelet suspension Cryoprecipitate Plasma depleted of cryoprecipitate Granulocytes Buffy coat Cytopheresis Plasmapheresis Multicomponent apheresis Processes Filtration Irradiation Washing Division into small volumes Pooling Viral inactivation Bacterial inactivation Storage of blood and blood components 20–22°C 2–8°C -18– -25°C Below -25°C Distribution of blood components Use

of blood

(b) Layout Plan

• Please draw an outline of the layout plan relating to the activities of the service unit specified above and briefly explain it.

(c) Service Unit Responsible Person Title Name Surname

Business Address

(d) Distribution Details Concerning Transfusion Centres

Hospital Name and Address

Hospital Name and Address

Hospital Name and Address

Hospital Name and Address

Hospital Name and Address

Hospital Name and Address

If more than one copy of this page has been made, the total number of pages must be indicated

(4) Declaration I confirm that the matters I have specified above are complete, definite and accurate, and we hereby apply for a licence to be granted on behalf of the service unit responsible person named in the form in order to provide services as ( ) Regional Blood Centre ( ) Blood Donation Centre ( ) Transfusion Centre within the framework of the activities specified.

Name and Surname of the Service Unit Responsible Person Date/Signature

Name and Surname of the Applicant Date/Signature

Name and Surname of the Institution's Supervisor Date/Signature

When you have completed the form, please send it to the following address: Ministry of Health General Directorate of Treatment Services Department of Medical Services Blood Branch Office Mithatpaşa Cad. No:3 Sıhhiye/ ANKARA

## **ANNEX-2 A GUIDE FOR COMPLETING THE LICENCE APPLICATION FORM FOR SERVICE UNITS**

General Explanation: This document has been prepared to assist you in completing the application form. The form should be completed taking into account the activities of the establishment wishing to obtain a licence. The final page of the application form must be signed by the service unit responsible person, the applicant and the institution's supervisor. Unsigned forms will not be accepted. The form consists of four sections: 1. Previous Information 2. Information on the Applicant 3. Service Unit Information 4. Declaration All sections of the form must be completed legibly in capital letters. Clear and understandable information in the form will facilitate the application process. Completed forms must be sent to the following address: Ministry of Health General Directorate of Treatment Services Department of Medical Services Blood Branch Office Mithatpaşa Cad. No: 3 Sıhhiye/ANKARA (1) Previous Information Licence Number – If the establishment applying for a licence has previously obtained a licence or opening approval from the Ministry of Health, the date and number of the relevant letter must also be indicated. Establishments without a number should leave this section blank. (2) Information on the Applicant Type of Service Unit • Please indicate the type of the service unit as specified in the Blood and Blood Products Law No. 5624 dated 11/4/2007 and the relevant regulation. Example: Regional Blood Centre Name of the Service Unit • Please write the name of the service unit. Example: Serpil Akdağ Blood Centre. Applicant • This is the person authorised to apply for a licence on behalf of the service unit. If the application is made by a third person (representative or consultant) on behalf of the applicant, the box below must be ticked and the contact details completed. "If you are a consultant or representative on behalf of the licence applicant, please tick here and complete the contact details below." Title of the Institution • Please write the name of the institution to which the service unit is affiliated. Example: Ankara University (3) Contact Details • In cases where there is no third person (representative or consultant) on behalf of the applicant, this section will be left blank and the information contained in the "Information on the applicant" section will be used for contact purposes. (4) Service Unit Information This section consists of four subsections: (a) Activities: The activities appropriate to the type of the service unit (regional blood centre, transfusion centre, blood donation centre) as specified in the Blood and Blood Products Law No. 5624 dated 11/4/2007 and the relevant regulation are ticked. (b) Layout Plan: The layout plan relating to the activities of the service units is outlined and explained in the box, and the architectural project of the service unit is submitted together with the application. (c) Service Unit Responsible Person: In addition to the information on the form relating to the service unit responsible person, the following documents specified in Annex-1 of the Regulation must also be attached to the form c-1 (Amended phrase: OG-2/8/2011-28013) A certified true copy of the diploma approved by the provincial health directorate or the original of the photo-bearing discharge certificate

c-2 Curriculum vitae form c-3 (Amended phrase: OG-2/8/2011-28013) Declaration of Turkish Republic identity number c-4 2 passport-size photographs (d) Distribution: The names and addresses of the hospitals and/or blood centres to which the service unit applying for the licence provides/will provide services shall be stated. If the number of hospitals/blood centres to be defined exceeds the number specified on the page, the page shall be reproduced, attached to the form, and the number of copies shall be indicated on the original page. Example: If a regional blood centre in region A distributes blood components to 15 transfusion centres, the names and addresses of these centres shall be written in the boxes. Similarly, if there is only one regional blood centre to which the blood donation centre is affiliated, its name and address shall likewise be written in a single box. (5) Declaration: In this section, only the box corresponding to the type of service unit for which the licence is being requested shall be ticked. The form shall be signed by all relevant parties, and the name, surname and date shall be stated.

### **ANNEX 3**

#### **INFORMATION AND DOCUMENTS REQUIRED FOR A PROVISIONAL LICENCE APPLICATION**

1. Completion of the service unit licence application form in Annex-2, 2. Building and layout plan of the service unit, 3. For the person in charge of the service unit: - (Amended phrase: OG-2/8/2011-28013) The original of a certified copy of the diploma approved by the Provincial Health Directorate or a photographic leaving certificate, - Documents demonstrating professional experience, - Republic of Türkiye Identity Number: - 2 passport-size photographs. 4. Bank receipt evidencing payment of the fee payable at the time of application.

#### **ANNEX-4 INFORMATION TO BE PROVIDED TO AND OBTAINED FROM BLOOD DONORS**

(SECTION A) Information to be provided to prospective donors of blood and blood components

1. Comprehensive educational materials, understandable to the general public, are provided on the essential nature of blood, the blood donation procedure, the components obtained from whole blood, and the significant benefits that apheresis donations provide to patients.
2. In both allogeneic and autologous donations, the reasons why donors undergo examination based on health and medical history and why donations need to be tested are explained, and the importance of consent is stated. For allogeneic donations, the reasons why individuals should not donate blood and blood components in cases of personal deferral, temporary and permanent deferral, or where there is a risk to the recipient are explained. For autologous donations, the possibility of deferral and the reasons why the donation procedure will not take place where autologous blood and blood components would pose a risk to the health of the person as donor or recipient are explained.
3. Information on the protection of personal data: The donor's identity, information relating to the donor's health and the results of the tests performed shall not be disclosed without authorisation.
4. The reasons requiring individuals to refrain from donations that could harm their own health are stated.
5. Specific information is provided on the nature of the procedures applied in both allogeneic and autologous donations and the risks associated with them. For autologous donations, the possibility that the autologous blood and blood components may be insufficient for the intended transfusion requirements is stated.
6. Donors are provided with information on the options to change their mind before a procedure is to take place, or on the possibility to withdraw or personally defer at any moment during the donation process, without any formality, embarrassment or inconvenience.
7. Service units inform the donor of the importance of providing the reason why their previous donation was found unsuitable for transfusion for any cause, where applicable.
8. Information is provided on the responsibility of the service unit to inform the donor through an appropriate mechanism where the test results indicate a specific abnormality in the donor's health.
9. Information is provided on why unused autologous blood and blood components are discarded and not transfused to other patients.
10. Information is provided that where markers of HIV, HBV, HCV viruses or other microbiological agents transmissible by blood are detected, the test results will lead to the rejection of the donor and the destruction of the unit collected.
11. Information is provided that donors always have the opportunity to ask questions.

(SECTION B) Information to be obtained from the donor at each donation by service units

- a) Identification of the donor; Personal information and contact details distinguishing the donor from other individuals, without risk of identification error.
- b) The donor's health and medical history; Health and medical history are obtained through a questionnaire and a personal interview conducted by qualified health personnel, and also cover other factors that may assist in identifying and monitoring individuals whose donations may pose a health risk to others — such as disease transmission — or to themselves.
- c) The donor's signature; The donor's signature in the donor questionnaire, which is also signed by the health care personnel responsible for taking the donor's health history. The donor questionnaire confirms that the donor: (1) has read and understood the educational materials provided; (2) has had the opportunity to ask questions; (3) has received satisfactory answers to all questions asked; (4) has given consent for the donation procedure; (5) in autologous donations, has been informed that the donated blood and blood components may not meet the intended transfusion requirements; and (6) acknowledges that all information provided by him/her (the donor), to the best of his/her knowledge, is accurate.

**ANNEX-5 ELIGIBILITY CRITERIA FOR BLOOD DONORS** The eligibility criteria for blood donors are set out below. These criteria do not apply to autologous donations. Temporary and permanent deferral criteria are assessed as specified in the current guideline. In exceptional cases, individual donations that do not comply with the criteria below may be permitted by the responsible physician of the service unit. Such cases are explicitly recorded and are subject to quality management requirements within the framework of Article 15 — quality system in the service

unit, and Article 16 — provisions concerning documentation, of this Regulation.

Age 18 – 65 years The prospective donor must have completed the legal age of 18 in order to be considered of age First donation over 60 years of age With the approval of the responsible physician of the service unit; over 65 years of age Body Weight  $\geq 50$  kg Haemoglobin Female Male  $\geq 12.5$  g/dl  $\geq 13.5$  g/dl Total protein

$\geq 6$  g/dl

For regular plasmapheresis donors, at least once a year Platelet count  $\geq 150 \times 10^9$  /l For plateletpheresis donors

ANNEX-6 RETENTION OF RECORDS (a) Information to be retained for 30 years; 1. Name of the service unit 2. Numerical or alphabetical identification of the donor 3. Identification of the blood/blood component 4. Collection and expiry dates of the blood (day/month/year) 5. Units to which the blood/blood component was distributed 6. Date of distribution (day/month/year) 7. Units in which the blood/blood component was used 8. Identification of the transfusion recipient 9. Date of transfusion (day/month/year) 10. Acceptance confirmation and date of the returned blood/blood component (day/month/year) 11. Date of destruction (day/month/year) 12. Reason for destruction (b) Information to be retained for 15 years; 1. Total number of donors (prospective and actual donors) 2. Total number of donations 3. List of other units affiliated to the service units or to which the service units are affiliated 4. Number of discarded donations 5. Number of blood/blood components produced and distributed 6. Microbiological screening test results (as %) 7. Number of withdrawn blood/blood components 8.

#### **8. Number of reported serious adverse events and incidents**

ANNEX-7 DATA RECORDING FOR TRACEABILITY Regional Blood Centre and Blood Donation Centre: 1. Name of the regional blood centre, 2. Name of the blood donation centre, 3. Donor identity, 4. Blood/blood component identity, 5. Date of collection (day/month/year),

6. Transfusion centres to which the blood/blood components were distributed, 7. Transfusion centre to which returned blood/blood components were re-distributed, 8. Date of disposal for blood/blood components not distributed (day/month/year), Transfusion Centres: 1. Name of the regional blood centre from which the blood/blood component was obtained, 2. Blood/blood component identity, 3. Identity of the transfusion recipient, 4. Reason for return or disposal of non-transfused blood/blood components, 5. Date of transfusion, return or disposal (day/month/year).

day/month/year).