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27 February 2018 [shall come into force on 2 March 2018];

18 January 2022 [shall come into force on 21 January 2022];

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8 March 2022 [shall come into force on 11 March 2022].

If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 1037

Adopted 27 December 2005

**Regulations Regarding Quality and Safety Standards for the Collection, Testing, Processing, Storage, and Distribution of Human Blood and Blood Components, Import and Export Conditions, and also Compensation for Expenditures for the Renewal of the Lost Volume of Blood**

[*8 March 2022*]

*Issued pursuant to*

*Section 34, Paragraph three of the Medical Treatment Law*

**I. General Provisions**

1. The Regulation prescribes quality and safety standards for the collection, testing, processing, storage, and distribution of whole blood collected from a donor and processed either for transfusion or for further manufacturing (hereinafter – the blood) and of therapeutic constituents of blood prepared by various methods (hereinafter – the blood components) and intended for blood transfusion to the donor himself or herself or to another person, for the use in medical devices or as starting materials for medicinal products, the import and export conditions thereof, and also compensation for expenditures for the renewal of the lost volume of blood.

[*8 March 2022*]

1.1 A blood service shall be an aggregate of medical treatment institutions or units thereof, comprising the State Blood Donor Centre, blood preparation divisions of medical treatment institutions, blood transfusion rooms, and units which ensure the supply of medical treatment institutions with the blood components conforming to the quality and safety requirements. The activity of the blood service shall be organised and coordinated by the State Blood Donor Centre.

[*18 January 2022*]

2. The collection of human blood and blood components shall be based on the voluntary principle, whereas the distribution and transfusion of human blood and blood components shall be based on the principles of anonymity and non-profit provision of services.

3. Human blood and blood components shall not be imported into the country and not exported from the country, except for the import and export in the cases referred to in Paragraphs 3.1 and 3.2 of this Regulation.

[*8 March 2022*]

3.1 Blood and blood components prepared by using State budget funds may be exported from the country for the manufacture of blood products. A starting material obtained in the country shall be used for the manufacture of blood products.

[*8 March 2022*]

3.2 In exceptional cases, on the basis of a separate decision, the State Blood Donor Centre shall ensure the import of human blood and blood components into the country or export thereof from the country.

[*8 March 2022*]

4. Distribution shall be the act of delivery of blood and blood components to the State Blood Donor Centre, blood preparation divisions, blood transfusion rooms of medical treatment institutions, or manufacturers of medicinal products for the manufacture of medicinal products derived from human blood and plasma. Distribution shall not include the issuing of blood or blood components for blood transfusion.

[*22 December 2009*]

5. Serious adverse reaction shall be an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

6. Adverse event shall be any untoward occurrence associated with the collection, testing, processing, storage, and distribution of blood and blood components that might lead to death or life-threatening, disabling, or incapacitating conditions for a patient or which results in, or prolongs, hospitalisation or morbidity.

6.1 Hemovigilance shall be a set of organised surveillance procedures relating to serious adverse events or serious adverse reactions in donors or recipients, and also the epidemiological follow-up of donors. In the event of a donor testing positive for a blood-borne disease, and also in the event of transmission of such diseases, the State Blood Donor Centre shall carry out retrospective testing of blood samples as part of haemovigilance. Blood samples stored in the archives for three years from the time of preparation shall be used for testing, unless otherwise specified by the manufacturer of the medicinal product derived from human blood or plasma.

[*18 January 2022*]

**II. Conformity Assessment**

7. The State Agency of Medicines (hereinafter – the Agency) shall assess the conformity of blood transfusion rooms of medical treatment institutions (hereinafter – the blood transfusion room), the State Blood Donor Centre, and blood preparation divisions with the requirements laid down in this Regulation.

[*5 April 2016*]

8. In order for the Agency to assess the conformity of the State Blood Donor Centre, blood preparation divisions, and blood transfusion rooms with the requirements laid down in this Regulation, the State Blood Donor Centre, blood preparation divisions, and blood transfusion rooms shall provide:

8.1. the following general information:

8.1.1. the name, registration number, if any, and registered office;

8.1.2. the given name, surname, qualification, and contact details of the responsible person;

8.1.3. the list of medical treatment institutions supplied with blood and blood components by the State Blood Donor Centre, blood preparation divisions, and blood transfusion rooms;

8.1.4. information on the entering into a contract for the supply of plasma for the manufacture of medicinal products derived from human blood and plasma, indicating the contract number, date, firm name of the manufacturer, registration number in the commercial register, registered office, special authorisation (licence) number for the manufacture of medicinal products;

8.1.5. information on a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment (hereinafter – the mobile site), if any;

8.1.6. information on the entering into a contract with a testing laboratory of another medical treatment institution or undertaking for the testing of human blood or blood components on a contractual basis;

8.2. a description of the quality system which shall include:

8.2.1. documentation on the State Blood Donor Centre, blood preparation division, and blood transfusion room subject to assessment, including the responsibilities and reporting obligations of the responsible persons;

8.2.2. a quality manual for the State Blood Donor Centre, blood preparation division, and blood transfusion room describing the quality assurance system in accordance with Paragraph 15 and Sub-paragraph 36.1 of this Regulation;

8.2.3. the number and qualifications of employees;

8.2.4. the hygiene provisions;

8.2.5. the premises and equipment;

8.2.6. the list of standard operating procedures which shall include the following information:

8.2.6.1. recruitment, retention, and assessment of donors;

8.2.6.2. preparation and testing, issuance and recall of blood and blood components;

8.2.6.3. the procedures for reporting on serious adverse reactions and adverse events and the procedures for the registration of the abovementioned information.

[*10 October 2006; 22 December 2009*]

9. If the State Blood Donor Centre, blood preparation division, or blood transfusion room conforms to the requirements of this Regulation, the Agency shall issue the certificate of conformity after conformity assessment. The certificate shall specify the activities that the State Blood Donor Centre, the blood preparation division, and the blood transfusion room may carry out and the conditions under which the activities may be carried out. Information on the issued certificates of conformity, the activities included therein, and the conditions for the performance thereof, and also the given name and surname of the responsible person referred to in Paragraph 11 of this Regulation shall be published on the website of the Agency.

[*18 January 2022*]

10. The State Blood Donor Centre, the blood preparation divisions, and the blood transfusion rooms may not change the conditions of their activities without the written approval of the Agency.

**III. Responsible Official**

11. The State Blood Donor Centre and the blood preparation divisions shall designate a responsible person (hereinafter – the responsible person). The responsible person shall have:

11.1. a higher education diploma in the field of medical or biological sciences awarded upon completion of a university education programme;

11.2. appropriate qualification as evidenced by a certificate of a transfusiologist;

11.3. at least two years of practical postgraduate experience in the field of transfusiology.

12. The responsible person shall organise measures to ensure the fulfilment of the following requirements:

12.1. any action with blood or blood components intended for transfusion takes place in accordance with this Regulation and other laws and regulations;

12.2. the Agency receives the necessary information to carry out the conformity assessment procedure in accordance with Paragraphs 7 and 8 of this Regulation;

12.3. the personnel directly involved in the preparation, testing, processing, storage, and distribution of blood and blood components is appropriately qualified and is provided with timely training to improve their qualifications;

12.4. conformity with the requirements referred to in Paragraphs 15, 16, and 20, and Chapter VI of this Regulation.

13. If the State Blood Donor Centre and the blood preparation divisions designate several responsible persons for the performance of the tasks referred to in Paragraph 8 of this Regulation, additional information on the specific tasks of the responsible persons under their responsibility shall be provided to the Agency.

14. When replacing the responsible person temporarily or permanently, the State Blood Donor Centre and the blood preparation divisions shall notify the Agency of the given name and surname of the new responsible person and the date of designation of the responsible person.

**IV. State Blood Donor Centre and Blood Preparation Divisions**

15. The State Blood Donor Centre and the blood preparation divisions shall establish and maintain a quality assurance system in accordance with the principles of good practice laid down in Annex 6 to this Regulation. In order to implement the quality system standards and specifications indicated in Annex 6 to this Regulation, the State Blood Donor Centre and the blood preparation divisions shall use the Good Practice Guidelines which have been jointly developed by the European Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and which are available in Latvian on the website of the State Agency of Medicines.

[*22 December 2009; 27 February 2018*]

16. The State Blood Donor Centre and the blood preparation divisions shall maintain and keep for five years documentation on the procedures for activities, personnel training, sample forms, and also provide access to documents for officials carrying out control measures.

17. The State Blood Donor Centre and the blood preparation divisions shall, through validated processes and procedures, ensure the following:

17.1. testing or examination of blood samples in accordance with Annex 1 to this Regulation. The State Blood Donor Centre and the blood preparation division may determine additional testing if necessary in accordance with the objectives established by national or international authorities or in accordance with a particular epidemiological situation;

17.2. conformity with the quality and safety requirements for blood and blood components and testing by an accredited testing laboratory in accordance with Annex 2 to this Regulation;

17.3. implementation and maintenance of the requirements applicable to the preparation of autologous blood;

17.3.1 leucocyte filtration of the prepared red cell mass;

17.4. conformity with the requirements for the storage, transportation, and distribution of blood and blood components in accordance with Annex 3 to this Regulation;

17.5. the assessment procedures for all donors of blood and blood components, and also conformity with the criteria for the acceptance of donors in accordance with Annex 4 to this Regulation. The results of the donor assessment and testing procedures shall be documented. The State Blood Donor Centre shall notify the donor or the general practitioner (at the choice of the donor) of any significant abnormalities within five working days after receipt of the confirmatory results;

17.6. the examination of donors, the information to be provided to and obtained from donors in accordance with Paragraphs 38 and 39 of this Regulation, and also, during assessment of the eligibility of donors, ensure conformity with the eligibility criteria for blood and plasma donors in accordance with Annex 5 to this Regulation. The criteria shall include the following:

17.6.1. the permanent criteria for refusal of donations of blood and blood components and the associated rejection of prospective donors;

17.6.2. temporary refusal criteria for the donation of blood and blood components;

17.7. implementation and maintenance of quality system standards and specifications in accordance with Paragraph 15 of this Regulation;

17.8. implementation and maintenance of a sample form for the report on serious adverse reactions and adverse events specified in Chapter VI of this Regulation;

17.9. implementation of and conformity with the traceability requirements referred to in Chapter VI of this Regulation;

17.10. non-distribution of poor quality blood or blood components in cases of potential threat to the quality and safety thereof;

17.11. compensation for expenditures for the renewal of the lost volume of blood in the following amounts:

17.11.1. for a blood donor – EUR 4.27;

17.11.2. [18 January 2022];

17.11.3. [18 January 2022];

17.11.4. for a donor of the plasmapheresis procedure – EUR 17.07;

17.11.5. for a donor of the cytapheresis procedure – EUR 28.46;

17.11.6. [18 January 2022];

17.11.7. a free meal for each donor – in the amount of EUR 1.42.

[*10 October 2006; 22 December 2009; 28 June 2011; 27 November 2012; 27 August 2013; 5 April 2016; 18 January 2022*]

17.1 The donor has the right to refuse from the compensation for expenditures for the renewal of the lost volume of blood.

[*27 February 2018*]

17.2 The State Blood Donor Centre may issue blood or blood components to a medical treatment institution which does not have the blood transfusion room referred to in Annex 7 to this Regulation for transfusion to a specific recipient if emergency medical assistance must be provided.

[*18 January 2022*]

18. Each year, the State Blood Donor Centre and the blood preparation divisions shall prepare a report on the activity thereof in the previous year by 15 February and by 25 January respectively. The following information shall be included in the report:

18.1. the number of donors;

18.2. the number of donations of blood or blood components;

18.3. the list of medical treatment institutions supplied with blood and blood components by the State Blood Donor Centre or blood preparation division;

18.4. the total number of unused doses of blood or blood components;

18.5. the number of the prepared and issued doses of blood or blood components;

18.5.1 the types and number of samples tested in accordance with the requirements laid down in Sub-paragraph 17.2 of this Regulation and a summary of the test results;

18.6. incidence and prevalence of transfusion transmissible infectious markers in donors;

18.7. the number of withdrawn (recalled) doses;

18.8. the number of serious adverse reactions and adverse events reported to the Agency.

[*22 December 2009*]

19. The annual report of a blood preparation division shall be submitted to the State Blood Donor Centre. A summary shall be prepared by the State Blood Donor Centre and submitted to the Agency by 15 February each year.

20. The State Blood Donor Centre and the blood preparation divisions shall keep the information related to the activities referred to in Paragraphs 17, 18, 38, and 39 of this Regulation for 15 years.

21. The State Blood Donor Centre shall develop technologies for the preparation and use of blood and blood components and submit them to the State Agency of Medicines for approval.

[*18 January 2022*]

**V. Obligations and Rights of the Agency**

22. The Agency shall ensure the following:

22.1. appropriate control measures at the State Blood Donor Centre, the blood preparation divisions, and the blood transfusion rooms in order to ensure conformity with the requirements laid down in this Regulation;

22.2. recording, registration, and analysis of serious adverse reactions and adverse events;

22.3. surveillance of haemovigilance;

22.4. registration of data submitted by the State Blood Donor Centre and the blood preparation divisions;

22.5. submission of the annual report (information referred to in Paragraphs 31 and 32 of this Regulation) to the European Commission by 30 June of the following year;

22.6. forwarding of a report on control measures to the European Commission every three years.

[*22 December 2009; 27 November 2012; 5 April 2016*]

23. In order to ensure compliance with this Regulation, the Agency:

23.1. shall, at least every two years, control the State Blood Donor Centre and the blood preparation divisions, including their mobile sites, if any, and also third parties whereto a blood preparation division has entrusted performance of the donor assessment and testing procedures referred to in Sub-paragraph 17.5 of this Regulation;

23.2. is entitled to take samples for examination and analysis;

23.3. shall examine all control-related documents;

23.4. shall inspect the conformity of blood transfusion rooms with the requirements referred to in Paragraphs 36 and 37 of this Regulation at least every five years.

[*5 April 2016*]

24. The Agency shall organise control measures when serious adverse reactions or adverse events are identified, or there is suspicion thereof.

25. If the control measures reveal that the State Blood Donor Centre, blood preparation division, or blood transfusion room does not conform to the requirements laid down in Annexes 6 and 7 to this Regulation, the Agency shall take the decision on suspension or withdrawal of the granted conformity and shall determine a specific period of time within which the State Blood Donor Centre, blood preparation division, or blood transfusion room must eliminate the established non-conformity.

26. The State Blood Donor Centre, blood preparation division, or blood transfusion room shall notify the Agency after the non-conformity established by the Agency has been eliminated. The Agency shall take the decision on renewal of the conformity of the State Blood Donor Centre, blood preparation division, or blood transfusion room and notify the State Blood Donor Centre, blood preparation division, or blood transfusion room thereof in writing within 10 days.

**VI. Traceability Requirements and Notification of Serious Adverse Reactions and Adverse Events**

27. The State Blood Donor Centre and the blood preparation divisions shall have a system in place in accordance with Annex 6 to this Regulation to identify each donor, each blood unit donated, and each blood component prepared, whatever its intended purpose, and the institutions to which the respective blood component has been delivered.

28. The State Blood Donor Centre, the blood preparation divisions, and the blood transfusion rooms shall have a system in place in accordance with Annexes 6 and 7 to this Regulation to record each blood unit or blood component received (whether or not processed at the respective institution) and the final destination of that received unit, whether transfused, discarded, or returned to the distributing blood establishment.

29. Medical treatment institutions in which blood and blood components are transfused shall have procedures in place to ensure that transfusion data are recorded and that any serious adverse reactions observed during or after transfusion in persons receiving blood or blood components (recipients) which may be attributed to the quality and safety of blood and blood components are promptly reported to the State Blood Donor Centre or blood preparation division which had prepared the relevant dose.

30. Blood transfusion rooms shall have procedures in place to report to the Agency as soon as known all relevant information on suspected serious adverse reactions. The sample forms for notification indicated in Parts A and C of Annex 8 shall be used to provide the abovementioned information.

31. Blood transfusion rooms shall:

31.1. notify to the Agency all information on serious adverse reactions of imputability level 2 or 3, in accordance with Part B of Annex 8, attributable to the quality and safety of blood and blood components;

31.2. notify the Agency and the State Blood Donor Centre or the blood preparation division that prepared the respective blood or blood components of any case of transmission of infectious agents by blood and blood components as soon as known and initiate retrospective testing of the recipient;

31.3. describe the actions taken in respect of other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;

31.4. evaluate suspected serious adverse reactions according to the imputability levels specified in Part B of Annex 8;

31.5. provide confirmation of a serious adverse reaction, upon conclusion of the investigation, in accordance with Part C of Annex 8;

31.6. submit a notification on serious adverse reactions to the Agency on an annual basis in accordance with Part D of Annex 8.

[*27 November 2012*]

32. The State Blood Donor Centre, the blood preparation divisions, and the blood transfusion rooms shall ensure that the following procedures are in place in relation to adverse events:

32.1. procedures for recording all adverse events which could affect the quality and safety of blood and blood components;

32.2. procedures by which, through the use of the sample form for notification included in Part A of Annex 9, all information on adverse events which could put in danger donors or persons receiving blood or blood components (recipients) is provided to the Agency as soon as known, but not later than within 48 hours.

33. The institutions referred to in Paragraph 32 of this Regulation shall:

33.1. evaluate adverse events to identify the preventable causes thereof;

33.2. provide confirmation of an adverse event, upon conclusion of the investigation, in accordance with Part B of Annex 9;

33.3. submit a notification on adverse events to the Agency on an annual basis in accordance with Part C of Annex 9.

34. The State Blood Donor Centre and the blood preparation divisions shall label all prepared, tested, processed, stored, distributed blood and blood components and shall indicate the following information on the label:

34.1. the official name of the component;

34.2. the volume, weight, or number of cells in the component;

34.3. the numerical or alphanumerical identification code for the blood donation;

34.4. the name of the producing blood establishment;

34.5. the ABO Group and Rh affiliation (not required for plasma intended only for fractionation);

34.6. the date or time of expiry;

34.7. the temperature of storage;

34.8. the name, composition, and volume of anticoagulant or additive solution.

35. The State Blood Donor Centre and the blood preparation divisions shall have a procedure in place in accordance with the requirements laid down in Annex 6 to this Regulation to ensure accurate, efficient, and verifiable withdrawal from distribution of blood or blood components if the information referred to in Sub-paragraphs 31.5 and 33.2 of this Regulation has been provided, and also to initiate retrospective testing of the donor after confirmation of a positive test result.

[*27 November 2012*]

**VII. Blood Transfusion Room of a Medical Treatment Institution**

36. The blood transfusion room shall:

36.1. establish and maintain, in conformity with the competence thereof, a quality system in accordance with Annex 7 to this Regulation;

36.2. receive blood components from the State Blood Donor Centre or a blood preparation division, store them, ensure the release of compatible blood components for transfusion and be responsible for their circulation;

36.3. maintain and store documentation on the procedures for activities, personnel training, guidelines and instruction manuals, sample forms, and also provide access to the abovementioned documents for officials carrying out control measures;

36.4. conform to the requirements laid down in Paragraphs 27, 28, and 41.2 of this Regulation for the storage of traceability data;

36.5. conform to the requirements laid down in Paragraphs 29, 30, 31, 32, and 33 of this Regulation for the reporting of adverse events and serious adverse reactions;

36.6. ensure the protection and confidentiality of data, and also genetic information.

[*22 December 2009*]

37. Only medical practitioners trained in transfusiology who have been issued a certificate of training by an authorised transfusiologist within the last five years may work in the blood transfusion room and transfuse blood components. The training of medical practitioners is paid for from funds of the person to be trained or a third party. Certificates for attendance of the relevant training courses in other European Union Member States within the last five years are also evaluated and recognised.

**VIII. Donor Information**

38. The State Blood Donor Centre and blood preparation divisions shall provide the following information to prospective donors:

38.1. accurate educational materials, comprehensible to the general public, about blood properties, the blood donation procedure, blood and blood components, and benefits to patients by donating blood;

38.2. for allogeneic blood and blood components or blood and blood components derived from an individual which are intended for blood transfusion to another individual for use in medical devices or as starting materials for medicinal products, and autologous blood and blood components or blood and blood components derived from an individual which are intended for blood transfusion or other use solely for that individual, blood or blood components, the reasons for testing and taking a history of the donor, the need to test blood samples, and the importance of informed consent;

38.3. for allogeneic blood or blood components, when to refuse to donate blood and when to temporarily and permanently prohibit the donation of blood, and the reasons why individuals should not donate blood or blood components if this could endanger the health of the patient;

38.4. the possible prohibition of the donation of autologous blood or blood components and the reasons why a blood donation procedure is not permissible if the donor or recipient of autologous blood or blood components may thereby endanger his or her health;

38.5. the reasons why individuals should not donate blood or blood components if this could be detrimental to their health;

38.6. the specific nature of the procedures for the donation of blood or blood components and the related risks, the possible non-conformity of autologous blood and blood components with blood transfusion requirements;

38.7. the right of donors to refuse to donate blood prior to proceeding further, and also the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort;

38.8. the reasons why it is important that donors inform the personnel of the State Blood Donor Centre or blood preparation divisions of any subsequent event that may render any donated blood or blood components unsuitable for transfusion;

38.9. the obligation of the personnel of the State Blood Donor Centre and the blood preparation divisions to inform the donor, as mutually agreed between the donor and the State Blood Donor Centre or blood preparation division, if test results of the donor show any abnormality;

38.10. in which case unused autologous blood and blood components shall be destroyed instead of transfused;

38.11. if the tests reveal markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, the donor shall be prohibited from donating blood and the unit of collected blood shall be destroyed. The results of the donor assessment and testing shall be documented;

38.12. the right of the donor to ask questions;

38.13. the protection of the personal data of the donor, i.e. no unauthorised disclosure of the identity of the donor, of information concerning the state of health of the donor, and of the results of the tests performed;

38.14. the right of the donor to refuse from the compensation for expenditures for the renewal of the lost volume of blood.

[*10 October 2006; 22 December 2009; 27 November 2012; 27 February 2018*]

39. The State Blood Donor Centre and the blood preparation divisions shall receive the following information from the prospective donor:

39.1. personal data by which the donor can be uniquely identified (given name, surname, and personal identity number or national identification number), and also contact information;

39.2. information provided in writing by the donor and obtained in individual interviews with the donor by the medical practitioner, including information on his or her state of health and previous illnesses, and also other relevant data that may help to identify persons whose donated blood or blood components could present a health risk to others (for example, the risk of transmission of a disease or health risk for the donor himself or herself);

39.3. information provided in writing and signed by the donor, and also certified by the medical practitioner responsible for obtaining the health history confirming that:

39.3.1. the donor has read and understood the educational materials provided thereto;

39.3.2. the donor had an opportunity to ask questions;

39.3.3. the donor had been provided with responses to any questions asked;

39.3.4. the person has knowingly consented to be a donor;

39.3.5. in the case of autologous blood or blood components, the donor has been informed of the possible non-conformity of the donated blood or blood components with the intended transfusion requirements;

39.3.6. the donor has certified the accuracy of the information provided thereby.

[*18 January 2022*]

**IX. Data Protection**

40. The State Blood Donor Centre and the blood preparation divisions shall ensure the protection and confidentiality of personal data, and also genetic information by organising:

40.1. security measures to prevent unauthorised addition, deletion, or modification of data in the donor records or in the register of rejected donations and to ensure secure transmission of information;

40.2. appropriate procedure in the event of a data discrepancy;

40.3. non-disclosure of personal data while ensuring traceability.

41. Information on the traceability of human blood and blood components shall be kept for 30 years.

[*10 October 2006*]

41.1 Information on the traceability of human blood and blood components from the State Blood Donor Centre and the blood preparation divisions shall include:

41.11. the name and address of the authority;

41.12. the given name, surname, personal identity number, and declared place of residence of the donor;

41.13. blood unit identification code;

41.14. individual blood component identification code;

41.15. date of blood preparation (day, month, year);

41.16. information on the distribution of blood and blood components to medical treatment institutions or disposal thereof.

[*10 October 2006*]

41.2 Information of the blood transfusion room on the traceability of human blood and blood components shall include:

41.21. supplier identification;

41.22. blood component identification code;

41.23. the given name, surname, personal identity number, and declared place of residence of the recipient;

41.24. for blood units not transfused, confirmation of subsequent disposal;

41.25. date of transfusion or disposition (day, month, year).

[*10 October 2006*]

**X. Closing Provisions**

[*22 December 2009*]

42. The Agency shall submit the report referred to in Sub-paragraph 22.6 of this Regulation on the preceding period to the European Commission for the first time by 1 March 2007.

43. Certificates issued by the Health Statistics and Medical Technologies State Agency to the State Blood Donor Centre, the blood preparation divisions, and the blood transfusion rooms shall be valid until their expiry date.

[*22 December 2009*]

**Informative Reference to European Union Directives**

[*22 December 2009; 28 June 2011; 27 February 2018*]

The Regulation contains legal norms arising from:

1) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;

2) Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components;

3) Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events;

4) Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments;

5) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

6) Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;

7) Commission Directive 2009/135/EC of 3 November 2009 allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic;

8) Commission Implementing Commission 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life;

9) Commission Directive (EU) 2014/110 of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations;

10) Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments.

Acting for the Prime Minister, Minister for Economics A. K. Kariņš

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 1**

Cabinet Regulation No. 1037

27 December 2005

**Blood Sample Testing Requirements**

[*18 January 2022*]

Each blood sample shall be tested as follows:

1. Each blood sample shall undergo immunohematological testing as follows:

1.1. determining the ABO Group and Rh affiliation;

1.2. phenotyping in Rh and Kell systems (first two donation times);

1.3. screening for anti-erythrocyte antibodies (at the first donation and every two years thereafter or as required);

1.4. additional screening for high titre agglutinins, identification of antibodies, detection of clinically relevant antigens of other systems, as required.

2. It shall be checked whether the donor has:

2.1. hepatitis B surface antigen (HBsAg);

2.2. hepatitis C virus antibodies (anti-HCV);

2.3. HIV ½ antibodies (anti-HIV ½);

2.4. antibodies for the causative agent of syphilis.

3. If a negative result is obtained in the tests referred to in Sub-paragraphs 2.1, 2.2, and 2.3 of this Annex, nucleic acid amplification tests (NAT) shall be carried out:

3.1. HCV-NAT;

3.2. HBV-NAT;

3.3. HIV1/2-NAT.

**Annex 2**

Cabinet Regulation No. 1037

27 December 2005

**Quality and Safety Control Requirements for Blood and Blood Components**

[*28 June 2011; 5 April 2016; 27 February 2018*]

Appropriate bacteriological control of the collection and manufacturing process must be performed for blood and blood components. Quality control and quality control results shall conform to the following requirements:

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Component | Quality measurements required(*the required frequency of sampling for all measurements shall be determined using statistical process control19)*) | Acceptable results for quality measurements |
| 1. | Red cell mass3) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis |
| Haemoglobin\* | Not less than 45 g per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 2. | Red cell mass, buffy coat removed4) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haematocrit |
|  | Haemoglobin\* | Not less than 43 g per dose |
| Haematocrit | 0.65–0.75 |
| Residual leucocyte count | Less than 1.2 x 109 per dose (90 % of tested samples must conform to the requirement) |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 3. | Red cell mass, leucocyte-depleted5) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis |
| Haemoglobin\* | Not less than 40 g per dose |
| Leucocyte content | Less than 1 × 106 per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 4. | Red cell mass, in additive solution6) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis |
| Haemoglobin\* | Not less than 45 g per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 5. | Red cell mass, buffy coat removed, in additive solution7) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haematocrit |
| Haemoglobin\* | Not less than 43 g per dose |
| Haematocrit | 0.50–0.70 |
| Residual leucocyte count | Less than 1.2 x 109 per dose (90 % of tested samples must conform to the requirement) |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 6. | Red cell mass, leucocyte-depleted, in additive solution8) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis |
| Haemoglobin\* | Not less than 40 g per dose |
| Leucocyte content | Less than 1 × 106 per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 7. | Red cell mass derived from apheresis9) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis |
| Haemoglobin\* | Not less than 40 g per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 8. | Whole blood1) | Volume | Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450 ml +/- 50 ml |
| For paediatric autologous whole blood collections – not to exceed 10.5 ml per kg body weight |
| Haemoglobin\* | Not less than 45 g per dose |
| Haemolysis | Less than 0.8 % of red cell mass at the end of the shelf life |
| 9. | Platelet mass derived from apheresis10) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per single donation are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 10. | Platelet mass derived from apheresis, leucocyte-depleted11) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per single donation are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| Leucocyte count | Less than 1 × 106 per dose |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 10.1 | Platelet mass derived from apheresis, leucocyte-depleted11)AFTER PATHOGEN INACTIVATION | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet count per single inactivation are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| 11. | Platelet mass derived from several whole-blood doses12) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per pool are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| Leucocyte count | Less than 0.2 × 109 per dose (platelet-rich plasma method). |
| Less than 0.05 × 109 per dose (buffy coat method) |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 12. | Leucocyte-depleted platelet mass derived from several whole-blood doses13) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per pool are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| Leucocyte count | Less than 1 × 106 combined per pool |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 12.1 | Leucocyte-depleted platelet mass derived from several whole-blood doses13)AFTER PATHOGEN INACTIVATION | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet count per single inactivation are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| 13. | Platelet mass derived from a single whole-blood dose14) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per dose are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| Leucocyte count | Less than 0.2 × 109 per dose (platelet-rich plasma method). |
| Less than 0.05 × 109 per single dose (buffy coat method) |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 14. | Leucocyte-depleted platelet mass derived from a single whole-blood dose15) | Volume | Valid for storage characteristics to maintain product within specifications for pH |
| Platelet count | Variations in platelet content per dose are acceptable, provided that they do not exceed limits that comply with validated preparation and preservation conditions |
| Leucocyte count | Less than 1 × 106 per dose |
| pH | not less than 6.4 at the end of the shelf life, at 22 °C |
| 15. | Plasma, fresh-frozen16) | Volume | Stated volume +/- 10 % |
| Factor VIII\* | Average (after freezing and thawing) – 70 % or more of the value of the freshly collected plasma factor VIII |
| Total protein\* | Not less than 50 g/l |
| Residual cellular content\* | Red cells – less than 6.0 × 109/l |
| Leucocytes – less than 0.1 × 109/l |
| Platelets – less than 50 × 109/l |
| 16. | Plasma, cryoprecipitate-depleted17) | Volume | Stated volume +/- 10 % |
| Residual cellular content\* | Red cells – less than 6.0 × 109/l |
| Leucocytes – less than 0.1 × 109/l |
| Platelets – less than 50 × 109/l |
| 17. | Cryoprecipitate2) | Fibrinogen content\* | ≥ 140 mg per unit |
| Factor VIII content\* | ≥ 70 IU per unit |
| Von Willebrand factor content\* | > 100 IU per unit |
| 18. /p> | Granulocytes derived from apheresis18) | Volume | Less than 500 ml |
| Granulocyte content | Greater than 1 × 1010 granulocytes per unit |

Notes. 1.\* For autologous blood or blood components, the requirements laid down in these Notes shall be of a recommendatory nature.

2.sup>1) Whole blood means the dose of blood obtained in a blood preparation procedure.

3.2) Cryoprecipitate means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.

4.3) Red cell mass means the red cells from whole blood with a large proportion of the plasma removed.

5.4) Red cells, buffy coat removed means the red cells from whole blood with a large proportion of the plasma, leucocytes, and platelets removed.

6.5) Leucocyte-depleted red cells means red cells from whole blood with a large proportion of the plasma and from which leucocytes are removed.

7.6) Red cell mass in replacement solution means the red cells from whole blood with a large proportion of the plasma removed and replacement solution added.

8.7) Red cell mass, buffy coat removed in replacement solution means red cells from whole blood with a large proportion of the plasma and buffy coat containing most of leucocytes and platelets removed and replacement solution added.

9.8) Leucocyte-depleted red cell mass in replacement solution means red cells from whole blood with a large proportion of the plasma and from which leucocytes are removed. Replacement solution added.

10.9) Red cell mass derived from apheresis means red cells obtained by the red cell apheresis procedure.

11.10) Platelet mass derived from apheresis means a concentrated suspension of platelets obtained by apheresis.

12.11) Leucocyte-depleted platelet mass derived from apheresis means a concentrated suspension of platelets obtained by apheresis from which leucocytes are removed.

13.12) Platelet mass derived from multiple doses of whole blood means a concentrated suspension of platelets obtained by processing doses of whole blood and combining the platelets from these doses during or after separation.

14.13) Leucocyte-depleted platelet mass derived from several whole-blood doses means a concentrated suspension of platelets derived from processing doses of whole blood and combining the platelets of these doses during or after separation and separating the leucocytes.

15.14) Platelet mass prepared from a single does of whole blood means a concentrated suspension of platelets obtained by processing a single dose of whole blood.

16.15) Leucocyte-depleted platelet mass derived from a single dose of whole blood means a concentrated suspension of platelets obtained by processing a single dose of whole blood from which leucocytes are removed.

17.16) Fresh-frozen plasma means plasma separated from whole blood by centrifugation or plasma obtained by apheresis and frozen for storage.

18.17) Cryoprecipitate-depleted plasma means the portion of plasma remaining from a single unit of fresh-frozen plasma after removal of the cryoprecipitate.

19.18) Granulocytes derived from apheresis means a concentrated suspension of granulocytes obtained by the apheresis procedure.

20.19) Statistical process control means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 3**

Cabinet Regulation No. 1037

27 December 2005

**Storage, Transportation, and Distribution of Blood and Blood Components**

[*10 October 2006*]

1. Storage of blood and blood components:

1.1. liquid storage

|  |  |  |
| --- | --- | --- |
| Component | Temperature of storage | Maximum storage time |
| Red cell preparations and whole blood (if used for transfusion as whole blood) | +2 to +6 °C | 28 to 49 days according to the processes used for collection, processing, and storage |
| Platelet preparations | +20 to +24 °C | Five days; may be stored for seven days in conjunction with detection or reduction of bacterial contamination |
| Granulocytes | +20 to +24 °C | 24 hours |

1.2. frozen storage

|  |  |
| --- | --- |
| Component | Storage conditions and duration |
| Red cells\* | Up to 30 years according to processes used for collection, processing, and storage |
| Platelets\* | Up to 24 months according to processes used for collection, processing, and storage |
| Plasma and cryoprecipitate | Up to 36 months according to processes used for collection, processing, and storage |

Note.\* Frozen red cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.

2. During transportation and distribution of blood and blood components, the State Blood Donor Centre and the blood preparation divisions shall ensure that the integrity and quality of the product is maintained at all stages.

3. During storage, transportation, and distribution of blood and blood components, the State Blood Donor Centre and the blood preparation divisions shall ensure conformity with the following requirements:

3.1. autologous blood and blood components shall be identified, stored, transported, and distributed separately from allogeneic blood and blood components;

3.2. the label of autologous blood and blood components must include the donor identification number and the warning: “Tikai autologai asins pārliešanai” [For autologous transfusion only].

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 4**

Cabinet Regulation No. 1037

27 December 2005

**Acceptance Criteria for Donors of Blood and Blood Components**

[*22 December 2009*]

1. Age and body weight of donors

|  |  |  |
| --- | --- | --- |
| 1.1. Age | 18 to 65 years |   |
| 17 to 18 years | if the donor is not a minor in accordance with laws and regulations or if there is written consent from a parent or lawful guardian who conforms to the requirements laid down in laws and regulations |
| donors over 60 years of age donating blood/blood components for the first time | at the discretion of the physician |
| over 65 years | with permission of the physician given annually |
| 1.2. Body weight | ≥ 50 kg for donors either of whole blood or apheresis blood components |

2. Haemoglobin levels in donor’s blood

|  |  |  |  |
| --- | --- | --- | --- |
| Haemoglobin\* | for females ≥ 125 g/l | for males ≥ 135 g/l | Applicable to allogeneic donors of whole blood and cellular components |

Note. \* Due to the risk of blood shortage caused by the influenza A (H1N1) pandemic, for the period until 30 June 2010, the Hb level shall be as follows: for women > 120 g/l, for men > 130 g/l (effective if the competent national authority declares an influenza A (H1N1) epidemic and the State Blood Donor Centre is informed that there is a risk of blood shortage).

3. Protein levels in donor’s blood

|  |  |  |
| --- | --- | --- |
| Proteins | > 60 g/l | The protein analysis for apheresis plasma donations must be performed at least annually |

4. Platelet levels in donor’s blood

|  |  |  |
| --- | --- | --- |
| Platelets | Platelet number greater than or equal to 150 × 109/l | Level required for apheresis platelet donors |

Note. \*Criteria do not apply to autologous blood and blood components.

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 5**

Cabinet Regulation No. 1037

27 December 2005

**Deferral Criteria for Donors of Whole Blood and Blood Components**

[*10 October 2006; 22 December 2009; 27 November 2012; 27 February 2018*]

1. Permanent deferral criteria for donors of allogeneic blood or blood donations

|  |  |
| --- | --- |
| 1.1. Cardiovascular disease | Prospective donors with active or past serious cardiovascular disease, except for congenital abnormalities with complete cure |
| 1.2. Central nervous system disease | History of serious central nervous system disease |
| 1.3. Increased tendency to bleed | Prospective donors who give a history of a coagulopathy |
| 1.4. Repeated episodes of syncope or a history of convulsions | Except for childhood convulsions or cases where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions |
| 1.5. Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases | Prospective donors with serious active, chronic, or relapsing disease |
| 1.6. Diabetes | If the donor is treated with insulin |
| 1.7. Infectious diseases | Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune |
| Hepatitis C |
| HIV-1/2 |
| HTLV I/II |
| Babesiosis\* |
| Kala Azar (visceral leishmaniasis)\* |
| Trypanosomiasis cruzi (Chagas’ disease)\* |
| 1.8. Malignant diseases | Except for cases of *in situ* cancer with complete recovery |
| 1.9. Transmissible spongiform encephalopathies (TSEs), (for example, Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease) | Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended |
| 1.10. Intravenous (IV) or intramuscular (IM) drug use | Any history of non-prescribed IV or IM drug use, including bodybuilding steroids or hormones |
| 1.11. Xenotransplant recipients |   |
| 1.12. Sexual behaviour | Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood |

2. Temporary deferral criteria for allogeneic blood and blood component donors

2.1. Infections

After an infectious disease, prospective donors shall be prohibited from donating blood or blood components at least two weeks following the date of full clinical recovery, except for infectious diseases whereto the following deferral periods apply:

|  |  |
| --- | --- |
| 2.1.1. Brucellosis\* | two years following the date of full recovery |
| 2.1.2. Osteomyelitis | two years after confirmed cured |
| 2.1.3. Q fever\* | two years after confirmed cured |
| 2.1.4. Syphilis\* | one year following the date of confirmed cured |
| 2.1.5. Toxoplasmosis\* | six months following the date of clinical recovery |
| 2.1.6. Tuberculosis | two years after confirmed cured |
| 2.1.7. Rheumatic fever | two years following the date of cessation of symptoms, unless evidence of chronic heart disease |
| 2.1.8. Fever > °C | two weeks following the date of cessation of symptom |
| 2.1.9. Flu-like illness | two weeks after cessation of symptoms\*\* |
| 2.1.10. Malaria\*: |   |
| 2.1.10.1. individuals who have lived in a malarial area within the first five years of life | three years following return from last visit to any endemic area, provided that the person remains symptom free; this period may be reduced to four months if an immunologic or molecular genomic test is negative at each donation |
| 2.1.10.2. individuals with a history of malaria | three years following cessation of treatment and absence of symptoms. This period shall be determined if an immunologic or molecular genomic test is negative |
| 2.1.10.3. asymptomatic visitors to endemic areas | six months after leaving the endemic area unless an immunologic or molecular genomic test is negative |
| 2.1.10.4. individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area | three years following resolution of symptoms; this period may be reduced to four months if an immunologic or molecular test is negative |
| 2.1.10.5. West Nile Virus (WNV)\* | 28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative |

2.2. Exposure to risk of acquiring a transfusion-transmissible infection

|  |  |
| --- | --- |
| 2.2.1. Endoscopic examination using flexible instruments | prohibit the donor from donating blood/blood components for six months, or for four months provided a NAT test for hepatitis C is negative |
| 2.2.2. Mucosal splash with blood or needlestick injury |
| 2.2.3. Transfusion of blood components |
| 2.2.4. Tissue or cell transplant of human origin |
| 2.2.5. Major surgery |
| 2.2.6. Tattoo or body piercing |
| 2.2.7. Acupuncture unless performed by a qualified practitioner and with sterile single-use needles |
| 2.2.8. Persons at risk due to close household contact with persons with hepatitis B |
| 2.2.9. Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood | prohibit the donor from donating blood/blood components after cessation of risk behaviour for a period determined by the respective disease and by the availability of appropriate tests |

2.3. Vaccination

|  |  |
| --- | --- |
| 2.3.1. Attenuated viruses or bacteria | four weeks |
| 2.3.2. Inactivated/killed viruses, bacteria or rickettsiae | no deferral if well |
| 2.3.3. Toxoids | no deferral if well |
| 2.3.4. Hepatitis A or hepatitis B vaccines | no deferral if well and if no exposure |
| 2.3.5. Rabies | no deferral if well and if no exposure. If vaccination is given after exposure of the donor to, defer for one year |
| 2.3.6. Tick-borne encephalitis vaccines | no deferral if well and if no exposure |

2.4. Other temporary deferrals

|  |  |
| --- | --- |
| 2.4.1. Pregnancy | six months after delivery or termination, except for exceptional circumstances and at the discretion of a physician |
| 2.4.2. Minor surgery | one week |
| 2.4.3. Dental treatment | minor treatment by dentist or dental hygienist – defer until next day. Tooth extraction, root-filling and similar treatment is considered as minor surgery |
| 2.4.4. Medication | based on the nature of the prescribed medicine, its mode of action, and the disease being treated |

3. Deferral for particular epidemiological situations

|  |  |
| --- | --- |
| Particular epidemiological situations (for example, disease outbreaks) | Deferral consistent with the epidemiological situation. (These deferrals should be notified by the competent authority to the European Commission with a view to Community action) |

4. Deferral criteria for donors of autologous blood/blood components

|  |  |
| --- | --- |
| 4.1. Serious cardiac disease | Depending on the clinical setting |
| 4.2. Persons with or with a history of: | Member States may establish specific provisions for autologous donations by such persons |
| 4.2.1. Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune |
| 4.2.2. Hepatitis C |  |
| 4.2.3. HIV-1/2 |  |
| 4.2.4. HTLV I/II |  |
| 4.2.5. Active bacterial infection |  |

Notes.

\* The abovementioned test and the deferral period shall not apply if the donated blood or blood components are used to obtain plasma for fractionation.

\*\* Due to the risk of blood shortage caused by pandemic influenza A (H1N1), until 30 June 2010, a refusal shall be established seven days after cessation of the disease, if the competent national authority has declared an influenza A (H1N1) epidemic and information has been received from the State Blood Donor Centre that there is a risk of blood shortage.

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 6**

Cabinet Regulation No. 1037

27 December 2005

**Quality System Standards and Specifications in the State Blood Donor Centre and the Blood Preparation Divisions**

[*10 October 2006; 22 December 2009; 27 November 2012; 5 April 2016*]

**1. Quality System**

1.1. Quality shall be ensured by all persons involved in the management of the State Blood Donor Centre and the blood preparation divisions who are responsible for the implementation and maintenance of the quality system.

1.2. The quality system shall cover quality management, quality assurance, continuous quality improvement, personnel, premises and medical devices, documentation, preparation, testing, and processing of blood and blood components, storage, distribution, quality control, blood component recall, internal and external audit, contract management, and non-conformity management.

1.3. The quality system shall be established by ensuring that all processes are covered by appropriate standard procedure descriptions. The management of the State Blood Donor Centre and the blood preparation divisions shall regularly review the quality system, examining the efficiency thereof and identifying corrective actions, where necessary.

**2. Quality Assurance**

All procedures, premises, and medical devices affecting the quality and safety of blood and blood components shall be validated prior to implementation and re-validated at scheduled regular intervals in accordance with the laws and regulations regarding the procedures for the registration, conformity assessment, distribution, operation, and technical supervision of medical devices.

**3. Personnel and Organisation**

3.1. The management of the State Blood Donor Centre and the blood preparation divisions shall determine the number of personnel to ensure the quality of the preparation, testing, processing, storage, and distribution of blood and blood components.

3.2. The personnel shall be trained and recognised as competent for the performance of the tasks assigned thereto.

3.3. The personnel shall have the appropriate knowledge in order to receive the certificate of a medical practitioner. The head of a medical treatment institution or unit shall assess the competence of the medical practitioner.

3.4. The duties and responsibilities of the personnel shall be defined in individual job descriptions that shall be updated as necessary.

3.5. The management of the State Blood Donor Centre and the blood preparation divisions shall designate several persons responsible for the organisation and quality assurance of the processing of blood and blood components and who shall act independently.

3.6. The management of the State Blood Donor Centre and the blood preparation divisions shall ensure regular improvement of the qualification of the personnel and shall keep documentary evidence of training related to improvement of the qualification. Training programmes shall cover the aspects of good practice.

3.7. The management of the State Blood Donor Centre and the blood preparation divisions shall periodically review the training programmes and assess the competence of the personnel.

3.8. The management of the State Blood Donor Centre and the blood preparation divisions shall ensure that written instructions on safety and hygiene are in place.

**4. Premises**

4.1. Premises, including mobile sites, shall be suitable and maintained according to the nature of the activities.

4.2. Premises shall be easily cleanable and maintained to minimise the risk of contamination.

4.3. Work shall be organised in a logical manner to minimise the risk of errors.

**5. Blood Donor Room**

A separate area shall be set up in the premises of the State Blood Donor Centre and the blood preparation divisions for confidential conversations with a person in order to assess the suitability of the person to donate blood.

**6. Blood Preparation Room**

The blood preparation room shall be equipped appropriately in order to ensure the safety of both donors and personnel and also to avoid errors in the collection procedure. The room shall be equipped appropriately for the safe withdrawal of blood from donors and, if necessary, to provide first aid to donors experiencing an adverse reaction or event related to the donation.

**7. Blood Testing and Processing Area**

7.1. There shall be a dedicated laboratory area for testing (hereinafter – the laboratory) which is separate from the blood donor room and the blood component processing area.

7.2. The State Blood Donor Centre and the blood preparation divisions shall organise the necessary measures to ensure that only authorised personnel may enter the laboratory.

**8. Blood and Blood Component Storage Area**

8.1. The blood and blood component storage area shall provide for properly secure and segregated storage of different categories of blood and blood components, including units of blood and blood components collected under special criteria (for example, autologous blood).

8.2. Measures shall be organised in the blood and blood component storage area to prevent damage to medical devices or power failure.

**9. Medical Waste Disposal Area**

The State Blood Donor Centre and the blood preparation divisions shall provide a place for the safe disposal of medical waste, disposable items used in withdrawal, testing, and processing of blood and for the storage of rejected blood or blood components.

**10. Medical Devices, Materials, and Reagents**

10.1. All medical devices of the State Blood Donor Centre and the blood preparation divisions shall be validated, calibrated, and maintained according to the intended purpose of use in accordance with the laws and regulations regarding the procedures for the registration, conformity assessment, distribution, operation, and technical supervision of medical devices.

10.2. Instructions for use (manuals) for the medical devices of the blood service shall be available to the personnel.

10.3. The State Blood Donor Centre and the blood preparation divisions shall take the necessary measures to record in writing all actions referred to Sub-paragraph 10.1 of this Annex.

10.4. The State Blood Donor Centre and the blood preparation divisions shall select such medical devices that minimise any risk to the donor, the personnel, the blood or blood components.

10.5. The State Blood Donor Centre and the blood preparation divisions shall use reagents and materials which are supplied by recognised (registered) suppliers in accordance with the established procedures and which conform to the documented requirements and specifications in accordance with the laws and regulations regarding the procedures for the registration, conformity assessment, distribution, operation, and technical supervision of medical devices.

10.6. Critical materials (materials that directly affect the quality of blood and blood components) shall be issued by a person who is recognised as being competent. The personnel shall have the appropriate knowledge in order to receive the certificate of a medical practitioner. The head of a medical treatment institution or unit shall assess the competence of the medical practitioner.

10.7. The list of medical devices shall be drawn up and kept by the State Blood Donor Centre and the blood preparation division in accordance with the requirements stipulated by the Agency.

10.8. If a computer system is used by the State Blood Donor Centre and the blood preparation division, regular checks of the software and hardware shall be organised and a procedure for the backing up of records shall be ensured. In order to ensure the reliability of records, systems shall be validated before use and maintained in such state as they were in at the time of validation.

10.9. The procedure for the backing up of records is organised in such a way as to prevent the loss or corruption of data (registered information) during computer system malfunctions.

10.10. The State Blood Donor Centre and the blood preparation division shall organise measures to ensure the protection of hardware and software against unauthorised use and modification.

**11. Documentation**

11.1. The documents of the State Blood Donor Centre and the blood preparation divisions containing the specifications, procedures, and records for each activity carried out shall be accessible to the personnel and shall be updated on a regular basis.

11.2. The records shall be clearly legible.

11.3. All significant changes to the documents shall be made, reviewed, dated, and signed by an authorised person the scope of whose authority shall be determined by the head of the State Blood Donor Centre, blood preparation division, or blood transfusion room.

**12. Donor Eligibility Assessment**

12.1. The State Blood Donor Centre and the blood preparation divisions shall develop and implement specific procedures in order to ensure safe donor identification, suitability interview of the donor, and eligibility assessment of donors. The abovementioned procedures shall be ensured before each blood donation.

12.2. Interview with the donor shall take place by ensuring confidentiality.

12.3. The notes on the eligibility assessment of the donor shall be signed by a medical practitioner who is recognised as being competent. The personnel shall have the appropriate knowledge in order to receive the certificate of a medical practitioner. The head of a medical treatment institution or unit shall assess the competence of the medical practitioner.

**13. Preparation, Testing, and Processing of Blood**

13.1. The blood withdrawal procedure shall be organised in a way to ensure that the identity of the donor is verified, that donor data are recorded, and that the link between the donor, blood, blood components, and blood samples is clearly traceable.

13.2. Sterile blood bag systems with CE conformity marking shall be used in the preparation and processing of blood and blood components. The serial numbers of the systems shall be traceable on all bags of blood or blood components.

13.3. Blood preparation procedures shall be carried out to avoid the risk of bacterial contamination.

13.4. Blood samples shall be taken at the time of donation and stored in accordance with storage requirements until examination thereof.

13.5. The procedure used for labelling records, bags of blood or blood components, and laboratory samples with blood dose numbers shall be designed to avoid the risk of misidentification.

13.6. After preparation, the bag of blood or blood components shall be handled in such a way as to preserve the quality of the blood prepared. The bag of blood or blood components shall be stored and transported at a temperature which meets the requirements for further handling in accordance with Annexes 2 and 3 to this Regulation.

13.7. The State Blood Donor Centre and the blood preparation divisions shall provide a system for linking each unit of blood to the State Blood Donor Centre or blood preparation division where the unit of blood has been prepared or processed.

**14. Laboratory Testing**

14.1. All laboratory testing procedures shall be validated before use.

14.2. Each blood sample shall be tested in accordance with the requirements laid down in Annex 1 to this Regulation.

14.3. The State Blood Donor Centre and the blood preparation divisions shall clearly define the procedures to resolve discrepant results and to ensure that blood and blood components which have a repeatedly reactive result in a serological screening test are not used for transfusion and be stored separately, and also to ensure appropriate confirmatory testing in an appropriate laboratory in accordance with the laws and regulations regarding mandatory requirements for medical treatment institutions and units thereof. In case of confirmed positive results, the donor shall be informed thereof in accordance with the approved procedures and retrospective testing shall be initiated.

14.4. There shall be data confirming the suitability of any laboratory reagents used in the testing of donor blood samples.

14.5. The quality of the laboratory testing shall be regularly monitored in periods specified by the head of the laboratory by the participation in a formal system of proficiency testing, for example, an external quality assurance programme.

14.6. Blood group serology testing shall include testing of specific groups of donors (for example, first time donors, donors with a history of transfusion).

**15. Processing and Validation**

15.1. All equipment and technical devices shall be used in accordance with validated procedures.

15.2. The processing of blood components shall be carried out in accordance with appropriate and validated procedures, including measures to avoid contamination of the prepared blood components.

**16. Labelling**

16.1. All bags of blood and blood components shall be labelled with relevant information on their identity in accordance with the requirements laid down in Paragraph 34 of this Regulation. In the absence of a validated computerised system for the control of the bags of blood and blood components, the bag of blood and blood components shall be labelled in a way to clearly distinguish distributed blood or blood components from non-distributed blood or blood components.

16.2. The labelling system for the prepared blood, intermediate products, blood components and samples shall be organised in a way to identify unmistakably the prepared blood, intermediate products, blood components and samples, and also to ensure the conformity of the system with the labelling and traceability requirements.

16.3. The label for autologous blood and blood components shall conform to specific requirements approved in accordance with the laws and regulations regarding the procedures for approving medical technologies to be used in medical treatment and for introducing new medical technologies.

**17. Release of Blood and Blood Components**

17.1. The State Blood Donor Centre and the blood preparation divisions shall organise a safe and secure system to prevent release of blood and blood components prior to fulfilment of mandatory requirements. There must be evidence that each dose of blood or blood components has been released by an authorised person. Records shall demonstrate that prior to release of components, all relevant forms, medical records, and test results conform to all acceptance criteria.

17.2. Prior to release, blood and blood components shall be kept separately from components subject to release. In the absence of a validated computerised system for the identification and control of blood and blood components, the label of blood and blood components shall identify the release status.

17.3. In the event of a failure to release blood or blood components due to a confirmed positive infection test result, a check shall be made to ensure identification of other blood and blood components from the same donation and from previous donations, and this shall be recorded immediately in the documentation.

**18. Storage and Distribution**

18.1. The quality system of the State Blood Donor Centre and the blood preparation divisions shall ensure the conformity of the requirements for the storage and distribution of blood and blood components intended for the manufacture of medicinal products with the principles and guidelines of good manufacturing practice of medicinal products laid down in the laws and regulations regarding manufacturing and control of medicinal products, and also with the requirements detailed in the guidelines of the European Commission regarding good manufacturing practice of medicinal products and investigational medicinal products (Annex 14 to the volume of documents “The rules governing medicinal products in the European Union”) published on the website of the State Agency of Medicines (www.zva.gov.lv).

18.2. Procedures for storage and distribution shall be validated to ensure blood component quality during the storage period and to exclude mix-ups of blood components. All transportation and storage procedures and specifications, including receipt and distribution, shall be drawn up in writing.

18.3. Autologous blood and blood components, and also blood components prepared for specific purposes shall be stored separately.

18.4. Necessary records on the circulation of medical devices, equipment, and blood or blood components shall be made and also kept.

18.5. Blood and blood components shall be appropriately packaged to ensure the integrity and temperature of blood and blood components in accordance with the requirements laid down in Annex 3 to this Regulation.

18.6. The State Blood Donor Centre and the blood preparation division shall not accept returned blood components and blood preparations that have undergone distribution.

**19. Non-conformity**

19.1. Blood components deviating from the requirements laid down in accordance with Annex 2 to this Regulation shall be allowed for transfusion only in exceptional circumstances and with written consent of the attending physician and the physician who is responsible for the activity of the respective unit.

19.2. All complaints and other information, including on serious adverse reactions and adverse events, which may suggest the release of defective blood components, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by corrective actions to prevent recurrence. A procedure shall be in place to ensure that the Agency is notified of serious adverse reactions or serious adverse events.

19.3. There shall be an authorised person with the capacity to assess the need for blood or blood component recall and to coordinate further actions.

19.4. A recall procedure shall be in place for blood and blood components unsuitable for effective use, containing a description of the responsibilities and actions to be taken in the case of a recall, including notification to the Agency.

19.5. Actions shall be taken within specific periods of time which include traceability of all blood components and, where applicable, also trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from the respective donor, and also to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

**20. Corrective and Preventive Actions**

20.1. The State Blood Donor Centre and the blood preparation division shall establish a system to ensure that the necessary corrective and preventive actions are taken if blood components deviate from the prescribed requirements and also deviate from quality requirements.

20.2. Available data shall be analysed in order to identify quality problems and to ensure that the necessary corrective actions are taken, and also to identify unfavourable trends and to ensure the necessary preventive actions for elimination thereof.

20.3. All errors and accidents shall be documented and investigated in order to identify problems that need to be eliminated.

**21. Internal Audit and Improvements**

21.1. The State Blood Donor Centre and the blood preparation division shall establish an internal audit system in order to ensure the fulfilment of conformity requirements of the blood service. The internal audit shall be carried out by an independent, appropriately trained personnel.

21.2. All results of the internal audit shall be documented and effective corrective and preventive actions shall be taken in the specific period of time.

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 7**

Cabinet Regulation No. 1037

27 December 2005

**Quality System Standards and Specifications for a Blood Transfusion Room**

[*10 October 2006*]

**1. Quality Assurance**

1.1. The receipt of blood components from the State Blood Donor Centre or blood preparation division (hereinafter – the establishment), the storage, the release of compatible components for transfusion in its medical treatment institution and also the transfusion assistance in a medical treatment institution shall be supervised by a designated unit of the medical treatment institution (hereinafter – the blood transfusion room).

1.2. A quality system shall be established to ensure the activity of the blood transfusion room.

1.3. All procedures, premises and devices of the blood transfusion room which might affect the quality and safety of blood components shall be validated prior to the use thereof and re-validated at scheduled regular intervals in accordance with the laws and regulations regarding the procedures for the registration, conformity assessment, distribution, operation, and technical supervision of medical devices.

**2. Personnel and Organisation**

2.1. The number of the personnel in the blood transfusion room shall be determined in a way to ensure the quality of all activities related to the continuous receipt of blood components from the establishment and their release for transfusion.

2.2. The personnel shall be trained and recognised as competent for the performance of the tasks assigned thereto.

2.3. The personnel shall have the appropriate knowledge in order to receive the certificate of a medical practitioner. The head of a medical treatment institution or unit shall assess the competence of the medical practitioner.

2.4. The duties and responsibilities of the personnel shall be defined in individual job descriptions that shall be updated as necessary. The person responsible for ensuring the operation of the blood transfusion room shall not be employed by the blood preparation division.

2.5. The personnel shall have initial and further training (improvement of the qualification) appropriate to their specific tasks. The personnel training shall be planned, organised, and monitored in accordance with a documented training programme which includes the principles of good practice.

2.6. The management of the blood transfusion room shall periodically review the training programmes and assess the competence of the personnel.

**3. Premises**

3.1. The blood transfusion room shall have a sufficient number of premises to accommodate the personnel and medical devices. The premises shall be easy to clean and maintain.

3.2. Work shall be organised in a logical manner to minimise the risk of errors.

3.3. Storage areas shall ensure properly secure and segregated storage of different categories of blood components.

3.4. Measures shall be taken in the blood and blood component storage area to prevent damage to medical devices or power failure.

**4. Medical Devices and Materials**

4.1. All medical devices of the blood transfusion room shall be validated or calibrated and maintained according to the intended purpose of use in accordance with the laws and regulations regarding the procedures for the registration, conformity assessment, distribution, operation, and technical supervision of medical devices.

4.2. Instructions for use (manuals) for the medical devices of the blood transfusion room shall be available to the personnel.

4.3. The blood transfusion room shall take the necessary measures to record in writing all actions referred to Sub-paragraph 4.1 of this Annex.

4.4. The blood transfusion room shall select such medical devices that minimise any risk to the personnel, the blood or blood components.

4.5. If a computer system is used, regular software and hardware checks and a procedure for backing up records shall be ensured. In order to ensure the reliability of records, systems shall be validated before use and maintained in such state as they were in at the time of validation.

4.6. The procedure for the backing up of records is organised in such a way as to prevent the loss or corruption of data (registered information) during computer system malfunctions.

4.7. The blood transfusion room shall organise measures to ensure the protection of hardware and software against unauthorised use and modification.

4.8. A high quality communication system (internal and external) shall be established and maintained in the blood transfusion room.

**5. Documentation**

5.1. The blood transfusion room shall ensure that the following information is kept in writing:

5.1.1. information on the request, receipt, and issuance of blood components for transfusion;

5.1.2. information on the storage conditions of blood components (continuous monitoring of the temperature);

5.1.3. information on the issuer and recipient of the blood components;

5.1.4. information on serious adverse reactions and adverse events during or after transfusion of blood or blood components;

5.1.5. information on prevented events;

5.1.6. information on the traceability of blood components, including:

5.1.6.1. the name and address of the blood component establishment;

5.1.6.2. the blood component identification code;

5.1.6.3. the given name, surname, personal identity number, declared place of residence of the recipient;

5.1.6.4. for blood units not transfused, confirmation of subsequent disposal;

5.1.6.5. the date of transfusion or disposal of blood components (date, month, year);

5.1.7. information on the training of the personnel and medical practitioners.

5.2. The blood transfusion room shall ensure written documentation of the following procedures:

5.2.1. the transportation, receipt, storage, issuance of blood components to ensure the quality of blood components until transfusion thereof. The documents of the blood transfusion room containing specifications, procedures, and records for each activity carried out shall include conditions for the control of storage parameters and, if necessary, for the transfer of blood components;

5.2.2. prompt cooperation with the blood establishment and the Agency in the event of serious adverse reactions and adverse events during or after transfusion of blood or blood components;

5.2.3. the action to be taken when the release of an incompatible red cell mass for transfusion is permissible;

5.2.4. the conditions under which blood components shall or shall not be issued for transfusion if they do not conform to the requirements laid down in Annex 2 to this Regulation;

5.2.5. the condition that any unit of blood components issued shall be transfused to the intended recipient or, if not transfused, disposal thereof shall be verified;

5.2.6. cooperate with the laboratory to ensure that compatible blood components are issued for transfusion;

5.2.7. return of non-transfused blood components.

5.3. The documents of the blood transfusion room containing the specifications, procedures, and records for each activity carried out shall be accessible to the personnel and shall be updated (if necessary).

5.4. All relevant changes to the documents shall be made, reviewed, dated, and signed by the authorised person.

5.5. The records shall be clearly legible. The blood transfusion room shall ensure that records are accessible to the personnel of the blood establishment, regardless of the information (data) carrier. Suitable conditions shall be ensured in the area where records are stored to prevent their deterioration, destruction, or unauthorised use.

**6. Storage and Issuance**

6.1. Procedures for the storage and issuance of blood components shall be validated to ensure blood component quality throughout the storage period and to exclude mix-ups of blood components.

6.2. Autologous blood and blood components, and also blood components prepared for specific purposes shall be stored separately.

**7. Corrective and Preventive Actions**

7.1. A system shall be established in the blood transfusion room to ensure that the necessary corrective actions are taken if blood components deviate from quality requirements.

7.2. Data (information) shall be regularly analysed to identify quality problems and to ensure that the necessary corrective actions are taken.

7.3. All errors and accidents shall be documented and investigated in the blood transfusion room in order to identify problems that need to be eliminated.

7.4. The blood transfusion room shall document and maintain the procedures for preventive actions to identify the possible cause of non-compliance of blood or blood components.

**8. Self-inspection and Improvements**

8.1. The blood transfusion room shall establish and maintain a self-inspection system to verify the conformity of the blood transfusion room with the requirements of this Regulation.

8.2. All results of the self-inspection shall be documented and effective corrective and preventive actions shall be taken in the specific period of time.

Acting for the Minister for Health, Minister for Finance O. Spurdziņš

**Annex 8**

Cabinet Regulation No. 1037

27 December 2005

**Notification of Serious Adverse Reactions**

[*22 February 2022*]

**PART A**

**Rapid Notification of Serious Adverse Reactions**

1. Reporting establishment

2. Report number

3. Reporting date . . .

4. Date of transfusion . . .

5. Age of recipient: \_\_\_\_\_ years

6. Sex of recipient:

male female

7. Date of serious adverse reaction . . .

8. Serious adverse reaction is related to:

 whole blood

red cells

platelets

plasma

other (please, specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Type of serious adverse reaction:

immunological haemolysis due to ABO incompatibility

immunological haemolysis due to other allo-antibody

 non-immunological haemolysis

transfusion-transmitted bacterial infection

anaphylaxis/hypersensitivity

transfusion related acute lung injury

transfusion-transmitted viral infection (HBV)

transfusion-transmitted viral infection (HCV)

transfusion-transmitted viral infection (HIV-I/II)

transfusion-transmitted viral infection (please, specify)

transfusion-transmitted parasitical infection (Malaria)

transfusion-transmitted parasitical infection, other (please, specify)

post-transfusion purpura

graft versus host disease (GVHD)

other serious reaction(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. Imputability level (NA, 0–3)

**PART B**

**Imputability Levels of Serious Adverse Reaction**

|  |  |
| --- | --- |
| Imputability levels | Explanation |
| NA | Not assessable | If there is insufficient data for imputability assessment |
| 0 | Excluded | If there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes |
| Unlikely | If the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components |
| 1 | Possible | If the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes |
| 2 | Likely, Probable | If the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component |
| 3 | Certain | If there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component |

**PART C**

**Confirmation of a Serious Adverse Reaction**

1. Reporting establishment

2. Report number

3. Confirmation date . . .

4. Date of serious adverse reaction . . .

5. Confirmation of serious adverse reaction:

yes no

6. Imputability level (NA, 0–3)

7. Change of type of serious adverse reaction:

yes no

if “yes”, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Clinical outcome (if known):

 complete recovery

minor sequelae

serious sequelae

death

**PART D**

**Annual Notification of Serious Adverse Reactions**

|  |
| --- |
| Reporting establishment |
| Reporting period |
| This Table refers to1:whole blood red cellsplateletsplasmaother | Number of units issued2 |
| Total number of recipients transfused with a given number of blood components3 (if available) |
| Number of units transfused4(if available) |
| Total number reported | Number of serious adverse reactions with imputability level 0 to 3 after confirmation |
| Number of deaths | Not assessable | Level 0 | Level 1 | Level 2 | Level 3 |
| Immunological haemolysis | Due to ABO incompatibility | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Due to other allo-antibodies | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Non-immunological haemolysis | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Transfusion-transmitted bacterial infection | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Anaphylaxis/hypersensitivity | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Transfusion related acute lung injury | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Transfusion-transmitted viral Infection | HBV | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| HCV | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| HIV–I/II | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Other (please, specify) | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Transfusion-transmitted parasitical infection | Malaria | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Other (please, specify) | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Post-transfusion purpura | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Graft versus host disease (GVHD) | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |
| Other serious adverse reactions (please, specify) | Total |  |  |  |  |  |
| Deaths |  |  |  |  |  |

Notes.

1A separate table shall be used for each component.

2Total number of the issued units of the respective blood component.

3Total number of recipients transfused with the blood component (number of units).

4Total number of the units of blood components transfused during the reporting period.

**Annex 9**

Cabinet Regulation No. 1037

27 December 2005

**Notification of Adverse Events**

**PART A**

**Rapid Notification of Adverse Events**

|  |
| --- |
| Reporting establishment |
| Report number |
| Reporting date (date, month, year) |
| Date of adverse event (date, month, year) |
| Adverse event which could affect the quality and safety of blood components due to deficiencies | Specifications |
| product defect | equipment failure | human error | other (please, specify) |
| in the following stages: |  |  |  |  |
| Whole blood preparation |  |  |  |  |
| Apheresis procedure |  |  |  |  |
| Testing of blood samples |  |  |  |  |
| Processing |  |  |  |  |
| Storage |  |  |  |  |
| Distribution |  |  |  |  |
| Materials |  |  |  |  |
| Other (please, specify) |  |  |  |  |

**PART B**

**Confirmation of an Adverse Event**

|  |
| --- |
| Reporting establishment |
| Report number |
| Confirmation date (date, month, year) |
| Date of adverse event (date, month, year) |
| Root cause analysis (details): |

**PART C**

**Annual Notification of Adverse Events**

|  |  |
| --- | --- |
| Reporting establishment |  |
| Reporting period | 1 January–31 December |
| Total number of blood and blood components processed: |
| Adverse event affecting the quality and safety of blood components due to deficiencies in the following stages: | Total number | Specification |
| product defect | equipment failure | human error | other (please, specify) |
| Whole blood preparation |  |  |  |  |  |
| Apheresis procedure |  |  |  |  |  |
| Testing of blood samples |  |  |  |  |  |
| Processing |  |  |  |  |  |
| Storage |  |  |  |  |  |
| Distribution |  |  |  |  |  |
| Materials |  |  |  |  |  |
| Other (please, specify) |  |  |  |  |  |

Acting for the Minister for Health, Minister for Finance O. Spurdziņš