PRINCIPLES
OF GOOD TRANSFUSION PRACTICES

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In collaboration with

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Préface

La performance du système de santé libanais connaît une dynamique significative en dépit des turbulences politiques et économiques. Un ensemble de réformes visant à mettre à niveau le secteur de soins notamment hospitaliers. Conscient des enjeux de la qualité et la sécurité des soins et souhaitant continuer dans ces réformes en renforçant son rôle régulateur, Le Ministère de la Santé a lancé, courant 2009, des travaux de réorganisation des activités de transfusion sanguine sur l'ensemble du territoire en vue de garantir l'autosuffisance et la sécurité sanitaire.

Considérant les liens traditionnels d'amitié qui unissent la France et le Liban et désireux de renforcer les relations de coopération, et reconnaissant que la qualité et les démarches d'évaluation en santé constituent des axes cruciaux pour l'amélioration des performance des systèmes de santé, de la sécurité des patients et de la pérennité des systèmes de protection sociale, un protocole de coopération a été signé entre la France et le Liban en novembre 2011.

Différents projets de partenariats ont été cités dans cet accord, dont le projet d'amélioration de la gestion transfusionnelle lui-même inscrit dans une convention de coopération entre l'Etablissement Français du Sang (EFS), reconnu pour son savoir faire en transfusion sanguine qui en fait un acteur prépondérant sur la scène internationale, l'Ecole Supérieure des Affaires (ESA) et le Ministère de la Santé Publique au Liban signée en 2011 pour une durée de trois ans renouvelable.

L'objectif de ce projet étant l'amélioration de la gestion du secteur de la transfusion sanguine au Liban pour que celle-ci soit conforme aux standards internationaux, le point de départ est l'harmonisation des pratiques métiers et l'appropriation par l'ensemble des acteurs de bonnes pratiques communes de la transfusion sanguine. Il vise également l'examen des possibilités d'une réorganisation nationale de la gestion transfusionnelle au Liban pour améliorer l'efficience du système. La première étape du projet fut la réalisation d'un état des lieux par l'EFS, la création d'un comité national de la transfusion sanguine, puis la conception d'un plan d'actions dont le premier grand chantier fut la rédaction des bonnes pratiques de la transfusion sanguine au Liban, le document présent en est le fruit primeur.

Je tiens tout d'abord à remercier nos partenaires, l'Etablissement Français du Sang, ainsi que l'Ecole Supérieure des Affaires, sous la direction de M. Stéphane Attali, qui nous ont démontré une fidélité sans faille dans un environnement parfois difficile et instable et une efficacité éprouvée nous rendant fiers de travailler ensemble sur un tel projet.

Je tiens aussi à remercier personnellement tous les acteurs qui, sous la conduite perspicace du directeur général, Dr Walid Ammar, ont permis à ces bonnes pratiques nationales d'être réalisées en travaillant, non seulement sans relâche depuis des mois, mais aussi avec un professionnalisme et un esprit d'unité nationale exemplaires, les experts libanais : Mme Sizar Akoum, Dr Vanda Baraket, Dr Elisabeth Kfoury-Baz, Dr Rita Feghali qui a accepté de coordonner le projet avec dynamisme, Dr Berthe Hachem, Dr Antoine Haddad, Dr Christian Haddad, Dr Tamina Jisr-Shaar, M. Georges Kettaneh, Mme Perrine Malaud Wakim et Dr Hanady Samaha, sans oublier les experts français Dr Alain Beauplet, Dr Bernard David, Dr Olivier Nasr, Dr Yves Piquet, Dr René Tardivel, Dr Sandrine Vanlaer, Dr Chantal Waller et Mme Badia Mouchrik et Mme Leslie Sobaga.

Les bonnes pratiques vont être maintenant diffusées et leur mise en place accompagnée à travers un programme de formations.

Ali Hassan KHALIL

Ministre de la Santé Publique au Liban

PREAMBLE

The aim of this decree is to define the principles of Good Transfusion Practices (GTP) for transfusion centers authorized to store and deliver blood and blood components.

It is one of the tools designed to guarantee blood safety. Its design enables integration of new information and technical advances.

This decree includes all aspects in the transfusion chain from the collection and testing of blood and blood components to their processing, distribution and delivery for therapeutic uses.

Blood/blood components safety and quality are based on:

- Rigorous standards in the collection, processing, biological qualification of donation, distribution and delivery processes;
- A quality system that includes all partners, and in particular blood donors, clinicians and hospitals.

This decree applies:

- To the collection of blood and blood components from suitable donors, while discarding donations by people when a risk to their own health or that of the recipient is identified;
- To the processing of blood and blood components that aims to get components of high quality.
- To the biological qualification of donation (BQD) with the aim of guaranteeing the recipients safety in terms of immunehematological risks and transfusion-transmitted diseases;
- To the delivery and the distribution of blood/blood component with the aim of providing medical prescribers, via transfusion centers or via blood distribution centers managed by healthcare facilities, with medically appropriate products. These activities require the establishment of collaboration between Blood Banks and Hospitals.

This decree is structured as follows:

- A core section combining chapters found in any guidelines: quality control, personnel, premises, equipment, and documentation.

This section applies to transfusion centers and blood distribution centers managed by healthcare facilities which are authorized to store and distribute blood/blood components.

- And specific guidelines covering the collection, processing, biological qualification of donation, delivery and distribution processes.

GLOSSARY AND ABBREVIATIONS

The following definitions apply for terms used in this decree. These terms may have different meanings in other contexts.

Adverse events: A harmful reaction suffered by donors, related to or likely to be related to the blood donation, or suffered by recipients and related to or likely to be related to the administration of blood/blood component.

Analysis: A set of operations designed to measure the quantitative or qualitative aspects of a sample.

Antibody detection: An immunohematologic test performed for each donation on an anticoagulated blood sample or taken in a dry tube without primary centrifugation. It must be performed using an indirect antiglobulin test or a technique of equivalent sensitivity. This test must be able to detect antibodies for the following antigens: D, C, E, c, e, Cw, K, k, Kpa, Kpb, Jsa, Jsb, Fya, Fyb, Jka, Jkb, M, N, S, s, P1, Lea, Leb, Lua, Lub, Xga.

Archiving: Storage of data for conservation in order to ensure its integrity during their corresponding mandatory data retention period.

Area of expertise: The entirety of subjects and/or functions assigned by an employer to an employee within an organization (hierarchical or functional).

Audit: A systematic, independent and documented examination to determine whether quality activities and related results are suitable to achieve predefined objectives.

Authorized person: A staff member having the qualifications required by law and the regulations, recognized by their responsible and able to carry out the duties assigned to him.

Autologous donations: Blood or blood components collected from one individual that are intended solely for later transfusion or any human applications for the same individual.

Backup: An operation enabling data to be restored.

Biological analyzes of biological qualification of donation: In transfusion, biological analyzes aim, on one hand, for the screening of transmissible diseases and, if necessary, additional analyzes contributing to the diagnosis. And, on the other hand, it aim the immunohematologic tests performed in order to ensure compatibility with the recipient.

Biological qualification of donation (or Pretransfusion Blood testing): Describes all operations related to the laboratory tests performed on blood in order to establish the immunohematologic characteristics of the donation and to evaluate its safety with respect to blood-borne diseases based on regulatory requirements. For a given analysis,

biological qualification of donation is established based on the results of this analysis and on previous donation test results when available.

Blood distribution center: A unit of a healthcare facility that stores or delivers, under the authority of a physician or pharmacist, blood/blood components solely intended to be administered in the healthcare facility services and have performed the appropriate compatibility testing.

Blood component: A blood constituent that can include plasma, red blood cells, white blood cells and platelets

Blood components characteristics: Specific features for each available blood component.

Blood Sample: A specimen taken from a donor, identified by the matching donation number, written as a bar code and in plain numbers, in accordance with good collection practice.

Blood Unit ID: Unique clear encoded identifiers that establish the irrevocable link with the corresponding donation ID.

Calibration: A set of operations that, under defined conditions, establish the relation between measurements obtained from an instrument or a measuring system or values from a standard device or material, with those obtained with the equipment being calibrated.

Claim: A complaint done by a person or an organization not related to the Transfusion or to the blood distribution center, stating that a service failed to meet their needs and expectations or failed to comply with the reference standards.

Closed system: A container or set of containers allowing blood/blood components to be collected and prepared without loss of sterility. This definition covers those systems physically and functionally closed (sterile connections for example).

Competence: Knowledge, know-how and skills which are immediately useful and implemented in the context of a particular work situation.
Compliance: Conclusion leaning towards the meeting of specified requirements: regulatory characteristics and/or internal and external specifications.

Computer system: A system that includes data entry, electronic processing and information output used in reports or for automatic checks.

Computer access management: The process of authorizing access to a computer system and the release of data.

Computerized document: A document posted or edited by the computer program that provides information stored in the computer memory while avoiding transcription errors.

Control: All operations designed to determine the compliance of a product with specific requirements.

Control by sampling: Testing performed on a set of units taken from a population and intended to provide information about this population (not to be confused with 100% testing).

Critical: A piece of equipment, material, service, or task whose failure can affect the personnel safety, quality and availability of blood/blood components.

Cross-contamination or carryover: Contamination of a sample by the previous one leading to change in the characteristics and/or introduction of an external agent.

Data: A set of raw information with the associated features that allow managing and/or reading of the stated raw information.

Data recovery: The process of salvaging data that is compatible with the current operating system

Data sustainability: Process guaranteeing data accessibility and intangibility throughout the mandatory data retention period. It includes periodic migrations to new formats which guarantee data legibility by recent technological advances.

Decisional algorithm: Description of a series of organized operations including information handling in order to reach a decision or outcome.

(A) Deliverable: The object(s) of a delivery (file, software, etc.)

Delivery or Issue: The provision of blood/blood component on a medical prescription for administration to a specific patient.

Derogation: Authorization to bypass original specified requirements, for a predefined period and situation.

Design Qualification (DQ): DQ aims to:

- Check that the process data are well defined, in order for the designer to fulfill the project needs in accordance with requirements.
- Check that all process requirements are taken into account within in the project proposed by the designer and supplier.

- Formalize all evaluations related to design and functional aspects in accordance with predetermined acceptance criteria.

It is performed if the qualification purpose has been specifically designed and in response to an order from the purchasing institution.

Directed donation: A donation that is characterized by the breakdown of the of the donor's anonymity to the recipient.

Distribution: The supply of blood/blood components from a Transfusion Center to another or to healthcare facility managing a blood distribution center.

Donor: A person who donated blood or blood component even if the donation was discarded due to the laboratory test results or due to post donation information.
Prospective donors from whom a sample intended for blood testing (without donation) has been collected are not considered donors.

Donation identification (ID): Unique clear encoded identifiers that establish the irrevocable link between records, blood components prepared and the blood samples obtained from a specific donation.

Donation status: Determined by the type of donation, mandatory immunohematologic and serologic blood testing data and other non-mandatory tests used to complete qualification of blood/blood components, in order to meet specific therapeutic requirements.

Donor ID: Unique clear encoded identifier assigned to each donor.

Equipment: A tool or instrument used in the laboratory, from pipettes to automate and data processing software.

Equipment maintenance: Operations carried out at fixed intervals to ensure that equipment performance is constant over time: maintenance (upkeep), calibration, and in-depth technical revisions.

Function: An assigned duty or activity performed by an employee.

Good practice for the Biological Qualification of Donation: Describes a set of methods to be implemented related to the personnel, premises, equipment, samples management, biological analyses, waste management, their documentation and automation. It starts from the blood sample reception to the release of results which contribute to the compliance checks for blood components.

Good transfusion practice: All the aspects of well-tested practice which provides blood/blood components in accordance with specified requirements and references standards.

Guidelines: A document prepared by the transfusion center to clarify application of good practice principles.

Hemovigilance: Organized surveillance procedures related to serious incidents or adverse events in donors or recipients, covering all activities of the transfusion chain, and the epidemiological follow up of donors.

TC: Transfusion Center

Incident: An accident or error related to the collection, testing, preparation, storage, distribution, delivery or to the administration of blood/blood components, which may affect the product safety or quality and cause serious adverse events.

Installation Qualification (IQ): IQ aims to:
- Verify that the system is appropriately installed. It is performed according to a protocol which describes responsibilities, objectives, and acceptance criteria related to the IQ phase. The documents include installation scripts, IQ reports and the incident sheets.

- Demonstrate to the users that the vendor documentation, e.g. study documents, the overall implementation plan, the diagram, calculation notes and technical documentation of its components (operating documentation and maintenance, reports of assembly and testing, certificates of calibration) are complete and can be used.

- Verify through documentation that the material or system was built, assembled, set up and connected in accordance with specified regulations and that the manufacturer's recommendations were taken into account.

Kit: A set of components and reagents used for biological analysis, certified by the Ministry of Health.

Known donor: A donor having donated blood/blood component at least once.

Logical access control (Computer access management): Tools that limit access to data files to individuals with the legal authority to access such information**.**

Maintenance: All actions involved in preserving or restoring a unit to an operational condition.

Mission: A duty imposed on a person to undertake an action or a series of actions.

Marker: A biological indicator of transfusion transmitted diseases.

New donor: A person who donates blood/blood component for the first time.

Operational Qualification (OQ): OQ aims to:

- Check compatibility between the service provider’s response and the system’s functionalities. It is conducted in accordance with a protocol, which describes the responsibilities, objectives and acceptance criteria related to the OQ phase. The documents include test cases, OQ report and incident reports.

- Provide a demonstration, supported by the documents defined during installation qualification, that the system or equipment components to be tested or measured (automatic operations, data acquisition systems, recording, regulation, alarms and safety mechanisms) operate in a reproducible manner within the performance ranges and the limits set by the specifications.
Operational qualification should follow installation qualification.

Operating mode: A detailed description of how an activity is undertaken.

Performance Qualification (PQ): PQ aims to:

- Check and demonstrate that the equipment or the entire system performs appropriately and consistently under actual operating conditions, and meets the requirements expressed in the user's specifications;

- Check and demonstrate, with the aid of suitable tests, that the entire system functions appropriately and consistently, under actual operating conditions, and that the resulting product is compliant.

Performance qualification follows operational qualification or is undertaken jointly with operational qualification.

Population: All the units that are under consideration.

Primary Processing: All operations performed between the reception of collected blood and the obtained blood components.

Procedure: A specified way of carrying out an activity or a process.

Processing: All operations involved in obtaining blood components from blood/blood components, raw or intermediate materials, and including primary and secondary processing, labelling, storage and the required laboratory tests.

Process: A set of related tasks and activities that transform input elements into output elements.

Product: A result of a process.

Programmed autologous transfusion: Transfusion where the donor and recipient are the same person and in which the blood/blood components were obtained by previous blood deposit(s).

Potential or prospective donor: Any person offering to donate blood (including for the purpose of a pre-donation assessment).

Qualification: An operation designed to demonstrate the ability of an equipment, system, device or facility to meet the specified quality and safety requirements. The testing of one of these elements requires the design qualification process to be implemented, if necessary, as well as the installation, operational and performance qualifications processes. In all cases, qualification operations can be performed by third parties, but the confirmation of qualification can only be established by the user.

Quality: The ability of a set of intrinsic characteristics to meet requirements.

Quality Assurance: A component of the quality management system designed to guarantee that blood/blood components, from the collection to the delivery, are of a suitable quality for the purpose which they are intended for.

Quality Control: A component of the quality management system. It contributes, through the results of testing, to the management of processes and products. Its

implementation is based on regulatory requirements, pre-established specifications or a particular specification.

Quality control of Biological analysis and screening tests: They cover the control of equipment, raw materials, analysis of internal controls along with results analysis, documentation and validation procedures which guarantee that the necessary and appropriate controls have actually been conducted and that the results are not issued unless their quality been judged as satisfactory.

Quality control of raw materials (critical consumables and reagents): It concerns the sampling of raw materials, specifications, control, organization, documentation and release procedures to ensure that the necessary and appropriate controls have been made so that the raw materials are not released unless their quality have been checked.

Quality indicator: A variable used to measure and assess a status or a modification.

Quality management: Coordinated processes and procedures designed to manage and to ensure that an organization is consistent with regards to quality at all levels.

Quarantine: A situation in which blood or blood components, equipment, medical devices or in-vitro medical diagnostic devices, are isolated physically or by another effective means for a variable length of time pending a decision concerning their compliance or status.

Raw material: A laboratory product used for the biological qualification of the donation.

Reagents: Any chemical or biological substances specially prepared for in vitro use, whether separately or combined, in view of biological analyses.

Registration: A record that displays obtained results or marks activity completion.

Release: A process that enables a quarantine to be lifted by making use of systems and procedures in such a way as to ensure that the released item complies with the necessary specifications for its release.

Required level of quality (RLQ): All measurements related to quality to which blood/blood component must comply in order to define a minimum or acceptable level of compliance.

Requirement: A need or stated expectation that is usually implied or imposed.

Return: The process of returning a blood or blood component to the Transfusion Center, or to the blood distribution center.

Sample: A fraction that is representative of an entity or a fraction that is representative of a population.

Sampling: The process of collecting or creating a sample.

Sampling procedure: Operational instructions for implementation of a sampling plan, i.e. listed method for selecting, collection and processing samples in order to determine the population characteristics.

Sampling plan: A specific plan that defines the required number of samples and their criteria in order to accept the population in question.

Secondary Processing: All operations performed in order to obtain a specific blood component from a primary blood component.

Software: A set of programs, procedures, algorithms and the documentation(s) required for the operation of a data processing system.

Specifications: A document outlining requirements. Specifications for blood/blood components include their characteristics and the procedures used. It is appropriate for the requirements to be expressed digitally, with their appropriate units and cut-offs, above and below which the parameter in question should not be situated.

Statistical process control: a statistical method used to monitor the quality of a product or a process, based on analyzing an appropriate sample size without the need to measure each product of the process.

Status of donation: is determined by the nature of the donation, the immuno-hematological and serological mandatory data in addition to other non-mandatory analyzes that complete the qualifications of Labile Blood Products (LBP) to respond to specific therapeutic uses.

System: A set of correlated or interactive group of elements.

Technique validation: Operations consisting of demonstrating that the used technique used is specific, sensitive, repeatable and reproducible**.**

Test result: "Initially Reactive": A sample is said to be "initially reactive" for a given marker if the resulting signal of the initial screening test is within the manufacturer's positives range.

Test result "Non-Repeatedly Reactive": A sample is said to be "non-repeatedly reactive" for a given marker when it is "initially reactive " and when repeating the same test twice with the initial screening reagent led to two negative results.

Test result "Repeat Reactive": A sample is said to be "repeatedly reactive" for a given marker when it is "initially reactive" and when repeating the initial test twice produced at least one positive result. .

Test result "Indeterminate": A sample is said to be "indeterminate" for a given marker when it is "repeatedly reactive" and when additional screening tests produced incomplete and/or negative results.

Test result "Second-method reactive": A donor sample is said to be "second-method reactive" for a given marker if it's reactive in two different methods.

Test result "Positive": A sample is said to be "positive" for a given marker when it is "repeatedly reactive" and/or "second-method reactive" and when additional screening tests produced positive reactions.

Traceability: The ability to follow the history, implementation or location of a product. Blood/blood component traceability means to establish the link between the donor, donation, blood products, their progress and end, whether used or not.

Transfusion advice: Assistance in the choice of therapeutic transfusion, prescribing blood/blood components, realizing transfusion, monitoring recipients, storing and transporting conditions for blood/blood components.

Transfusion Emergency: Three levels are defined:

- Immediate vital emergency: A situation where no delay is acceptable. Blood/blood components may be released before completion of immunohematologic tests required for the recipient as defined by regulations.

- Relative Emergency: A situation where two to three hours delay is acceptable, that enables all pretransfusionimmunohematologic tests to be performed as required the by regulations. Released Red blood cells concentrates are ABO compatibles, crossmatched if necessary (according to the antibody detection result).

- Vital emergency: A situation where the delay for obtaining blood/blood components is less than 30 minutes. Red blood cells concentrates are released after two determination of ABO/Rh type, even before the result of the antibody detection or compatibility testing if not yet available.

Transfusion protocol: A set of rules to be complied with, as part of a therapeutic strategy, involving a transfusion procedure and incorporated into an overall transfusion safety approach

Ultimate pre-transfusion control: This is ultimate control of concordance between patient identifier, product identifier and documents relating to the delivery. It is performed in the presence of the patient.

Validation: Confirmation by objective evidence that the requirements for a specific or intended use have been met.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Chapter 1

Quality Control

Principle

Quality control is a component of the quality management system. Through regular results of the quality checkup, quality control contributes to the management and monitoring of processes and products. It is made according to predefined specifications.

1.1. Scope

Quality control covers all products, raw materials, samples, consumables, intermediates, premises and equipment. Preparation processes are carried out under appropriate conditions to ensure a good bacteriological safety of blood/blood components.

1.2. Quality control includes:

- Conducting assessments, analyzing and deciding to accept or reject results;
- Establishing internal specifications for products;
- Compiling and monitoring test plans;
- Test methods and their validation;
- Implementing provisions to ensure that the necessary and appropriate tests have been conducted.

Blood/blood components, controls and reagents shall not be used until their compliance with the applicable guideline(s) has been demonstrated.

Organization of assessments

1.3. As soon as the process can be standardized, a statistical process assessment method is implemented. Internal and external assessments of operations and quality systems are conducted regularly in order to ensure their compliance with the regulations.

1.4. Compliance of a series of products issued from the same process may be verified using a sampling inspection plan which defines the appropriate sample size and frequency based on relevant statistical rules

1.5. Blood/blood component assessment plan takes into account the required quality level defined for each product type as well as the results of previous assessments. This quality level must be defined for the parameters or values mentioned in the regulations and must refer to an approved standard or guideline.

1.6. Blood/ blood components sampling shall be performed in a way that does not carry any risk to the issued product.

1.7. Assessments conducted in the collection or preparation area by personnel from these sectors or by quality control personnel are carried out in accordance with procedures

1.8. Assessment upon receipt of consumables, in vitro diagnostic tests and raw materials identified as critical is conducted and documented. It may be established in partnership with the supplier, when the objective conclusion regarding conformity is guaranteed.

1.9. A Transfusion center has internal and external quality control measures: use of quality control samples, periodical proficiency testing, exchanges and inter-laboratory method comparisons.

1.10. Data related to the tested products, use of assessments, results and acceptance or rejection decisions should be recorded.

Results

1.11. The results of assessments shall be made directly available to enable suitable corrective and preventive actions to be taken if necessary

1.12. The results and interpretation of assessments shall be regularly provided to the involved personnel within a suitable time to allow for process improvement.

Chapter 2

Personnel

Principle

2.1. A sufficient number of qualified personnel are required to successfully perform, verify and manage all activities in the blood bank. Personnel performing critical tasks must be trained.

2.2. The individual tasks and duties are clearly understood by involved personnel, documented and updated. The workload assigned to a single person must not interfere with his tasks execution.

2.3. A workflow chart proper for each TC, detailing the various activities, shall be established. This chart describes work positions, without any gaps or duplication. It guarantees the independence of positions with responsibility and avoids conflicts of interest, in terms of quality control and preparation

2.4. Competence areas and responsibility for each personnel is documented clearly. Evaluations of competence shall be documented and performed at specified intervals

2.5. Supervisors are granted the authority needed to exercise their responsibilities. Their duties may be delegated or appointed to other similarly qualified personnel.

They organize all performed activities, ensure compliance with hygiene and safety rules, and organize the provision of information to and training for personnel.

They are familiar with and apply the principles of good practices, procedures or operating procedures related to their activities.

2.6. All staff members must swear to professional secrecy.

Training

2.7. Management personnel shall provide training for personnel and ensure that they meet the required qualifications. Personnel shall receive job-related theoretical and practical training.

This training is documented and relates specifically to good practices, quality, hygiene and safety measures for personnel, products and the environment.

It results in an authorization decision, taken on the basis of the personnel evaluation, to assume the tasks and responsibilities appearing in the document describing their duties, with the exception of blood distribution centers personnel who are subject to specific regulations. Healthcare facilities with a blood distribution center will

guarantees the qualification of professionals, who follow continuous training programs or job-related training.

2.8. Continuous training, which includes best practice, shall be provided and its efficacy evaluated periodically.

2.9. Training plan proper for each health care facility is available and is approved by the Director. Personnel records for each employee shall be maintained.

2.10. Those in charge of various activities are routinely informed of technological developments in their field.

Personnel Hygiene and Safety

2.11. Hygiene, safety, protective clothing for personnel and waste disposal measures are implemented in each sector of the health care facility. These measures shall be documented, understood and followed by all personnel. Written safety and hygiene instructions shall be adapted to the performed activities and shall be compliant with national and international standards.

2.12. Any person entering a restricted access area must wear protective clothing appropriate to the procedures undertaken there.

2.13. Unauthorized personnel and visitors have access only to the reception and collection areas.

Access to other areas, where this is necessary, requires these people to be accompanied and the appropriate hygiene and safety measures to be applied.

2.14. The risk of blood/blood components contamination from personnel suffering from an infectious disease or having open wounds shall be assessed and appropriate measures shall be implemented.

Chapter 3

Premises and Equipment

Principle

The premises shall be located, designed, built, adapted, maintained and cleaned. Circulation areas must be separated from operating areas.

Specific areas for each activity must be indicated clearly.

Their environment, plan, layout, design and use should minimize risks and allow for effective cleaning and maintenance.

Selected equipment should not pose any risk to personnel, blood and blood components.

Premises and equipment intended for procedures that are essential for quality and blood products safety are tested and validated prior to their use.

Equipment must meet specific regulations related to the personnel safety, in particular electrical, mechanical and fire hazards.

Premises

General

3.1. Premises and facilities should be thoroughly maintained; repairs should not carry any risk for product quality. Premises shall be cleaned and, when necessary, disinfected, in accordance with written procedures approved by the healthcare facility.

3.2. Lighting, temperature, humidity and ventilation must be appropriate, in order not to directly or indirectly affect either the products during their preparation and storage or the proper functioning of equipment or the results of analyses conducted on blood samples.

3.3. Infestation by insects and other animals must be controlled by appropriate measures. Plants shall not be allowed, except in reception and administrative areas.

3.4. Premises are organized according to the logical order of procedures conducted on blood, blood components and blood samples with respect to sanitation rules.

3.5. Records shall be stored in specific and accessible areas

3.6. Non-removable pipes and taps shall be clearly identified to indicate their content and, where necessary, the flow direction.

3.7. Distilled and deionized water systems are maintained and checked in accordance with procedures.

Storage Area

3.8. Storage areas shall be of a sufficient size to enable separate storage of the various categories of products: raw materials, *in vitro* diagnostic devices, intermediate products, quarantined products, products ready for use, non-compliant products and products pending destruction.

3.9. Storage areas for blood and blood components shall be properly designed to ensure appropriate storage conditions. In specific terms, they must be cleaned according to written procedures and kept at appropriate temperatures specific for each blood product type. Specific storage conditions must be met, assessed and monitored periodically. These areas shall be equipped with an effective alarm system.

Health care facilities shall have procedures defining the actions to be taken in case of power failure.

3.10. A separate quarantine area shall be clearly identified and access to it is restricted to authorized personnel. Any other area replacing this quarantine area has the same security level.

Laboratory Areas

3.11. Laboratory activities shall be done in a suitable area separately from all transfusion-related activities.

3.12. A storage area shall be assigned for biological samples.

Appendices Areas

3.13. Personnel lounge are must be separated from other areas.

3.14. Personnel locker rooms and toilets must be easily accessible and appropriate for the number of users.

Toilet facilities must not be directly connected to preparation and storage areas.

3.15. Maintenance area must be separated from transfusion-related areas.

3.16. A specific area shall be reserved for the storage of waste, disposable equipment and non-compliant blood products prior to their secure disposal.

Equipment

3.17. Equipment shall be designed, installed, maintained, and cleaned according to their use to reduce risk. Equipment must meet specific regulations and ensure personnel safety. Cleaning must follow specific operating procedures.

3.18. Each health care facility must establish a list of critical equipment requiring qualification. Critical equipment suppliers shall be evaluated and selected.

3.19. The objective of equipment qualification is to demonstrate that the equipment in question functions correctly and provides the anticipated results. It is performed in order to ensure that it is in accordance with manufacturer specifications and users requirements. Calibration of equipment must be documented and performed by authorized personnel in three situations:

- When new equipment is installed;
- After any repairs that may affect equipment operation
- If there is any doubt regarding correct functioning of the equipment;

It shall be performed in accordance with a written protocol; the equipment qualification record includes, specifically:

- User's specifications or requirements,
- Data resulting from the qualification protocol,
- Qualification report,
- Conclusion specifying the conditions for use of the equipment, demonstrating that it is fit for the purpose for which it is designed.

This document must be dated, signed and available at all times. It must be kept for three years after the equipment has stopped being used.

3.20. Quality control involves qualification of equipment and automated systems used for transfusion-service-related activities. A conclusion regarding compliance is taken jointly with the person responsible for the activity in question.

3.21. For each piece of equipment, an equipment log book shall include identification and maintenance details. This log book shall be preserved.

3.22. In the event of equipment breakdown, operation in safe mode must be defined and documented.

3.23. Cleaning, disinfection and decontamination equipment and products are appropriate to the surfaces to be cleaned, and are chosen and used in such a way as not to represent a source of contamination.

3.24. Equipment used must have adequate accuracy and precision.

3.25. Calibration and/or adjustments shall be performed at prescribed intervals.

3.26. Defective or unused equipment shall be removed from transfusion service areas or shall be labeled as such.

3.27. Spare parts or tools, when kept in transfusion areas, shall be stored aside in specific areas.

Chapter 4

Documentation

Principle

Documentation is a key component of the quality management system. Clear records prevent errors that are inherent in verbal communication and allow the history of operations to be retraced.

Establishments gather and record information that allows them to guarantee traceability and monitoring.

4.28. The documents can be kept on any storage medium: paper, magnetic, electronic, optical, photographic disks or a combination of all.

4.29. Records shall be kept to demonstrate compliance with requirements and the effective operation of the quality system.

4.30. Any data entry or record on paper or electronic media requires operator identification.

4.31. Detailed standard operating procedures must be available and records integrity shall be checked.

4.32. Complete or partial access to data is restricted to authorized personnel.

4.33. Documentation shall include:

- Internal documents, such as:
  - General procedures relating to major process stages;
  - Operating procedures for the quality system;
  - Other documents needed to conduct activities, including operating procedures, forms and records;
  - Regulation texts such as the principles of Good Manufacturing Practice and the blood/blood components characteristics

4.34. Documentation must be comprehensible. It must be updated and made available to the concerned personnel. Any significant changes must be carried out immediately, reviewed, dated and signed by a person authorized to perform this task.

4.35. Internal documents are approved by authorized personnel, when they are created and updated. In addition, any document that has an influence on the products quality and safety must be validated periodically.

Archiving

Records related to the collection, preparation, blood testing, delivery/distribution and transport of blood/blood components shall be stored and archived in accordance with record retention policies.

GUIDELINES ON THE COLLECTION OF ALLOGENEIC BLOOD AND BLOOD COMPONENTS

Principle

This guideline provides organization and implementation of:

- Donor reception and education
- Donor and blood products identification
- Selection and care of donor

These activities are performed in order to protect donors from any potential harm which may occur as a direct result of the donation process and to protect blood transfusions recipients from adverse events. All blood donations should be voluntary and non-remunerated.

I. Personnel

Phlebotomists manage prospective donors from their arrival through their departure.

Each collection team is managed by a clearly identified and officially authorized person.

1. Qualifications

Collection activities require adequate number of qualified personnel.

A medically qualified consultant, who should be a doctor in medicine, shall be responsible for the selection, health and welfare of the donors.

2. Training

The personnel must receive initial and regular training including theoretical and practical aspects of blood collection. New staff members shall receive appropriate training relative to their tasks.

II. Premises, equipment, medical and administrative documents

1. Premises

Premises and mobile blood drives must have a number of separate areas:

- A reception area;
- One or more areas suitable for donor interviews and examinations, arranged and fit in such a way as to guarantee confidentiality;
- A suitable area for collection;

- A rest area with a bed;
- A snack and refreshment area.

For mobile blood drives, the vehicles and rooms provided must take the following aspects into account: General cleanliness, ventilation, brightness, safety and adequate space.

2. Equipment

Measurement, recording and monitoring equipment must be calibrated and adjusted at prescribed intervals. Assessment reports must be filed. Regular equipment maintenance is an essential condition to ensure quality.

Phlebotomists must have the necessary equipment for pre-donation examination, blood collection and medical care, enabling donors to be well managed during and after donation. This equipment is listed in national procedures.

Snacks or Drinks shall be stored and preserved in specific storage areas.

Collection devices must meet national requirements and/or CE or FDA requirements.

The batch numbers for collection devices must be recorded for each bag of blood or blood component, either at the collection or preparation stage.

3. Medical and administrative documents

3.1. Donor's record

Information about the donor should be kept in the donor's record, preferably in an electronic format, which contains the history of previous donations along with:

- Date, type and ID number of each donation;
- Any possible temporary or definitive deferral for donation must be recorded in a coded manner. The national contraindications list shall be regularly updated.
- Any possible adverse effects suffered during or following the donation;
- Previous screening result tests
- And, when applicable, data involved in medical and biological monitoring of the donor.

Access to donor records must be defined in written documents in order to ensure data privacy.

The record or part of it must be available at the collection site and must contain the necessary information as regards to the safety of donors and blood products.

The donor's record shall be consulted, verified and completed on each donation.

3.2. Questionnaire

Necessary information for donor selection is collected through regularly updated national questionnaire. The questionnaire shall identify health status of prospective donors, medical contraindications for blood donations and other potential health risks.

TC must include in their own questionnaire all subjects addressed by the national questionnaire.

3.3. Collection form

A collection form, designed to follow the donor through the different steps of the collection process, shall be used to identify the donor as well as the medico-technical instructions. Information generated during the course of donation should be added.

3.4. Donor card

The card may be issued after a second donation, following validation of immuno-hematological data.

The donor shall be identified on it by their family name (maiden name for women), in addition to their marital name when applicable, first name(s), sex, date and place of birth, donor ID and their home address.

III. Information, Reception and Donor identification

1. Information and Reception

Prospective donors shall receive national educational materials which they must read carefully before each donation.

This document shall contain at least the following:

- Accurate clear information on blood characteristics, blood donation procedure, blood products derived from whole blood collection or apheresis and provided benefits for patients;

- Reasons for requesting medical history and examination, testing the donations and the importance of "informed consent";

- Self-deferral, temporary and permanent deferral criteria
- Reasons for which the donor is excluded, when there are risks for their health
- Evidence on personal information privacy, including the fact that there will be no unauthorized disclosure of donor identity, information on their health status or the performed tests results;

- Detailed information on the nature of the procedures involved in the donation process and their respective associated risks;
- Information on the possibility for donors to change their mind about donation, or the possibility of withdrawing or self-deferring at any time during or after the donation process, without any undue embarrassment or discomfort;
- Reasons for which it is important that donors inform the TC of any subsequent event that may render any previous donation unsuitable for transfusion;
- Donor shall be notified by the TC of abnormal findings or test results
- Information that reactive screening tests for HIV, HBV, HCV and HTLV will result in donor deferral and disposal of the collection;
- Information on the opportunity for donors to ask questions at any time.

Furthermore, this document must draw attention of potential donors to:

- The main risk factors associated with transfusion-transmitted diseases;
- The importance of the questions that will be asked during the pre-donation interview and the honesty of answers to these questions in order to ensure blood safety
- The retention of a blood sample for the purpose of subsequent tests.

Information shall also details the donation conditions (donor age limits and frequency of donation).

Prospective donor identity shall be verified and administrative documents created or updated.

It is important that TC should have specific areas that offer privacy for donor interview and that the prospective donor has sufficient time, prior to donation, to complete the questionnaire in a confidential manner.

2. Donor and Donation Identification

Donor identification requires the following information:
- Family name (for a woman, her maiden name);
- First name (s);
- Marital name or nickname;
- Father first name;
- Sex;
- Date and place of birth (town/city, caza or country).

It requires also:
- Donor home address;
- Personal phone number and, if applicable, work phone number.

On the first donation, it is recommended to verify the donor ID by requesting the donor official ID card. This is essential should there be any doubt concerning the verification of the provided information.

A unique identifier shall be assigned to the donor on his first donation.

For all prospective donors as well as for all donors requested to give a blood sample, a donation ID shall be assigned and recorded on the collection form. The unique ID character shall be guaranteed by the Transfusion center.

The donor and donation identifiers are made up of numbers.

The procedure used to attach donation ID labels on the collection form shall be designed in such a way as to avoid any risk of identification errors or confusion.

IV. Selection of Donors

1. Pre-donation interview and physical examination

Each donation must be preceded by a personal interview and a brief physical examination. These two steps, which are essential for the safety of the donor and the recipient, focus on screening:

- For medical condition that rules out donation in order to protect the donor;
- For transfusion-transmitted diseases in order to protect the recipient.

The interview and examination shall be conducted under specific conditions to guarantee a suitable level of trust and medical secrecy.

1.1. Pre-donation interview

The interview shall be performed by qualified personnel.

During the interview, this personal shall:

- Confirms the identity of the prospective donor and ensures that the donor clearly understand all medical information provided to the donor;
- Evaluates donor qualification for donation
- Informs prospective donors on the option to complete or to edit his responses during or after the donation process and that he could indicate that his blood donation may not be used for transfusion purpose.
- Informs new donor on the donation process elements and their respective risks.

In case of deferral, the prospective donor shall be informed about the reasons related to his ineligibility for the donation and may be directed to a medical care unit.

When a donation requires the modification of the blood characteristics, a Medical staff must inform the donor and obtain his informed written consent. .

At the end of the interview, the prospective donor must sign the donor questionnaire, countersigned by the qualified personnel.

1.2. Physical Examination

Physical examination of the donor shall include an assessment of the overall state of health, blood pressure and weight measurement. Special attention must be made for any changes in heart rate; abnormal sweating, and that venipuncture site must be free of skin lesions.

It shall include also an assessment for contraindication to apheresis, especially in the cardiovascular, digestive and hematologic fields.

In all cases, the TC medical director remains alone competent to decide whether the donor can donate blood.

2. Laboratory tests before donation

In the cases outlined below, laboratory tests are conducted to confirm eligibility for donation.

These tests are different from tests used for the biological qualification of the donation. They differ depending on the donation type and are intended to guarantee donor protection as well as the blood/blood components quality.

2.1. Recommendations for all types of blood/blood components collection

A hemoglobin or hematocrit level shall be performed prior to each donation. .

2.2. Recommendations for collecting platelets by automated apheresis methods

A platelet count should be performed prior to the first donation and then at the beginning of donation for subsequent donations.

The physician in charge shall assess the need to perform a coagulation profile and/or a total serum proteins measurement.

2.3. Recommendations for collecting plasma by automated apheresis methods

Determination of total serum proteins shall be performed after the first plasma donation, and then at least once per year. Total serum proteins must not be less than 60 g/l and the result must be available before the subsequent donation. Any abnormal findings shall be explored by a serum protein electrophoresis.

The physician in charge shall evaluate the need to perform a complete coagulation profile.

2.4. Recommendations for collecting granulocytes by automated apheresis methods

Complete blood count and full coagulation profile shall be performed prior to each granulocytes donation.

2.5. Recommendations for collecting red blood cells by automated apheresis methods

Complete count shall be performed prior to each donation and a ferritin measurement performed after the first donation.

In case of a ferritin concentration less than 20 ng/ml, the donor must be permanently

differed from donating red blood cells by automated apheresis methods.

The physician in charge shall assess the need to perform a complete coagulation profile.

3. Collection rules

Health professionals must comply with the national regulations concerning the frequency, the volume and the minimum interval between donations of blood and blood components.

Nevertheless, in exceptional cases, collection of donation could be authorized by the Transfusion Center Medical Director, regardless of the above conditions, from subjects whose blood or blood components display properties that are of special interest. This decision shall be recorded in the donor's personal record.

V. Collection

Measures are taken to prevent:

- Accidental contamination of donations;
- Spread of blood outside the closed collection system;
- Incident or accident affecting the donor, personnel or, subsequently, the recipient.

1. Settling

Donor settling is intended to reconcile satisfactory technical conditions for collection with the donor comfort.

At this point, the following shall be assessed:
- Donor identity;
- Donation, collection bags and blood samples identifiers;
- Completion of the pre-donation review and examination.

Any change in the donor's site shall require a new assessment.
Collection personnel shall remind the donor to inform them of any discomfort occurring during collection.

2. Collection and monitoring

Collection personnel shall secure that the donor is taken care of and that collection runs smoothly. They must pay particular attention to the appearance of any clinical signs revealing intolerance to donation.

The presence of trained personnel in emergency cases is essential.

Each collection bag and blood sample resulting from the donation shall be identified using the unique donation ID.

The procedure used to attach donation ID labels on the collection bags and blood samples shall be designed in such a way as to avoid any risk of identification errors or confusion.

The electronic link would be ideally provided between the donor ID and the donation ID on the collection form, collected bags and blood samples.

Blood samples intended for laboratory tests and sample retention shall not be taken from the collection bags. Blood samples are appropriately stored before testing the donation.

At the end of collection, the bag is sealed before being packed for transport.

3. Rest and snack

Following collection, the donor shall rests for a medically determined period, during the course of which he is offered s snack. This period is designed to extend monitoring of the donor following collection.

The rest area shall be in proximity, in order to allow for rapid intervention if an incident occurs.

Personnel shall be trained to detect any sign of adverse reaction, to answer donor questions and to refer them to physicians when their health is at stake.

4. Post-donation information

A post-donation document containing the TC telephone number shall be issued to the donor. This document shall draw the donor's attention to the need to inform the TC as soon as possible of any:

- Doubt regarding the answers given during the pre-donation interview;
- Appearance of symptoms suggestive of disease;
- Information they consider should be forwarded to the TC

The TC shall ensure that post-donation information will be taken into account.

5. Incidents and adverse events

The TC shall have a policy to ensure that appropriate measures will be taken in case of an incident/adverse event that occurred during or after the collection, or new information provided by the donor that is likely to endanger the donor and/or blood/blood components safety.

6. Circuit of Blood Products and pre-donation blood samples

Blood samples and products collected and separated shall be placed in appropriate transport bags.

Non-conforming blood/blood components shall be evaluated and their disposition determined

VI. Activity Reports

1. Collection reports

These documents enable personnel to describe the conditions under which each collection took place and to draw up activity management charts that could be used to improve organization of future collections and the quality of donor selection.

Reports, written by the collection personnel, shall include an evaluation of the collection process and its sterile conditions. This evaluation, as well as other factors such as laboratory tests results or donors follow up data, will enable to consider if the collection appropriate for transfusion or not.

Furthermore, consistency between donations and collected bags shall be verified and documented.

2. Apheresis collection reports

For each collection done by apheresis, a report shows contain at least the following:
- Donation ID;
- Materials and consumables used (type and batch number of the injected solutions);
- Personnel identity;
- Apheresis course

GUIDELINES ON THE PREPARATION AND PROCESSING OF BLOOD COMPONENTS

Principle

This document of guidelines applies to Transfusion centers authorized to collect, store and distribute blood/blood components. It provides a framework for the organization of blood/blood components preparation, and applies from the reception of collected blood products to storage before distribution.

Processes used for preparation, assessment and storage shall comply with specific requirements for each blood component type. Primary and secondary processing may be performed in the collection, delivery or distribution areas.

They can then be placed under the responsibility of those in charge of these sectors which apply the provisions of this Decree.

When a preparation process of a particular component cannot technically be performed under sterile conditions, special measures are taken to avoid contamination.

I. Premises

Blood/blood components workflow shall be established, shall respect the chronological order of the different process elements and shall avoid carrying any contamination risks.

Reception area:

A designated area shall be reserved for the receipt of blood/blood components. This area shall be restricted to authorized personnel.

If this area is used as storage area while waiting for products to be processed, the storage conditions for blood and blood components, in particular the temperature, shall be controlled.

Preparation area:

This area shall only be accessed by authorized personnel.

Sampling area for quality control:

An area shall be designated for the collection of quality control samples.

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

II. Preparation

1. General aspects

Preparation includes various validated procedures, depending on the required blood component. Measures designed to prevent the risk of contamination and microbial proliferation shall be taken.

When new methods or concepts are used, they shall be validated by the TC and evaluated for registration by the Ministry of Health.

For all processing methods, parameters affecting the process efficiency and standard operating procedures shall be validated and approved.

Processing of different blood/blood components shall be done separately in time and place.

Blood/blood component bags must be properly labeled and documented at the different processing steps in order to ensure identification of the donation at the various steps.

All precautions shall be taken to preserve the donation identification (ID) integrity attached during collection.

When blood/blood components are transferred to a new bag, their traceability shall be ensured prior to removing the labels.

Each section, where processing is being performed, shall have a detailed list of all processed blood/blood components.

2. Collected blood Components

Blood/blood components may be prepared either from whole blood or by apheresis.

Blood/blood components processing and use depends on the collected volume, duration of collection, transport and storage times and temperatures between collection and processing.

Some of these preparation operations require their own specific equipment and environment.

Whole Blood may be stored for 24 hours at temperature between +18°C and +24°C, during which it can be used to prepare platelets. From this period and up to three days after collection, it must be stored at temperature between +2°C and +6°C.

Whole Blood for blood components preparation may be transported at temperature between +18°C and +24°C if it has not first been stored at temperature between +2°C and +6°C.

After the period of twenty-four hours, it shall be transported at temperature between +2°C and +10°C, the +6°C temperature must not be exceeded more than twenty-four hours.

Blood products collected by apheresis shall be processed in accordance with good collection practices.

3. Processing steps

The section below describes only the most critical performed steps.

3.1. Handling

This step should comprise:

- A coherent inspection with the collection data;
- A detailed examination of whole blood/blood components in order to guarantee their compliance with the specific requirements of preparation;
- A registration, upon receipt, of the volume, collection number, device number and temperature conditions.

3.2. Centrifugation

Centrifuges shall be of appropriate capacity.

Centrifugation shall require compliance with the following:

- Blood bags shall be loaded appropriately in the centrifuge compartments
- Appropriate counterweight shall be used to balance the centrifuge to avoid damage to the bags
- Correct balancing of the centrifuge compartments will prevent vibration or damage to the centrifuge
- Loading should be carried out according to the previous steps. It should be verified that no obstacles prevent the compartments from spinning freely.
- Centrifugation shall be performed under strict conditions according to pre-defined parameters such as acceleration level, speed, time, deceleration and temperature.
- Bags, tubing or labels should not be damaged during centrifugation.
- Bags should be unloaded carefully in order not to disturb blood components separation.

3.3. Separation

Manual, semi-automated or fully automated separation of blood components may be used.

Automated separation equipment and software shall be validated.

This process requires compliance with the following:

- Centrifuged blood bags should be carefully placed onto the plasma extractor Proper sedimentation should be checked visually
- During separation, the pressure placed on the bag can be variable or constant; it must be controlled and suited to the flow rate selected.
- Separated blood bags should be carefully unloaded from the plasma extractor.

3.4. Weighing

Blood/blood components should be weighed at various steps of the preparation process.

Weighing includes the following steps:

- The scales should have appropriate range and accuracy. Calibration shall be performed prior to use.
- Blood bags should be placed in the center of the tray and should not be pulled.

3.5. Leukocyte reduction.

Required materials shall be incorporated within the collection kit or connected in a sterile manner.

These materials shall be used in accordance with suppliers' recommendations. Methods used for preparing leukocyte-reduced blood/ blood components shall be validated.

3.5. Weld

Methods that ensure appropriate sealing and welding shall be employed.

If a weld is used, the following requirements shall apply:

- Before use, the cleanliness of the clamps and the sealing elements shall be checked.
- The tubing shall be sealed perpendicularly to the clamps, without tension, for clear and airtight sealing.
- Leak shall be verified by exerting manual pressure on the bag, above and below the seal.

3.6. Sterile Connection

This consists of using a device that enables one piece of tubing to be connected to another in a sterile manner under specific conditions. This process shall comply with the supplier's recommendations.

Appropriate measures are taken to guarantee sterile conditions.

It is appropriate to prevent the risk of leak caused by the seal.

3.7. Freezing

Blood/blood component freezing occurs according to specific requirements.

3.8. Thawing

Thawing procedures and equipment are adapted to the blood bag number, presence or absence of a cryopreservative solution and the blood/blood component characteristics.

3.9. Additive Solution

Selected solution shall allow maintenance of blood cells viability in the cellular suspension.

This operation is conducted according to the steps below:

- Addition and homogenization methods, asepsis and labeling rules shall be written in standard operating procedures.
- Labeling and label inspection shall ensure blood product traceability.

3.10. Product pooling

Identification accuracy between the donation IDs and the pool ID must be assured.

3.11. Plasma extraction

Plasma extraction consists of removing the majority of the plasma from a cellular blood component in a sterile manner.

The method, choice and volume of compatible solution are adapted to the specifications of the blood component to be processed.

3.12. Irradiation

The term “Irradiated blood/blood components” applies to all components that received an irradiation dose between 25 and 45 gray.

Exposure time for each blood/blood components shall be present in written procedures.

The following steps shall be followed:

- A radiosensitive control at a minimum dose of 25 grays can be used.
- Exposure time is fixed to reach an irradiation dose between 25 and 45 grays.
- The dose flow rate in the irradiation chamber should be checked regularly and adjusted if necessary. Exposure time shall be checked periodically.
- An irradiation register should be established and mention the following:

• Irradiation date;
• Component type;
• Component number;
• Exposure time;
• Name of Operator.

This register is used to ensure irradiation traceability and to verify the radiosensitive controls.

It is appropriate to prevent the risk of confusion between an irradiated product and a non-irradiated product by all appropriate means. All irradiated products should be re-labeled or bear additional labeling.

This operation must be traced by the TC when it is performed in-house and when the irradiation was conducted by a certified service provider.

3.13. Blood/blood component labeling

The purpose of labeling is to document, in a clear and readable manner, all the blood/blood component characteristics.

It is performed once all laboratory tests have been collected.

Labeling involves the following operations:

- Labeling;
- Re-labeling;

- Final labeling.

Labeling must be accurate to prevent the risk of non-compliance between the donation ID and the ID appearing on the blood/blood component label and the details appearing on the final label with the nature of the concerned component.

In the absence of an approved computerized system for managing the status of blood/blood components, labeling enables clear distinction between quarantined units and units that are ready for release.

Blood/blood component labeling shall be in compliance with reference standards.

III. Storage

Blood/blood components are stored according to requirements specific for each blood component and other internal standards.

IV. Consistency Assessment

Consistency between collected and prepared blood products shall be assessed.

GUIDELINES FOR BIOLOGICAL QUALIFICATION OF THE DONATED BLOOD (PRETRANSFUSION BLOOD TESTING)

Principle

Pretransfusion blood testing regulation aims to define a framework for the "Biological qualification of the blood donation" organization in TC and, more specifically, rules for each laboratory test. A qualified blood donation is a donation which has undergone all laboratory tests required by regulations. Test results will contribute to verify compliance to regulations in order to ensure blood/blood components quality and safety.

Application of the Pretransfusion blood testing regulation shall lead to the establishment of quality control and surveillance systems, in order to provide maximum safety level.

This regulation will be regularly updated, according to the rapid technological advancements in this field.

Blood/Blood Components Testing shall include:

- All mandatory laboratory tests, systematic or not, performed on collected samples
- Processing available information related to the donation or donor which can be useful, such as donor demographic and clinical data, information from the pre-donation interview, post-donation information, vigilance data and quality monitoring results,
- Other non-mandatory tests required for specific therapeutic uses of blood/blood components

All together, this data contributes to the determination of the donation status.

Blood/Blood Components testing has several objectives:

- Ensuring the recipient safety from risks associated with immunological and hematological compatibility and transfusion-transmitted diseases;
- Informing donor of abnormal findings and tests results;
- Participating to public health missions through the laboratory test results.

I. Personnel

The Blood Bank/Laboratory director should have competence in certain areas including:

- Compliance with standards required by Lebanese regulation related to the Management of Blood Banks (Law NO. 766 dated 11.11.2006) and in vitro diagnostic devices (Laboratory Accreditation Standards, chapter Laboratory Department, 2003);
- General organization of the laboratory, approval of procedures and verification of their application and compliance to guidelines;
- Monitoring quality control and implementing corrective measures, if necessary;
- Training of personnel and balance between the personnel number and workload generated by application of the current regulation;

- Monitoring of technological developments in order to improve laboratory tests performance.

Personnel shall be appropriately qualified, shall receive initial adequate and regular training. This training aims at meeting the qualification requirements and updating their knowledge. Initially, it requires the acquisition of general knowledge on blood transfusion practices and biological qualification of the donation. Training should include a part dedicated to the transfusion activity as a whole. Personnel should be able to situate their role in the transfusion process and their responsibility in ensuring blood/blood components safety.

Training includes special focus on the information required to understand and conduct the delegated tests. Computer training and use of automaton is necessary for the use of these tools in the laboratory.

Training effectiveness shall be evaluated regularly through Competency Assessments.

Blood bank technologists shall keep a critical eye on their work and the conditions under which it is performed. They can propose any modifications that might improve the performance, quality or conditions under which it is performed. They participate in disseminating important information within the blood bank and in monitoring related technological developments.

Personnel shall be sworn to secrecy and laboratory test result confidentiality.

II. Premises

Premises are organized to guarantee, in particular:

- A logical order to reduce the risk of samples contamination;
- The One-way flow principle: clean/dirty equipment, tested/non-tested samples, and devices in stock/devices being used.
- An Effective cleaning and maintenance;
- Personnel and environment safety.

A document describes the flow of activities, reagents, waste and personnel movement.

The analysis area is physically separated and organized into workstations according to the logical order of operations to be performed, in order to avoid any risk of contamination and error during analysis.

A special work area shall be dedicated for data and results processing.

Storage areas shall be of an adequate size to allow orderly and separate storage of various product types: raw materials, in vitro diagnostic medical devices, non-compliant products and products pending destruction.

Other areas such as rest and refreshments areas, locker rooms and toilets shall be separate from the analysis and storage areas. The locker room shall be designed to keep work and personal clothes separate.

Electricity and water supply, lighting, temperature, humidity, ventilation and sound proofing shall be appropriate. Temperature and humidity shall be checked regularly.

Cleaning, installations and repairs shall not carry any risk to the quality of laboratory tests. The list of cleaning products is defined.

An area is allocated for waste storage prior to its safe disposal. A waste management procedure shall be established.

A procedure validating the results before and after corrective or preventive maintenance shall be established.

Maintenance areas are separated from transfusion activities-related areas.

III. Automation and Computerization

Pretransfusion blood testing methodologies require whenever possible automated blood-test system and computer control. However, some specialized tests are currently non-automated. In these cases and/or in the event of automation or computer system breakdown, specific procedures shall be established to specify manual testing methods.

Automation and computerization include:

- Processing of donation and donor information
- Management, operation and maintenance of automated systems;
- Quality control and validation of test results;
- Management of information that help to establish the donation status and the to update donor information;
- Traceability.

IV. Sample Handling

1. General aspects

Samples are characterized in terms of their container and content.

The container shall guarantee content integrity, personnel and environment safety. It is approved for the appropriate analytical process and identified by a donation number.

For automated analyses, positive identification of the samples shall be performed using an automated bar code reader.

Samples identification and registration shall ensure traceability between donor, laboratory tests and previous screening tests results.

Automated barcode readers shall be connected to computer systems that allow to associate blood samples bar code with the corresponding tests results. Barcode readers shall be controlled and validated.

The setup for identifying samples shall be appropriate in order to allow proper differentiation between donor, quality control and patients samples.

Proper sample handling allows avoiding technical and human errors and minimizing the risks for personnel and the environment

2. Pre-analytical Phase

Pre-analytical phase includes all actions starting form the receipt of samples to their analytical processing. Specific transport, storage and processing conditions for each sample shall be defined and validated.

A procedure shall specify appropriate measures taken during sample handling and the course of action in case of non-compliance. Non-compliances are recorded and analyzed using indicators.

3. Storage Conditions

Laboratory analyses shall be performed as soon as possible after the collection. Samples shall be stored at temperatures between + 2°C and + 8°C and shall be placed at room temperature prior to analysis.

A sample from each donation shall be stored for at least 1 week. Another serum sample should be stored for 6 months at a temperature below - 20˚C. Storage conditions (temperature and time) are validated for each analysis and recorded.

V. Blood Testing

General Concept

Tests shall be conducted according to standard operating procedures reflecting current good practices, periodically revised and updated by competent experts. A review procedure shall also take into account all scientific advances made in the detection of transfusion-transmitted diseases.

Required blood tests that should be performed on samples taken when blood was donated are established by the regulations.

A donation is qualified on the basis of the mandatory laboratory test results and, if necessary, additional tests, taking into account the donor immunological and hematological status and previous donation testing results if applicable.

Technical details for blood tests, procedures and decision-making algorithms are clearly defined, considered as guidelines established at the national level competent authorities before implementation and modification. They include:

- Determining donor blood group;
- Procedures in case of results discrepancy;
- Procedures in case of repeat reactive test result (donations not intended for therapeutic use);

- Additional procedures for result confirmation;
- Procedure managing information delivered to the donor in case of abnormal test results. This information shall be provided by the TC director;
- Procedure in case of donation-donor misidentification either in relation to the current donation or the previous donation (donation qualification, donor status).

Pretransfusion blood testing requires evidence that this analytical process enables the anticipated results to be achieved, that includes:

1. Methods validation

Methods validation aims to establish and guarantee the analytical process performance.

Prior to their implementation, blood testing processes are approved for a consumable, a reagent, equipment, a computer system and its configuration, in accordance with a protocol.

Any modification shall be validated, which in this case may include one or more parameters depending on the type and scale of the modification made. Any validation shall be signed, dated and documented.

2. Quality control for analytical reagents

Upon receipt, each batch of reagents is submitted for quality control procedures which must be defined in a procedure.

Compliance of the reagents shall be verified daily using internal controls and periodically (every 3 to 6 months) by external controls. Result analysis from these controls allows monitoring reagent quality over time.

Reagents shall be stored according to the manufacturer's recommendations. Inventory shall be appropriately managed in order to exclude non-validated, non-compliant or expired batches, and to allow them to be used before their expiry date.

The traceability used for each blood donation tested shall be ensured.

In case of non-compliance of a batch of reagents that may affect the quality of blood tests and transfusion safety, competent national authorities shall be informed immediately (Ministry of Health).

3. Analytical validation

Analytical validation is performed by technical personnel and if possible using an automated validation system, according to a predefined procedure. It shall be documented and:

- Guarantees that the conditions for conducting blood tests shall comply with procedures;
- Verifies that analytical processes are compliant with the established quality system;
- Verifies results consistency for each test according to the available donor data;
- Enables product labeling and donor status update.

The statistical process control method contributes for the analytical validation of quantitative methods. Laboratory tests quality shall be regularly evaluated using an external quality control system.

4. Biological validation

Biological validation follows analytical validation and is conducted by the TC director. It validates all procedures used for product qualification. It is performed using an automated validation system when possible. This validation is performed regularly and systematically according to predefined procedures.

VI. Traceability

Traceability system will enable:

- Through the donation ID to establish connections between a particular donation and its corresponding tests results, and between donor and his/her previous screening tests results;
- To associate to each donation ID the interpreted tests results, all intermediate data and the involved internal quality controls, critical devices and personnel.

The efficiency of the traceability system is evaluated periodically. All modifications are recorded and justified.

Information confidentiality shall be guaranteed by specific procedures.

Data required for effective traceability shall be kept at least five years.

GUIDELINES FOR THE ACTIVITIES OF SUPPLY AND DISTRIBUTION

Principle

These guidelines describe the transfusion process that includes:

- Management of workflows from the selection of blood/blood components, to their handling, processing, testing, distributing and releasing for transfusion;
- Management of information and documents, from the transfusion request to the blood/blood components traceability;
- Transfusion advice.

This process requires collaboration between healthcare facilities in order to guarantee transfusion safety and continuity of the Supply/Distribution activity.

Supply

This section applies to TC authorized to store and to deliver or distribute blood/blood components.

1. Personnel

Only qualified medical professionals, registered at the Ministry of Health, are authorized to deliver blood/blood components and to provide transfusion advice.

1.1. Duties/Responsibilities

Duties and responsibilities of the distribution manager cover the following areas:

- Within the distribution section
  - Organization: organization chart, delegation, replacement, procedures, etc.
  - Compliance with safety regulations;
  - Setting and monitoring blood/blood components stock;
  - Blood/blood components clearance;
  - Personnel education and training

- In collaboration with hospital departments:
  - Transfusion advice;
  - Monitoring blood product uses in hospitals;
  - Blood products traceability;
  - Hospital employee training.

To perform such functions, medical professional responsible for the distribution shall be granted authority by the TC director.

Organizational charts shall strive to eliminate any gaps in terms of personnel responsibilities involved in the application of good distribution practices.

It shall be adapted to the transfusion centers and blood distribution centers workload.

1.2. Qualifications

A person is qualified in distribution activities when this person has the required skills and training for fulfilling these functions.

The qualification level should be defined according to the position, performed tasks, responsibility level and acquired skills.

1.3. Training

The purpose of training is to ensure qualification of the personnel in good distribution practices. Training shall include the theoretical and practical aspects of good distribution practices. It applies to all personnel categories.

Special attention should be paid for the training of new employees.

It shall be provided and assessed regularly.

Internal or external training shall be recorded and assessed.

Distribution manager and supervisors personnel shall ensure that personnel are appropriately and adequately trained.

1.4. Personnel number

Distribution activity shall be organized in order to ensure its continuity.

Personnel number should be adapted to the institution activity and workload.

2. Premises

Access to premises shall be exclusively reserved to authorized personnel. They should be used for distribution activities only.

Distribution and storage areas shall be clearly identified.

Premises shall be located, designed, built, and maintained to suits the performed procedures.

They shall be located in a safe environment that does not carry any hazard for blood products.

Their design, plan, arrangement and use shall respect the logical order of the distribution procedures in order to reduce the risk of errors. They shall be designed to ensure the users safety indicated by clear signposting

a. Delivery area

Access shall be reserved for authorized personnel only.

It includes:

- A reception area for blood requests (it shall have rapid means of communication with prescribers for emergency situations, a bell with intercom for requests received during on-call duties).
- A separate area for preparing requested blood in order to ensure the best vigilance
- A transformation room (secondary processing room) where applicable (sealing and labeling devices).
- A release area equipped with:
  - A computer and a bar code reader providing access to the potential recipients and blood/blood components tests result;
  - A printer.

2.2. Storage areas

Access shall be reserved for authorized personnel only.

Blood/blood components storage areas shall be designed and adapted to ensure proper storage conditions and avoid errors or risks.

Blood/blood component storage areas include:

- Allogeneic blood/blood components ready for release
- Autologous blood/blood components;
- Returned and recalled blood/blood components;
- Non-compliant blood/blood components pending disposal.

These areas are clearly marked and located.

Temperature should be appropriate for stored blood/blood components and regularly checked.

Temperature alarm and recording systems are required.

They shall be clean and cleaned regularly, and disinfected when necessary (procedure, schedule, cleaning methods, frequency and workstation defined and recorded).

Blood sampling tubes and equipment required for transport may be stored if there is enough space and in an area reserved for this purpose.

A procedure describing the identification, category, access and temperature of each area is established.

3. Equipment

Equipment should meet the following requirements:

- Reliability;
- Respect of personnel safety standards;
- Suitable for the storage method;
- Easily accessible and proper brightness;
- Designed using materials resistant to cleaning and asepsis products;
- Efficiently cleaned;
- Easily accessible for maintenance operations;
- Uniform temperature distribution within the area.

3.1. General Characteristics

Refrigerated storage equipment shall:
- Have sufficient power to maintain stable temperature regardless of the frequency of access;
- Have a device allowing efficient air flow;
- Be provided with a continuous temperature measuring system, with a recording device taking regular and frequent readings;
- Include an efficient alarm system.

3.2. Refrigerators and freezers

Refrigerators shall be equipped with high and low temperature alarms and freezers with high temperature alarm.

Temperature sensors should be installed to control temperature homogeneity within the unit.

3.3. Storage area for Platelets at temperature between + 20°C and + 24°C

Shall be equipped with high and low temperature alarm system.

The storage area could be a closed device or a temperature-controlled room capable of maintaining the required temperature.

Where an air-conditioning system is used, air quality shall be closely monitored.

3.4. Platelet agitators

Platelet agitators shall be specifically designed to preserve platelet quality. Agitation shall be gentle and continuous. They shall be away from sunlight or in a temperature-controlled closed device.

Platelets should be stored in agitators to facilitate gas exchange through the bag.

3.5. Storage conditions control

All storage equipment shall be regularly maintained.
New acquired equipment shall be qualified and validated before use.
A monitoring and maintenance log shall be placed near the equipment.

The log shall include:
- Supplier name and reference;
- Purchase, validation, and in use date;
- Optionally, planned maintenance dates and involved personnel

The following are recorded:

- Maintenance operations, date and identification of the operator;
- Alarm testing and maintenance.

Records and registers are analyzed and archived.

Abnormal findings shall be notified, recorded and managed.

Temperature and alarm systems, as well as alarm triggering thresholds shall be checked at least once a year.

3.6. Maintenance and Cleaning

Maintenance, cleaning and defrosting shall be performed regularly according to a schedule while taking into account the department's activity.

Following repair, the equipment shall be validated again before use.

Defrosting procedures for freezers temperature of - 30°C and below shall be established.

Cleaning and decontamination procedures are established according to predefined schedule, methods, frequency and workstation. Cleaning or decontamination procedures shall be documented.

3.7. Transport

Temperature variations during blood/blood components transportation cause deterioration in their quality.

Therefore, necessary steps shall be implemented in order to reduce such risks and ensure appropriate storage conditions. Blood/blood components shall be transported of inside and outside health care facilities according to clearly defined rules.
The container used during transportation shall be reserved only for blood/blood components. Transport equipment and temperature shall be assessed and validated.

A procedure defining the transportation process shall be established.
The choice of transport mode shall be done in accordance with safety criteria, compliance

with storage conditions (at the nearest possible temperature to that of the regulatory storage temperature) and fast delivery.

Upon receipt, it is necessary to check that blood/blood components have been delivered in accordance with their specifications and in appropriate packaging.

3.8. Packaging

The packaging for transport outside the TC should have a label that mentions at least the following information:
- Place of departure;
- Destination and consignee;
- Product (s) type and their number;
- Storage conditions;
- Action to be taken upon receipt if applicable (e.g. "upon receipt, store blood/blood components at +4 ° C").

Thermal insulation materials of appropriate size shall be used. The package is selected according to storage conditions, transport time and vehicle type.
A written procedure shall define packaging methods and used materials.
It must take into account the majority of cases encountered and the critical periods of the year (summer and winter).

Ice-packs shall not come into direct contact with the blood/blood components. Packaging quality and size of the packaging are chosen according to the number of accumulators and their distribution.

It is recommended to use an accumulator matching the required temperature (e.g.: do not use ice packs for storing blood/blood components at a temperature of +4°C).

Hospital departments shall receive, for each patient, blood/blood components in suitable packaging, along with the appropriate documents. These documents shall include:

- Hospital department name;
- Patient triple name;
- Delivery date and time;
- Blood/blood components type, quantity, identification numbers, and their storage conditions.

  Documents relating to the delivery should also be provided (request form, immunological and hematological test results)

  The contents shall be checked one last time before sealing the package.

4. Procedures for issuing blood

Issue of blood and blood components should be assisted using a computerized system in order to manage:

- Traceability;
- Blood/blood components stock;
- Statistical data of issue

It is recommended that blood request forms become standardized using preprinted papers.
The distribution section shall establish transfusion protocols, in accordance with the prescribing physicians.

In case of discrepancy between the blood request form and the established protocol, the prescribing physician shall be informed.

In case of non availability of a blood component, the prescribing physician shall be notified.

Issue of blood and blood components shall be ensured permanently ice-packs(24/24) by establishing an on-call duty system.

4.1. Blood request form (or prescription)

Regardless of the blood product type, prescription is filled accurately and shall include:

- The hospital and department name;
- The prescriber physician name;
- The prescriber signature;
- The patient identity: (Triple name} last name (maiden name for a woman), and, if applicable, marital name, first name(s), father or husband's name, date of birth, gender;
- The prescription date;
- The desired date and time for delivery;
- The blood/blood components type, quantity, qualification and transformation.
- The transfusion degree emergency.

It is accompanied by the appropriate clinical and biological information and the transfusion protocol if applicable.

Any discrepancy between the blood request and the established protocol or any unavailability of blood/blood component should be discussed with the prescribing physicians. Changes to the initial request, except for those subjects of a transfusion protocol, shall be formally approved by the prescribing physician.

Arrangements are made by health care facilities in order to limit emergency delivery situations. Delivery department should be informed about complex immunological situations in order to take appropriate actions.

4.2. Selection of blood/blood components for issuance

Determining ABO, RH1 (RhD) and KEL1 (K) phenotypes shall be conducted on two different blood samples.

Consistency check between the blood request data, immunohematologic test results and patient history when available, is ensured. Any discrepancy shall stop the selection and the prescribing physician shall be informed.

Transfusion history and serologic tests results used for blood issue shall be retained by the transfusion center or blood distribution center.

Selection is conducted using a computerized processing system, which enables secure blood/blood component selection by comparing:

- Patient immunohematologic characteristics;
- Blood/blood component characteristics;
- Transfusion protocols, when available.

A procedure enables the security of selection and traceability in fail-safe mode, in the following cases:

- Glitch in the computerized transfer of data needed for selection;
- Unavailability of the computerized system;
- Vital or immediate emergency situation.

4.3. Release form

Blood/blood component types and IDs are systematically recorded with the patient name and ID number.

A release form shall accompany each blood/blood component issued.

It establish the link between patient name/ID number with issued blood product ID number, and represents one of the fundamental steps of traceability.

It reminds the mandatory final pre-transfusion check in the presence of the patient.

Blood/blood component transfusion shall start within six hours following their reception at hospital department; depending on whether the storage and transport conditions were respected (storage at ambient temperature shall not exceed 30 minutes before initiating transfusion). Hospital services are clearly notified about the date and the time of delivery.

4.4. Selection of red blood cells

Recipients shall receive ABO group-compatible packed red blood cells.

Antibody screen shall be performed before selecting packed red blood cells. A blood sample from the recipient shall accompany the blood request form.

Result of antibody screen is valid for 3 days. With the formal indication by the prescribing physician and in the absence of a prior transfusion or other immunizing events (pregnancy, graft, etc.) within the previous six months, the validity period for a negative antibody screen may be extended to 21 days. Operating protocols between the prescribing physician and the blood bank shall be established.

If the patient received a transfusion, it is recommended that antibody screen for irregular antibodies should be performed between one month and three months after the transfusion.

Phenotype-matched red blood cells concentrates may be useful for some patients. Two types can be identified:

- Rh and Kell phenotype: Must be used, depending on red blood cells availability and the level of emergency, for female subjects until menopause, for recipients having alloantibodies and for multi-transfused patients;
- Extended phenotype: Rh and Kell phenotype associated with the determination of at least one other erythrocyte antigen. It is used for cases of allo-immunization complex and as prevention for multi-transfused patients.

Crossmatch shall be performed for all patients having one or multiple alloantibodies. It can also replace the antibody screening test. Cross-matching remains valid for 3 days.

Blood bank shall define the optimal transfusion strategy for each patient with the prescribing physicians.

4.5. Selection of platelet concentrates

The rule for platelet transfusion is, whenever possible, ABO group compatibility.

In case of deviation from this rule, all necessary measures shall be taken to ensure transfusion safety and maximum efficiency.

Due to the scarcity and short expiration date, the most suitable concentrate is chosen, taking into account the desired efficacy and patient compatibility.

In the event of an incompatible Rh D transfusion to recipient having no anti-D antibodies, and if the clinical situation requires it, prophylaxis for anti-D allo immunization shall be given.

The request form shall include:

- Patient's weight and height if known;
- Platelet count;
- The dosage requested by the prescribing physician according to the disease.

The distribution site should be informed, by the hospital department, in case of transfusion inefficacy.

4.6. Selection of granulocytes concentrates

Limited indications for these products require an examination of the clinical chart with the prescribing physician. These products shall be irradiated.

4.7. Selection of plasma products

Plasma transfusion follows the rules of ABO compatibility.

The request form shall mention the indication for transfusion:

- Consumption coagulopathy with coagulation factors deficiency;
- Acute hemorrhage with coagulation factor deficiency;
- Rare complex coagulation factor deficiencies in which specific coagulation factors are absent.

For other indications, indication for transfusion shall be discussed between with the physicians and the hospital.

Frozen plasma is delivered immediately after thawing in a water bath device at + 37°C, at the TC or at the blood distribution center. Labeling shall be checked after thawing, and the plasma shall not be frozen again under any circumstances.

5. Neonatal and pediatric transfusion

Transfusion shall take into account the child immune status during the first three months and any specific physiological aspects during the neonatal period. Transfusions shall be compatible with the mother antibodies and the child erythrocyte antigens.

The delivery site in the TC shall establish, in agreement with the physicians, transfusion protocols taking into account additional constraints concerning the blood/blood component quality for pediatric use, such as:

- Storage time;
- Leukodepletion;
- Negative for CMV;
- Irradiation.

It is recommended to reduce donor exposures in pediatric patients by splitting the original donation into several bags and by reserving them for one child.

If, in the physician opinion, specific immunological conditions require transfusion from within the family, the blood/blood component shall be irradiated.

6. Emergency

In case of vital emergency, distribution shall be adapted to ensure the patient best chance of survival.

The TC therefore shall establish transfusion protocols and procedures adapted to the level of emergency, in agreement with the prescribing physicians.

7. Control and release of blood/blood components

A final inspection shall be made prior to the release. Consistency between the request form, the release form, immuno-hematological tests results and the products to be delivered should be checked. Release date and time are recorded.

Blood/blood components are released to a person having a document that enables identification of the blood recipient (request, request copy, blood grouping card, transport order, etc.). In case of vital or immediate vital emergency, derogation could be done to this requirement (according to emergency procedures).

II. DISTRIBUTION

1. Personnel

Personnel shall have the legally required qualifications.

2. Premises

Distribution and storage areas are clearly identified and reserved for these activities and, when necessary, for secondary processing or delivery operations.

The distribution area is located close to blood/blood components storage areas and is organized in order to guarantee:

- Reception of distribution requests;
- Preparation and packaging of blood/blood component requests.

3. Distribution procedures

Distribution procedures comprise:

- Identification of the TC
- Identification of the requesting physician or site
- Request date or periodicity;
- Desired date and time for delivery;
- Blood/blood component type and quantity.

A delivery receipt shall accompany the blood products. It establishes the link between blood/blood components ID and recipient hospital blood bank ID. This receipt represents one of the fundamental steps of traceability.

III. TRANSFUSION ADVICE

Transfusion advice accompanies the issue of blood/blood components and shall be always available. Only qualified physicians are authorized to dispense it.

It is intended for the prescribing physicians and personnel involved in transfusion practices.

1. Scope

- Assist in the choice of the transfusion therapy;
- Assist in ordering laboratory tests;
- Assist in prescribing blood/blood components;
- Assist in monitoring recipients;
- Assist in the pre-transfusion screening tests;
- Assist in the completion of transfusion;
- Assist in the storage conditions and blood/blood components transport

2. Methods

- Interventions at the request of the receiving hospital blood banks;
- Participating in departmental meetings (neonatology, pediatrics, hematology, intensive care, etc);
- Establishment of transfusion protocols in cooperation with the prescribing physicians;
- Writing information documents used by medical and paramedical personnel;
- Training;
- Establishing recommendations and procedures for the use of blood/blood components.

IV. MANAGEMENT OF BLOOD/BLOOD COMPONENT

1. Blood/blood components stock

Blood/blood requirements shall be managed according to their characteristics, which necessitate specific quantitative and qualitative requirements to be met.

Blood/blood components stock shall be checked periodically, in terms of quality and quantity, according to anticipated needs. The composition of the stock is based on the needs. Records and inventories are established in accordance with a pre-defined schedule.

2. Return of conforming blood/blood components

Conforming blood/blood components may only be returned in agreement with the TC and according to a written procedure.

They could still be used as long as they have been stored and transported according to established procedures. Compliance with these procedures shall be verified, starting from their departure from hospital departments to their arrival at the blood bank.

3. Return of Non-Conforming blood/blood components

Non-conforming blood/blood components are expired, damaged or contaminated blood products.

These products shall be returned to the TC which released or distributed them, in order to be destroyed.

Upon receipt, the TC shall record the return along with the reason. Otherwise, the receiving hospital blood bank shall communicate to the TC the blood/blood component identity (product code and type), reason and date on which it was destroyed.

The TC shall take the appropriate measures to reduce the rate of destroyed blood products.

4. Blood/blood component Recall

Blood/blood components may be returned to the TC or to the blood distribution center upon their request. Depending on the reason for the recall, blood products are returned to stock, placed in quarantine or destroyed.

5. Transfusion Confirmation

The link between the released blood/blood component and the recipient is established by the person who administered the transfusion. Confirmation of transfusion consists of recording this link or the fate of a blood product that has not been transfused.

This information is recorded and transmitted, in accordance with predefined procedures between the health care facility and the TC or the person who released or distributed the product.

The aim of this operation is to update the recipient records at the healthcare facility and at the TC. This traceability operation can be performed by a computerized system.