# The Regulations of Cord Blood and Stem Cells Storage Centers attached to Cabinets' Decision No. (6) of 2020

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# Council of Ministers' Decision No. (6) of Year 2020

## on Endorsement of the Regulations of Cord Blood and Stem Cells Storage Centers*

**The Cabinet:**

- After reviewing the constitution;
- Federal Law No. (1) of 1972 on the Jurisdictions of the Ministries and the Competences of the Ministers, and its amendments;
- Council of Ministers' Decision No. (28) of 2008 on Blood Transfusion System;
- And based on the presentations of the Minister of Health and Prevention and the approval of the **Cabinet**;

**Decided the following:**

### Article (1)

The Regulations of Cord Blood and Stem Cells Storage Centers attached to this Decision are endorsed.

### Article (2)

A higher Committee for Cord Blood and Stem Cells shall be established. Its formation, functions and work system shall be issued by a Decision of the Minister of Health and Prevention.

### Article (3)

Before the issuance of this Decision, the Cord Blood and Stem Cells Storage Centers must adjust their conditions in a manner consistent with its provisions within six months from the date of its enforcement.

### Article (4)

This Decision shall be published in the Official Gazette, and it shall come into effect six months after the date of its publication.

**Mohammed bin Rashed Al-Maktoom**
**Prime Minister**

Issued by us:
Corresponding to Jumada al-awwal 14, 1441 H,
Dated: January 9, 2020 G

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## Chapter one:
## Conditions for Licensing Facilities

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| | | |
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| **Donation** | : | Giving cells or tissues intended for human use. |
| **Donor** | : | The living human source of human tissue or cells. |
| **End User** | : | The health facilities or units affiliated to a hospital or any institution that carries out the human use of cells, and the end user must obtain a license if he intends to keep tissues for a period longer than 48 hours. |
| **Export** | : | Export from the United Arab Emirates to another country. |
| **Human Use** | : | The use of tissues or cells inside or outside the recipient's body. |
| **Import** | : | Supply to the United Arab Emirates |
| **Preservation** | : | The use of chemical means, and the change of surrounding conditions or other means during the treatment process, in order to prevent or delay biological or physical deterioration of cells. |
| **Treatment** | : | All operations that take place during the preparation, preservation, and packaging of tissues or cells intended for human use. |
| **Introduction of tissues or cells** | : | The process of providing, making available, and obtaining tissues or cells |
| **Facilities** | : | The settings where the licensed facilities carry out their activities. |
| **Quarantine** | : | The actual (physical) isolation of cells by any effective means, while awaiting the decision to be accepted or rejected. |
| **Quality Management** | : | The coordination activities used to manage and monitor the work of the facility, regarding quality issues. |
| **Quality Manager** | : | The person responsible for coordinating and monitoring activities, and ensuring the implementation of the Quality Management System. His/her mission is to monitor the performance of the quality management system, and write evaluation reports according to a set of indicators. He/she also provides consultations and provides employees with training, tools and techniques that enable them to achieve quality. |
| **Serious Negative Complications** | : | An unwanted response, which includes serious complications and infectious diseases of the donor or recipient, which relate to the introduction or use of life-threatening harmful cells, causing disruption or disability of some kind, or prolonging the period of illness and impeding th recovery process |
| **Storage** | : | Keeping the product in a suitable controlled environment, until distribution. |
| **Stem cells** | : | The cells that have the ability to regenerate and self-differentiate. |

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## Chapter One:

## Conditions for Licensing Facilities

**Licensing Authority:**

All facilities engaged in activities related to the use of primary human cells and stem cells must obtain a license from health authorities within their jurisdiction.

**Licensing procedures:**

The license is obtained after ensuring that the facility complies with the Regulations mentioned in this Decision.

**The first step: (Submitting the application)**

1. Submit a license application attached with the required documents, mentioned in the table below, to the relevant health authority.
2. The application is sent by the concerned health authority to the Committee for study.
3. Fees for submitting the application shall be paid according to the fees prescribed in this regard with regard to fertility centers licensed by the Ministry of Health and Prevention, or according to the fees applied, as the case may be, at other health authorities.
4. Receive an official response letter with a reference number from the relevant health authority once the application procedures are completed.
5. The Committee studies and decides on the submitted application and documents and notifies the relevant health authority, which in turn sends an official response to the applicant explaining the status of the application.
6. Duration of procedures: Does not exceed one month.

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| **Self regeneration** | : | The ability of cells to reproduce, without losing the advantage of differentiation and without being subjected to aging (biological aging). Self-regeneration does not mean that the division of each cell results in an identical pair of stem cells, as the newborn cells may be stem cells or more differentiated cells, and the stem cells are either fully developed, stimulated, multi-capacity or is single-growth. |

**Objectives:**

- Specify the conditions for licensing health facilities that intend to carry out activities related to cord blood, stem cells and other nuclei cells derived from blood-forming cells; such as bone marrow, peripheral blood, and cord blood. These Regulations also aim to establish a list of necessary standards.
- Determining quality and safety standards for stem cells and human tissues specialized for human applications.
- Provide a base for the concerned authorities to evaluate the performance of licensed facilities to ensure safe and high quality service delivery in order to protect donors, beneficiaries and the public.

**Scope of Application:**

The Regulations approved under this Decision include the rules and standards to be applied during the granting, collection, testing, processing, preservation, storage, distribution, import, export and implementation of procedures related to Cord Blood and Stem Cells, and other nuclei cells derived from blood-forming cells such as the bone marrow, peripheral blood, and cord blood.

These regulations don't include fetal tissues, embryonic stem cells, blood and blood products (except for hematopoietic stem cells), reproductive cells (eggs and sperms), and human organs.

These Regulations apply to all government and private health facilities at the country level that perform any of the activities covered by the scope of application and are responsible for any of these activities. These facilities are called, within the scope of application of this Decision, the Cord Blood and Stem Cells Storage Centers. The Cord Blood Storage Centers may be affiliated to a health facility or to be an independent health facility specialized only in this area.

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## Introductory Chapter: General Provisions

**Definitions**

| | | |
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| **Country** | : | United Arab Emirates |
| **Health Authorities** | : | The Ministry of Health and Prevention, the Department of Health – Abu Dhabi, Dubai Health Authority, Sharjah Health Authority and Dubai Healthcare City authority. |
| **The Committee** | : | The Supreme Committee of Cord blood and Stem Cells established pursuant to this Decision. |
| **Cord Blood and Stem Cells Storage Centers** | : | The health facility that grants, collects, tests, equips, keeps, stores, distributes, imports, exports and executes procedures related to Cord Blood and Stem Cells, and other nuclei cells derived from hematopoietic cells such as bone marrow, peripheral blood, and cord blood. |
| **Allogeneic Use** | : | Refers to the cells or tissues that are taken from one person and transplanted to another. |
| **Autologous use** | : | Means the cells or tissues that are taken from and transplanted to the same person. |
| **Authorized Employees** | : | Those persons authorized to carry out specific tasks in the field of dealing with cord blood and stem cells, and this person is required to receive adequate knowledge and training in this regard. |
| **Blood components** | : | The main therapeutic components of human blood (red blood cells, white blood cells, platelets, and plasma) that can be prepared in several ways, with the exception of lymphocytes intended for use after transplanting blood-producing stem cells. |
| **Blood** | : | It is the whole blood that is taken from the donor, and it is been treated either for transportation or any other manufacturing purposes. |
| **Cells** | : | Human cells or a group of human cells when they do not take any form of connective tissue. |
| **Critical cases** | : | The cases that may affect the quality and/or safety of tissues and cells. |
| **Direct Use** | : | Any action that is made by donating tissues and using them without previously storing them. |
| **Distribution** | : | Transfer and delivery of tissues intended for human use. |
| **Distributor** | : | The person assigned by the facility that oversees the provision of transfer services of cells or tissues intended for distribution by those facilities. |

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## Chapter Two
## Regulatory and Operational Conditions

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| The Documents Required for the Private Facility | Special Considerations |
|---|---|
| A photocopy of the passport of the owner and the partner (if any) | Colored copies |
| The Emirates ID of the owner and the partner (if any) (for holders of Emirati citizenship) | Colored copies |
| Certified signature of the owner, certified by the competent authorities. | Colored copies |
| The approval of the Department of Economic Development on the name of the health facility (if applicable) | Colored copies |
| A presentation about the project, accompanied by scientific information, and supported by references and research. | Hard disk containing the presentation (Power Point) |
| - The proposed engineering plan.<br>- Site location. | Colored copies |
| **The facility's plan on:**<br>1. Objectives<br>2. Scope of application<br>3. Organizational Structure<br>4. Administrative policy<br>5. Employees<br>6. Control Policy<br>7. Infection control policies and guidelines<br>8. Medical Equipment Management Policy<br>9. Medical waste management policy<br>10. Records and documents management policy<br>11. Donor rights and duties<br>12. Quality Management Policy<br>13. Policy of notification of negative complications<br>14. Distribution and return policy<br>15. Risk assessment<br>16. Accreditation plan | Hard copy and electronic copy |

**Step two: (Preliminary approval)**

1. The initial approval fees are paid according to the fees prescribed in this regard for fertility centers licensed by the Ministry of Health and Prevention, or according to the fees applied, as the case may be, at other health authorities.
2. Once the Committee approves the documents and after payment of the prescribed fees, the concerned health authority sends a letter of initial approval to the applicant.

**Step Three: (License)**

1. After obtaining the initial approval, the applicant fulfills the rest of the licensing procedures at the relevant health authority.

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shall be responsible for selecting the facilities that they contract with, and to bear the responsibility for conforming these facilities to all standards, bear the responsibility for the quality and safety of the products transported, the quality and safety of the team carrying out the transfer process and that the responsibilities of each party to the agreement are clear and specific. A photocopy of this agreement shall be provided to the concerned authorities. The licensed facilities that work in cord blood stem cells transfer shall not hold such agreement described above with physicians or specialists in the field of health care in their individual capacities.

2. The license fees are paid according to the fees prescribed in this regard for the fertility centers licensed by the Ministry of Health and Prevention, or according to the fees applied as the case may be, at other health authorities.
3. The license applicant must provide a bank guarantee of AED 10 million, and in the event of a violation committed by the licensed facility, an amount commensurate with the nature of the violation committed shall be deducted from this guarantee, provided that the amount deducted due to the violation is returned to the bank guarantee balance by the licensed facility within a period not to exceed two months from the date of the deduction.
4. The concerned health authority shall check and inspect the facility in accordance with the criteria and regulations mentioned in this Decision, before allowing the facility to start its activities. The Committee may delegate a representative to participate in the check and inspection procedures upon previous coordination with the concerned authority.
5. **License renewal**: Upon renewing the license, the annual renewal fees for the license shall be paid according to the fees prescribed in this regard for the fertility centers licensed by the Ministry of Health and Prevention, or according to the fees applied, as the case may be, at other health authorities.
6. **Request to add or change activities**: With regard to the request to add or change activities, fees shall be fulfilled for changing new additional activities or services in accordance with the fees prescribed in this regard with regard to fertility centers licensed by the Ministry of Health and Prevention or according to the fees applied, as the case may be, at other health authorities.

**Inspection and oversight:**

a. Licensed facilities must allow inspectors of the relevant health authority to perform the oversight role over the facility, its institutions, equipment, products, and treatment operations carried out therein; record notes, and write reports on the facility's application of the conditions contained in this Decision, and inspections may be made upon prior notice or without notice.
b. The frequency of inspection depends on the facility's compliance record.
c. The facility manager must accompany the inspector while performing his work and the inspector may question the facility's employees, as necessary from his point of view.
d. The inspector has the right to review any records and obtain copies of them.
e. It is prohibited to copy any records that contain the name of donor or recipient of human cells, or any information about them, except after an appropriate anonymity of the identity.
f. Health authorities must ensure that the personnel responsible for inspection and evaluation are adequately qualified and trained.

## Chapter Three
## Quality Assurance Requirements

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**Ending activities**

The licensed facility must have alternative agreements and procedures to ensure that the cells stored therewith will be transferred, in the event that the facility is suspended for any reason (including the closure of the facility), to one or other facilities that have a license to store human cells, within the country. Such agreements and procedures must be preserved in such a way that the data stored can be accessed for 30 years after the last use or after being disposed of.

**Authorization to perform treatment and preparation of a new type of cell**

In the event the facility desires to perform operations to collect, test, treat, store, distribute, import or export a new type of cell or tissue, and in the event that this new cell type or tissues is fundamentally different from the types that the facility deals with, the facility must inform the health authorities to obtain their approval to implement these activities, after obtaining the approval of the Committee.

**Import and export cord blood cells and stem cells:**

It is forbidden to import or export cells without obtaining prior formal permission by the Ministry of Health and Prevention; an official request must be submitted to the said Ministry that includes explaining the reasons in detail.

The Committee studies the application for final approval. In the event that the request is approved, the cells must be shipped in accordance with the standards approved in this regard.

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12) **Accreditation**: Any facility operating in the field of Cord Blood and Stem Cells whose activities are testing, processing, preserving, storing and distributing human cells intended for therapeutic purposes must obtain accreditation for its activities from an accredited and internationally recognized organization periodically based on the established system of accreditation. This accreditation must be within a period not exceeding two years from the date of commencement of work by one of the following international organizations: The International Foundation for the Accreditation of Cellular Therapy (**Net Cord - FACT**), the American Association of Blood Banks (**AABB**), the College of American Pathologists (**CAP**), and the Foundation for the Accreditation of Cellular Therapy (**FACT**), the Joint Accreditation Committee of the American Society for Blood and Marrow Transplantation, and the International Society for Cellular Therapy (**JACIE**). In the event that the international accreditation is not obtained or renewed, the facility is granted an additional period of six months, after which the health authority has the right to close the facility.
13) **Maintaining records**: Facilities that work in the field of Cord Blood and Stem Cells must maintain records of all their activities, and these records include the types and quantities of cells that were introduced, tested, preserved, stored, distributed, and even the cells that were disposed of, in addition to sources and destination of the cells prepared for human treatment purposes.
14) **Reporting serious complications and negative reactions**: The licensed facility must ensure that there is a system for reporting, investigating, recording, and transmitting information about the occurrence of any serious complications or negative reactions that affect the quality and safety of cells, which may be due to an error in the process of transferring, testing, treating, storing and distributing the Cord Blood and Stem Cells, as well as reporting on monitoring of any serious complications or negative reactions, during or after the transplant process, that will affect the safety and quality of the Cord Blood and Stem Cells inside the patient's body, this system must be connected to the health authorities, which in turn informs the Committee.
15) **Acknowledgment of approval**: It is not permitted to carry out the process of transferring the Cord Blood and Stem Cells until all the mandatory conditions and approvals are fulfilled; the licensed facility must take all necessary measures to ensure that the donor, his relatives or any person authorized by him is aware of all the information on the process and agrees thereon.
16) **Confidentiality and data preservation**: The licensed facility must take all necessary measures to ensure the protection of the data and maintain its confidentiality, and the information must be kept up to date, away of any manipulation of it, and be completely secured, so that there is no possibility of deletion, change or transfer or any unauthorized additions.
17) To ensure adequate safety and quality for the intended purpose of the cord and stem cell transfusion, it is necessary to identify and reduce the risks involved in the process, and to deal with and minimize the biological materials used.
18) All licensed facilities operating in the field of cord blood and stem cells transfer must have an agreement with licensed health facilities that carry out collection and transport of cells for its account, provided that the licensed facilities operating in cord blood and stem cells transfer

## Chapter two

## Regulatory and Operational Conditions

1) The licensed facility must possess an organizational structure and operating procedures that are appropriate to the activities for which it is authorized to carry out; there must be an organizational chart that defines responsibilities and determines the relationships between the departments and members of the facility.
2) All licensed activities must comply with the documented quality management system.
3) There must be a documented system, which includes tracking and identifying the activities of each unit of the cord blood or stem cells, from the stage of introduction of cells and tissues to the stage of the last use.
4) The process of granting, introduction, testing, treating, preserving, storing and distributing human cells prepared for therapeutic purposes must be carried out according to the highest standards of quality and safety, in order to ensure the highest levels of health protection in society.
5) The transplantation of hematopoietic cells may cause disease and cause undesirable results. To avoid such things occurring, careful examination and evaluation of the donor must be carried out, and the cells transferred from the donor must be tested according to established and updated rules, using the best available scientific methods.
6) Donations are voluntary and unpaid.
7) All necessary measures must be taken to provide potential donors with cord blood with all guarantees about the confidentiality of any health information related to them, to provide them with the results of tests conducted on the cells taken from them, and to provide them in the future with any other information in this regard.
8) The licensed facility must have a facility accreditation system for cell therapy, and a system for reporting any complications or adverse reactions related to the introduction, testing, treatment, preservation, storage, and distribution of Cord Blood and Stem Cells.
9) Health authorities should organize inspection and monitoring programs to ensure that cord blood and stem cells facilities are in compliance with all conditions of these Regulations.
10) Personnel working directly in the transportation, introduction, testing, treatment, preservation, storage and distribution of Cord Blood and Stem Cells must be properly trained and qualified in relation to these tasks.
11) **Tracking**: Health authorities must ensure that the Cord Blood and Stem Cells transferred, treated, stored, or distributed can be tracked, and the traceability process is possible through close examination of the material, the donor, the facility overseeing the transportation, the laboratory identification procedures and the labeling system, in addition to reviewing the records. This traceability also applies to all data related to the products and materials related to those cells. Therefore, an appropriate system is required to ensure traceability of the cord blood and stem cells.

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## Chapter Three

## Quality Assurance Requirements

This chapter explains the requirements of quality management with regard to licensing facilities that carry out the operations of introduction, testing, treatment, distribution and storage of Cord Blood and Stem Cells for the purpose of human use.

### Quality Management

1. The licensed facilities must contain quality management requirements that ensure that the cells are suitable for their intended use and that patients or donors are not exposed to any risk, nor should the measures taken on cells be ineffective or clinically harmful.
2. Quality management requirements should be commensurate with the nature of the procedures implemented, as the cell formation process requires more control over most of the other storage activities.
3. The critical quality characteristics of tissues or cells must be identified and described, as well as the methodologies necessary to achieve these specifications. Based on these requirements, licensed facilities must identify and document all its critical activities.
4. Chemical reagents and materials necessary to maintain the critical quality characteristics of cells must be included in a list. These reagents and materials must be subject to acceptance regulations, and all critical equipment must be identified and be subject to the regulations stated in the equipment section.
5. For each critical activity, all materials, equipment and personnel involved in this activity must be identified and documented.
6. The licensed facilities are responsible for implementing the requirements of quality management and the participation and commitment of all employees working under this license is necessary to establish an effective system.
7. The quality management requirements must contain the following documents:
   a. Quality guide that provides an overview of the quality system
   b. Standard operating procedures
   c. Instructions provided by relevant professional bodies or advisory committees
   d. Training manuals and references
   e. Reporting forms
   f. Donor records
   g. Special information about the final destination of cells
   h. Risk management system
   i. Monitor mismatches and accidents, including serious adverse events, and manage interaction.
   j. The existence of a mechanism to control changes to ensure that they do not negatively affect the quality and safety of cells, which allow reducing the risks associated with the change.

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18. All employees should have knowledge of microbiology and hygiene and should be constantly aware of the necessity of avoiding bacterial contamination or injury to donors, recipients, cells and buildings. Hygiene guidelines should be shown in each department and these instructions should be understood and followed by all employees.

**Equipment and materials used**

19. The licensed facility must ensure that it has the necessary equipment and materials to carry out activities effectively.
20. All equipment that can affect the critical quality and safety standards of cells should be designed, validated and maintained to suit the intended purpose and to reduce any risk to donors, recipients or employees and should be effectively cleanable, and a commitment should be undertaken to carry out regular maintenance, monitoring and calibration on condition of using a standard that can be followed, if available.
21. All equipment used in critical operations must have a set of operational conditions (such as temperature, humidity, etc.) and must be monitored.
22. Procedures for the operation of each piece of equipment used in critical operations must be in place, detailing those measures to be taken in case of malfunctions.
23. The specifications of the important reagents and the materials used must be documented, and the suppliers must be selected on the basis of their ability to meet those specifications. The licensed facility should have a list of acceptable suppliers to supply the important reagents and the materials used, and the suppliers should provide a certificate of compliance for each supply shipment.
24. Inventory records must be maintained for tracking purposes and to prevent the use of materials after their expiration date.
25. Clear deviations in the quality and performance of equipment and materials should be investigated, the results should be documented, and the results of those investigations and corrective actions taken should be reported.
26. All relevant data for products and materials related to cells must be recorded and ensured to be traceable.
27. When using reusable tools, hygiene and sterilization procedures should be put in place to ensure that infection factors are removed.
28. CE European-branded devices or FDA approved medical devices should be used whenever possible, and individuals should receive training on using these devices. In the event that devices are CE-branded are not available or are not suitable for operations, a commitment must be made to obtain appropriate certification.

period. These standard operating procedures should describe how records are accessed, identified; collected, indexed, and stored, maintaining its confidentiality and safe disposal procedures, and audits and certifications should be done on the database to ensure that the records are correct.

50. Records must be easy to be read and not easy to erase and may be handwritten or transferred to another validated system, such as the electronic system.
51. All records, including primary data, must be kept for at least 30 years after the expiration date, clinical use, or cell disposal.

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## Chapter Four
## Operations Control

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8. Licensed facilities should consider appointing a quality manager to coordinate the activities necessary to meet quality standards.

**Quality Review**

9. A system of monitoring the licensed activities must be implemented at least every two years. The standard operating procedures must be adhered to, and the regulatory requirements must be monitored by trained and qualified people independently. The health systems that ensure applying monitoring process without bias must be applied. The facts and the correct actions taken must be documented.
10. Any deviations from the critical quality characteristics should be followed by documented investigations, which include issuing a decision regarding possible corrective and preventive measures, and the fate of the non-conforming cells must be determined in accordance with the procedures written under the supervision of the medical director and that incident must be recorded, and all affected cells must be identified.
11. Corrective and preventive measures should be documented and initiated and completed in a timely and effective manner and should be evaluated in order to obtain effectiveness after implementation.
12. The licensed facility should have a system to review the performance of the quality management system to ensure a continuous and systematic improvement process. This review should include in particular a study of the findings of any investigations into suspected incidents or serious adverse reactions. The results of the quality review must be recorded and maintained, including all proposed decisions and procedures related to improving the quality management system.
13. The licensed facility must complete self-evaluation forms to evaluate the facility's compliance with the standards at least every 12 months.

**Employees**

14. All health and technical services personnel must be licensed by the health authorities
15. **The director**: There must be a qualified person in one of the medical specialties related to the field of work of the center and must have the required expertise, and the director must have responsibility and authority in all medical and technical policies, processes and procedures.
16. The facility must have appropriately qualified individuals to carry out all the tasks assigned to them. All individuals should have clear, documented, and up-to-date job titles, and the facility must maintain personnel records that include all relevant employment information, training records and registration at any professional or legal bodies.
17. Employees should receive initial and continuous appropriate training on the tasks assigned to them, and the training programs should be applied and their effectiveness must be monitored by regular assessments of individual competency. The training should be documented and training records maintained. The staff must be trained on quality standards and legal and ethical aspects related to their work.

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**Institutions and Facilities**

29. Facilities must be fit for licensed activities and comply with health and safety requirements with an assessment of potential risks, and when it comes to critical activities they should be given the highest importance.
30. The licensed facilities must have written policies and procedures regarding maintenance of their buildings and facilities regarding the following:
    a. Access control
    b. Cleanliness and maintenance.
    c. Trash disposal
    d. Providing services and procedures to be taken in the event of an emergency
    e. Regular review and evaluation of facilities' risks.
31. Wherever cells or any mediator that is directly related to the environment is exposed during the treatment process without the presence of bacterial inhibition, this should be done in a working environment with an enumeration of air particles and a colony population that is equal to those in class (A) as defined in the Current European Manual on Good Manufacturing Practices and Appendix 1 of European Directive 2003/94/EC. The processing environment for the cells must be at least equal to the provisions of class (D). In order to comply with the requirements of the necessary air particles, measurements must be taken into consideration at both the operating and closure time.
32. Housekeeping and air purifiers should be routinely monitored during operation. With regard to the regions of class (A), particle monitoring should be carried out throughout the critical treatment period, and in the event that this cannot be achieved technically due to the nature of the operations, the reasons must be documented and in this case the implementation should be carried out in the manner of simulations and media packages
33. Hygiene protocol must be established to address and comply with the surrounding environments to ensure that contamination risks between samples are minimized.
34. Less stringent environment than stipulated in Paragraph 31 of this Chapter may be accepted in the following cases:
    a. When applying the existing bacterial inhibition and final sterilization and checking their validation
    b. When making sure that the cells' exposure to the environment (class A) results in a harmful effect on the required characteristics of the cell concerned.
    c. When making sure that cell transplantation for the recipient carries a much lower risk of transmitting a bacterial or fungal infection to the recipient than he would be exposed to with the transfer of cells.
    d. When it is not possible technically to perform the necessary operation in the class (A) environment.
35. In each case, the environment must be defined and should be established that the chosen environment is appropriate to maintain quality and safety characteristics, taking into account the intended purpose, system of use and the immune status of the recipient.

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36. Clothing, Personal Protective Equipment and general hygiene equipment must be provided in all relevant departments of the licensed facility in addition to following general hygiene instructions and written protective clothing guidelines. Protective clothing should be appropriate to the specified air quality levels and appropriate sterilization.
37. When cells are stored, conditions must be defined to preserve the required characteristics of the cells and set tolerance limits.
38. Storage areas should be designated to avoid or minimize chemical contact or exposure to the atmosphere or any other possible source of infection.
39. There must be special procedures and precautions for emergencies to deal with any deficiencies in the required equipment in order to maintain storage conditions.
40. Cell storage facilities that are held in the quarantine area must be separated and distinguished from those that are permitted and those that are rejected and, when necessary, there must be separate storage rules for cells collected in accordance with the special standards.
41. Control procedures should extend to the packing areas to ensure no damage, exposure to contamination, or mixing cell.
42. The licensed facility must have a policy regarding the regulation of cord blood units and includes, at least:
    a. Special cord blood units for clinical use
    b. Cord blood units used for quality assurance activities
    c. Disposed cord blood units
43. The facility licensed should have an annual contract to dispose the medical waste with one of the authorities officially authorized by the government authorities in the same emirate.

**Documents and records**

44. Documentation and records must be provided as evidence that all aspects of quality management systems have been satisfactorily implemented and that the cells match the critical quality characteristics that have been identified.
45. Records must ensure that all steps are traceable, including coding process, donor eligibility, introduction, testing, processing, filing, storage, transportation, distribution, disposal, import, or export.
46. The documents and records must be clear and include correct information.
47. All quality documents must be subject to the documentation control system, with a clear indication of their date, source, and approval authority. Quality documents (standard operating procedures and risk assessment) should be reviewed regularly at least every two years. The document control system must also ensure that only copies of existing documents are in use.
48. All changes to data must be reviewed in documents and records, dated, approved and documented by appropriate personnel.
49. Records management must be described in "Standard Operating Procedures". The standard operating procedures must ensure that the records of the customer/ patient and records of all quality standards for critical processes and procedures are maintained for the required time

## Chapter Four
## Operations Control

The licensed facilities must have approved policies and procedures that guarantee the quality of cord blood and stem cells services while ensuring that they are carried out under the terms of control.

### Donor approvals

1. The health facility must ensure that approval information is provided to the potential donor before making a donation.
2. The health facility must include the following:
   a. The information is provided by trained individuals and in a simple way through the use of terms understood by the potential donor.
   b. The information should cover at least the purpose and nature of the donation, its specific risks and consequences, any required medical analyses, procedures for protecting the donor's data, confidentiality of medical information, the therapeutic purpose, the potential benefits of the donation, and information about the applicable guarantees that are intended to protect the potential donor.
   c. That the potential donor be informed that he has the right to receive the results of the medical tests.
   d. The potential donor should be informed of the need to obtain his prior approval before the introduction process.
3. The mother's consent to donate cord blood during pregnancy or immediately after birth should be obtained for storing the cord blood of her child for possible future use and she is encouraged to contact the health care providers who care for her to help her make the decision.
4. The facility is responsible for providing adequate information to the mother so that she can make a correct and appropriate decision. The information should be provided in the mother's language if possible and should review the approval process with the tests and checks necessary for the mother's donation and approval of the potential use of samples in the laboratory or scientific research when the cells taken are not suitable for clinical use.

### Selecting the donor, assessing his/her condition and testing him/her

### Standard of test for cell donors

5. For donors, the test criterion should be based on analyzing the risks related to the use of specific cells. Indicators of those risks should be determined by conducting a biological test, reviewing medical and behavioral history, medical examinations, and any other appropriate procedures.
6. There should be reliable procedures for donor selection which stipulate the criteria for selection, exclusion, and the analyses to be performed and the person responsible for selecting the donor.
7. A special record must be created for each donor to evaluate the action performed.

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Allogeneic evaluation of the donor

8. The person designated by the health facility must collect and register the medical and behavioral information relevant to the donor in accordance with the set of requirements described in this Decision.
9. Personal interviews must be conducted by a registered health care employee.
10. Donor's full records must be reviewed and evaluated to demonstrate the suitability and must be signed by a registered health care worker.

**Special considerations for choosing a cord blood donor**

High selection criteria should be used to ensure the safety and quality of the cord blood, and this includes obtaining approval from the donor in addition to taking the full medical history, and performing a laboratory test for the mother's blood according to the required laboratory tests. At the time of delivery, the data of the mother and child shall be reviewed in order to demonstrate the signs or symptoms of a congenital acquired infection, birth factors that can make the donor child and the collected stem cells at risk of infection.

In the case of donating to one of the brothers and sisters for a medical purpose, and the cord blood is intended for family use only, it is possible not to adhere to the results of the clinical analysis and clinical examination for the mother and the examination of the newborn, and in this case the facility will license the cord blood unit taken and determine its safety and adequacy.

**Donor's documents**

11. For each donor, there should be a special record containing:
    a. Identification of the donor (first name, last name, and date of birth - if the mother and child are involved in the donation, both the name and date of birth of the mother and the name and date of birth of the child)
    b. Age, gender, medical and behavioral history (information must be sufficient to allow the exclusion criterion to be applied, if necessary)
    c. The results of the medical examination, when necessary
    d. Evidence of consent, including the purpose for which the cells may be used and any specific instructions for their use and disposal.
    e. Clinical data, laboratory test results, and other results of any tests performed.
    f. The appropriateness of the donor should be documented for the recipient chosen and for donations that are not relevant. If the facility has limited access to the recipient data, the donor's data should be provided to the facility where the transplant will take place to ensure the appropriateness.
12. Donor's records must be kept in the facility's archive for full tracking purposes for at least 30 years after clinical use or disposal, and in the format that ensures continuous access during that period.

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**Laboratory tests required for donors**

13. Cell donors must pass clinical laboratory tests in accordance with the regulations listed in the legislation in force in the country, and in accordance with the standards of Netcord, FACT, and AABB, which require a blood sample from each allogeneic donation to be tested by an approved testing instrument bearing the mark of the US Food and Drug Administration/ CE for testing the Hepatitis B surface antigen (HBsAg), Hepatitis B antibodies, hepatitis B virus DNA, Hepatitis C antibodies, Hepatitis C RNA, antibodies for Human Immunodeficiency- 1/2, RNA for Human Immunodeficiency- 1/2, Human Lymphoid Tissue virus T1/2, laboratory testing for syphilis and blood type ABO/ Rh, and human pellet antigens class 1 (A & B) and class 2 of human pellet antigens ( DRB1).
    Serological checks on CMV and Herpes virus are also routinely performed for donors of Cord Blood and Stem Cells, and some other tests may be done as needed, such as tests for malaria, Chagas Disease and West Nile virus, and a genetic test should be done to detect hemoglobinopathy before using blood cells, and the samples should not be distributed or used unless the results of the above tests are negative and nonreactive.
14. The licensed facility is responsible for ensuring that the required additional tests are completed in accordance with the regulations listed in the legislation in force in the country.
15. If the cord blood is stored for long periods, taking samples must be repeated and tested again after a 180-day interval, or the donation sample should be additionally tested using a DNA test (NAT)
16. If the conforming stored cord blood is imported for allogeneic use in the treatment of severe cases, an additional DNA test (NAT) should be performed from the donation sample of the original mother or untreated cord blood sample if possible.
17. Any blood sample taken for testing should be accurately labeled to ensure that the donor is recognized and must include a record of the time and place where the sample was obtained.

**Autologous Donor**

18. If the cells are stored or in case of creating lab culture, the same minimum set of biological testing requirements must be applied, such as those applied to the allogeneic donor, and the tested cells may have been stored and have a positive result and used in cases of self-cultivation of stem cells that can provide treatment or potential cure for life-threatening diseases at the discretion of the attending physician or the doctor performing the implantation. In such cases, the positive test results of the cells or any product derived from them do not prevent them from being stored, treated, and replanted, provided that the facility allows their storage and separation properly to ensure no risk of contamination transmission with other processes.

**Cell introduction procedures**

19. The process of human cell introduction must be carried out by registered health care personnel, who have the necessary experience to carry out the introduction procedures, and this is

a. Donor documents: Includes the approval/ delegation documents
b. Introduction records
c. For allogeneic donors: The documented results of donor evaluation in light of the selection criterion.

37. The facility must have adequate procedures for managing and separating mismatched consignments, or incomplete test results, to ensure that there are no risks from contamination of other cells being processed, preserved, or stored.
38. The facilities should carry out site-specific risk assessment to determine the fate of cells that do not meet the required specifications. This assessment should contain a justification for continuing treatment or storage of non-conforming cells.

**Cell processing**

39. The processing activity must be carried out in the context of the appropriate quality management system and the specific criteria needed to be identified and described in detail.
40. Critical treatment steps must be identified and validated to reduce ineffective or harmful cells for the recipient. Verification may be carried out based on studies conducted by the facility itself, or through published data or by assessing the retroactive effect of the results of clinical studies on the received cells.
41. It must be demonstrated that the verification process can be implemented continuously and effectively in the facility's environment by employees.
42. The treatment steps and method of validation must be documented in standard operating procedures and the medical director must ensure this. They must also be subject to regular clinical evaluation, ensuring that they continue to achieve the desired results.
43. The bacterial inhibition of cells must be identified, documented, and validated when being applied.
44. Before implementing any noticeable change in the treatment process, the adjustment process must be validated and documented. There should be regular review and evaluation of the cumulative effects of slight changes in relation to the treatment method. Procedures for disposal of discarded cells should ensure that other products, the treatment environment or individuals are not contaminated.

evidenced either by their general job responsibilities or through their completion of the documented training program.

20. The licensed facility must have written agreements with the staff or clinical teams responsible for cell introduction, unless they are employed by the same facility, to specify:
    a. Cell types and/ or test samples to be introduced.
    b. The protocols to be followed.
21. There must be standard operating procedures (SOPs) to ensure that the person designated by the health facility checks and records the following before cell transplantation:
    a. Introduction approval.
    b. How to identify the donor.

    And, if possible, to follow the following procedures:

    c. Conducting the assessment of the donor selection criterion.
    d. Conducting the evaluation of the required laboratory tests as mentioned previously.
22. Standard operating procedures should specify procedures for the following operations:
    a. Induction
    b. Packaging
    c. Mark the packaging
    d. Transfer cells
    e. Transfer the cell samples to the test laboratories
    f. Report complications and/ or serious negative reactions
23. The introduction procedures should be appropriate in relation to the type of cells donated, and should protect the characteristics of the cells required for their clinical use.
24. The introduction procedures should reduce the risks of microbiological or other cell contamination, and include the risks to which cells are exposed through the source, especially in cases where cells cannot be sterilized later. The enforced policies and procedures must be followed to reduce the risk of cell contamination that could be caused by health personnel who may have infectious diseases.
25. The risks must be evaluated in the facilities from which the samples are introduced, provided that the evaluation is documented against the risks in relation to the risks of contamination, health, and safety by the person in charge of the introduction process for each of its stages.
26. The introduction process should take place in an environment that guarantees the health, safety and privacy of cells.
27. Any negative events occurring during the introduction process that may lead to damage to the living donor must be recorded and reviewed and the results of the investigation should be studied to determine the cause.
28. Sterile tools and devices should only be used for cell introduction, and materials and equipment must comply with the principles laid down in the equipment section.

**The introduction records**

29. The health facility that implements the introduction process must prepare the report of introduction and this report should include, at least, the following:
    a. Determine the name and address of the cell-delivered facility.
    b. Donor identity data (includes how to identify the donor)
    c. Description and identification of cells brought in (including samples for testing)
    d. Identify the person responsible for the introduction, including his signature
    e. The date, time and place of introduction and procedure used, including any accidents that occurred
    f. Environmental conditions in the introduction facility, including a description of the environment where the introduction took place and a risk assessment in order to determine the suitability of the introduction locations
    g. Identifiers of the reagents and transport solutions used.
30. All records must be processed according to the policies provided for in the documents and records framework, and the records of the donor must be maintained as stipulated.
31. A unique identifier must be assigned for the donor and the cells donated during the introduction process, provided that a record of the symbols is kept in order to ensure that the donor is identified and all donated material is tracked.

**Cell receipt by the facility**

32. The facility authorized to deal with cord blood cells and stem cells must ensure that human cells are correctly identified at all times, and each consignment or batch of cells must identify the identification code to ensure tracking, and the facility approves the use of this symbol.
33. The licensed facility must have a receipt for receiving the standard operating procedures for cells, the process for accessing the facility must be documented, and receipt procedures must ensure that the consignment conforms to the specifications and labeling requirements mentioned above.
34. The recipient should verify the validity and record the following:
    a. Receive the correct cells and have the appropriate markings on them
    b. The time taken in the transportation process, which includes any exceeding of the maximum time allowed for transportation (the transportation time is the full time spent in the shipping container, including the hospital delivery phase).
    c. The packaging process is intact
    d. Conform to technical requirements or standards to ensure quality is maintained.
    e. The blood samples to be tested shall comply with the requirements of transportation and marking
35. Deviations must be recorded and monitored, and the cells must be quarantined until their integrity has been verified, along with the associated documentation that conform to the requirements.
36. The data that must be registered in the facility include the following:

Serious events or complications and adverse reactions

57. The licensed facility must have a system in place to perform reporting, investigation, recording and information regarding events and serious adverse reactions that may affect the quality and safety of cells.
58. There should be employees assigned by the facility to carry out the evaluation, investigation and take the necessary measures.
59. The necessary measures must contain a notification to the health authorities in the country.

**Cord blood sampling, treatment and storage procedures**

**Sampling of cord blood:**

Special protocols are prepared to take a sample of cord blood to avoid interfering with the delivery operation, maintain sterilization and take the minimum sample size represented by the number of hematopoietic stem cell units taken as samples in the cord blood unit. The sampling process of cord blood should never expose the safety of mothers or children to risk during the delivery operation, and appropriate birth procedures should not be altered in order to take the cord blood sample. It should be noted that tying the cord late to improve the iron stock of the child, but it negatively affects the size and quantity of cells from the cord blood units taken in the sample that if it is planned to take a blood sample from the cord, tying the cord late should be avoided.

The cord blood sample may be taken either before the completion of the delivery operation, "**inside the uterus**" or following the release of the placenta "**outside the uterus**". Below are descriptions of the types of procedures for collecting blood samples:

**Collecting the sample outside the uterus:** After the placenta is released, it is immediately taken to the sample collection room and hanged on the sample holder. The cord that has been tied to the antiseptic solution shall be disinfected. A measuring needle No. 16 connected to the cord blood collection bag containing an anticoagulant solution is injected into the cord vein at the place disinfected and the blood is allowed to go to the collection bag, and the sample is collected outside the uterus by two trained professionals.

**Collecting the sample inside the uterus:** After birth, the cord is tied and cut in the usual way. Before the placenta is released, four to eight inches of the cord are disinfected with an antiseptic solution. A measuring needle No. 16 connected to the cord blood collection bag containing an anticoagulant solution is injected into the cord vein at the place disinfected and the blood is allowed to go to the collection bag. Intrauterine blood collection can be done by the obstetrician during the natural or cesarean delivery.

If the needle is re-entered, the new insertion site must be thoroughly disinfected before insertion. In general, it is preferable to collect the blood sample from outside the uterus because this is

**Storing and approving the cells**

45. The maximum storage time for cells should be determined as storage can take place under different conditions and temperatures.
46. The system for identifying cells through any stage of treatment in the facility must be clearly distinguished for the approved cells from those that are not approved, quarantined or neglected.
47. There should be standard operating procedures detailing the conditions, responsibilities and procedures for cell authorization for distribution according to these directions.
48. The records must demonstrate that before approving the cells they are checked for compliance with the appropriate specifications, in particular with all relevant approval forms and medical records and the validated test results according to the procedure written he a person assigned to this task.
49. A documented and certified risk assessment should be performed by the licensed facility to determine the fate of all stored cells following the selection and identification of the new donor, or a modified test standard or any significantly modified treatment steps that enhance the safety and quality process.
50. All storing operations must be carried out under controlled conditions.

**Transfer of cells**

51. The transfer of cells must be carried out in accordance with international standards and under the conditions that guarantee their safety and quality at all times. Transport conditions must be specified, including the temperature and the maximum duration of transfer.
52. The shipping container must be suitable for transporting biological materials and be able to preserve cells in specified conditions for their safety and quality. The packaging process must reduce the risk of contamination and be able to keep cells at the set temperature for the maximum transport time that has been established, and the packaging process must protect those processes for handling and transporting cells from potential biological hazards, and all the containers and packaging process must be checked to ensure that they are appropriate for their intended use.
53. The guide enforced in the country for the transport of biological samples should be followed with regard to the shipment of biological samples.

**Restoration process**

54. Each facility must ensure the application of accurate, prompt, and verifiable procedures that enable it to restore any product (for example after an event or negative reaction is discovered).
55. There must be staff assigned to the facility to assess the need for recovery and to coordinate the necessary procedures in this regard.
56. Restoration procedures must include a description of the responsibilities and actions taken, including notification to health authorities in the country.

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1. Unit size, weight, and total nuclei cells count with a difference, in addition to a possible evaluation of the unit's blood components after treatment (for example, CD34 + cell count or colony forming the unit count).
2. ABO/ Rh Blood Type, Human Leukocyte Antigen Class 1 (A, B), Class 2 Versions (DRB1)
3. Hepatitis B Test, Hepatitis C Test, HIV 1 and 2, HIV P24, syphilis, CMV, and bacterial culture.
4. Hemoglobin test to find out the presence of hemoglobinopathy in the donated sample.
5. Unicellular, plasma and DNA cells from the cord blood unit may be stored in a separate section of the main unit for testing for infection and/ or genetic diseases.

The cord blood units can be stored with little or no treatment or by removing most of the plasma and red blood cells in order to store the units in a smaller size. In general, the treated units are preferred and this is the main reason that the cord blood samples that still contain red blood cells require washing before being used to remove the depositions of red cells and free hemoglobin that may cause major reactions. Additionally, untreated cord blood units usually contain more Dimethyl sulfoxide $(CH_3)_2SO$ that can lead to allergic reactions. Whenever possible, the division results should be collected. After completing testing and treatment, the hematopoietic stem cells will be kept by storing each unit in either liquid or nitrogen gas in the vapor phase for its safety.

Processing and storage can be carried out successfully in remote locations, in which case proper shipping procedures are necessary for the units to be processed and stored within 48 hours.

**The life span of the units:**

There is no acceptable life span for cord blood units, and the life of the stored unit does not usually affect choosing the unit. However, the newly collected units are preferred due to the changes in the criteria of sample collection, processing and storage over time.

**Licensing Units for transplantation:** The transplantation centers are searching the public databases to determine the locations of donors and cord blood units that are suitable for patients who need to perform the transplant. If the appropriate cord blood sample is determined and a decision is made to proceed with the transplant process, the unit is sent to the transplant center in the case of its cryopreservation, reconstitution, and pumping to the recipient according to standardized protocols.

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technically easier and safer without compromising the size of the sample or sterilization, and the appropriate birth procedures should not be changed for the process of taking cord blood sample or tying the cord.

Whether the sample is collected inside or outside the uterus, and when the remaining blood sample is collected, the bleeding stops and the cord appears empty and mostly white and this usually happens after two to four minutes at least, and at this stage the tube is hanged between the needle and the blood bag. After that, the needle is removed from the cord that is being cut from the side of the tube and the blood bag is stamped and marked. In standard terms, 40 to 60 ml of blood is collected (in addition to an anticoagulant) and the volume of blood taken should not be less than 40 ml to contain a sufficient number of cells that allow subsequent use. The cord blood is stored at room temperature in order to maintain the safety of the cell until it is shipped or transferred to the treatment laboratory.

**Follow-up studies**: A blood sample is obtained from the mother within seven days of collection of the cord blood sample to examine the infection that can be transmitted to the child. In general, this examination contains a test for the mother's human leukocyte antigen (HLA) type and human immunodeficiency viruses (HIV) (antibodies, chain reaction of polymers, hepatitis C, hepatitis B, surface antigen, primary antigen, chain reaction of polymers), human lymphatic virus T, human lymphocyte virus T2/ 1, the Treponema pallidum hemagglutination test, West Nile virus, and test for CMV IgG, and it is also possible, as needed, to carry out testing on malaria and Chagas disease.

A swab of saliva may be taken from the newborn in order to check for the presence of CMV, while some require a follow-up examination at the age of six months to determine related factors such as serological change and the post-natal history of disease or the presence of a genetic disease that can be transmitted. These conditions may abandon the stored cord blood sample or being used for research purposes.

**The importance of the sample volume:**

It is preferable to use larger units with greater numbers of nuclei cells (NTC) cells with a value of NTC 109 x1 per unit as the results of transplantation are significantly affected by the number of hematopoietic stem cells that are in the cord blood unit that was measured by the total number of nuclei cells (NTC) or the number of stem cells + CD34, as the volume of the sample collection is related to both NTC and the number of existing stem cells + CD34. It is not known whether the volume of collected cord blood or the total number of nuclei cells or the number of stem cells + CD34 varies significantly according to the method of birth.

**Treatment and preservation process**: After collection of the sample, the cord blood units should be tested, processed and stored for future use within 48 hours of collection of the sample. The complete characteristics of the cord blood unit should include the following standards: