CHAMBER OF DEPUTIES OF THE H. CONGRESS OF THE UNION
General Secretariat
Secretariat of Parliamentary Services

Last Reform DOF 03-26-2014

REGULATIONS OF THE GENERAL HEALTH LAW REGARDING SANITARY CONTROL ON THE DISPOSITION OF ORGANS, TISSUES AND CADAVERS OF HUMAN BEINGS

New Regulation published in the Official Gazette of the Federation on February 20, 1985

CURRENT TEXT

Last reform published DOF 03-26-2014

Note regarding the full validity of this Regulation:

The validity of this Regulation is subject to the provisions of the Second Transitory Article of the Regulation of the General Health Law on Transplants, published in the Official Gazette of the Federation on March 26, 2014, which literally states:

> **"SECOND.** The provisions of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings, which refer to the donation, disposal and transplantation of organs, tissues and cells, other than blood and its components, hematopoietic progenitor cells or stem cells, as well as those provisions that oppose this Regulation, are repealed.
>
> Consequently, Sections Three and Four of Chapter III; Chapter IV, and Chapter V of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings, as well as the other provisions of the same regulation, that are necessary for the application of said Sections and Chapters cited above, remain in force."

On the margin, a seal with the National Coat of Arms, which reads: United Mexican States.-Presidency of the Republic.

MIGUEL DE LA MADRID H., Constitutional President of the United Mexican States, in exercise of the power conferred upon the Federal Executive under my charge by section I of Article 89 of the Political Constitution of the United Mexican States, and pursuant to Articles 1; 2; 3, section XXVI; 4; 7; 13 "A", sections I, II and X; 14; 18; 23; 24, section I; 27, section III; 32; 33; 45; 47; 100; 313 to 350 and other related provisions of the General Health Law, and

CONSIDERING

That on February 3, 1983, the addition to Article 4 was published in the Official Gazette of the Federation. Constitutional, in whose third paragraph it was established that "Every person has the right to health protection. The Law will define the bases and modalities for access to health services and will establish the concurrence of the Federation and the Federal Entities in matters of General Health, in accordance with the provisions of section XVI of article 73 of this Constitution";

That the aforementioned constitutional addition represents, in addition to elevating the aforementioned social right to the highest hierarchy, the basis according to which government programs in health matters will be carried out, as well as the foundation of the new Mexican health legislation;

That on December 26, 1983, the Congress of the Union approved the General Health Law, regulating the third paragraph of Article 4 of the Constitution, which was published in the Official Gazette of the Federation on February 7, 1984, and in force on July 1 of the same year;

That in the aforementioned Law, in compliance with the constitutional mandate, the bases and modalities for access to health services were defined; the integration, objectives and functions of the System National Health System, as well as the distribution of powers between the Federation and the Entities Federal authorities in matters of General Health;

That the National Health System has been conceived and definitively established as the instance through which the Public, Social and Private Sectors must share responsibility for the effective fulfillment of the right to health protection, through mechanisms of coordination and agreement of actions, as well as the rationalization of the resources available for this purpose;

That the distribution of powers between the Federation and the Federated Entities in matters of General Health represents a vigorous step towards the decentralization of health services and strengthens the Mexican Federal State;

That the sanitary control of the disposal of organs, tissues and their derivatives, products and corpses of human beings, as one of the matters of General Health, is the responsibility, according to the Law General of Health, to the Ministry of Health, therefore it is necessary that this Department has sufficient legal and regulatory instruments to effectively exercise its powers;

Scientific advances have made organ and tissue transplantation in humans a therapeutic, sometimes unique, means of preserving life and health; therefore, the General Health Law established, in its Fourteenth Title, the legal bases according to which the sanitary control of the disposal of organs, tissues, and corpses of human beings must be carried out, and

That in exercise of the power conferred upon the Federal Executive by the Political Constitution of the States United Mexicans, in order to provide, in the administrative sphere, for the exact observance of the Law, I have seen fit to issue the following

REGULATIONS of the General Health Law regarding the sanitary control of the disposal of organs, tissues and corpses of human beings.

CHAPTER I
General Provisions

ARTICLE 1. This Regulation aims to ensure, within the administrative sphere, compliance with the General Health Law, specifically regarding the sanitary control of the disposal of organs, tissues and their components and derivatives, products, and cadavers of human beings for therapeutic, research, and teaching purposes. It applies throughout the Republic, and its provisions are of public order and social interest.

ARTICLE 2.- When this Regulation refers to the "Law" and the "Secretariat", it will be understood as referring to the General Health Law and the Ministry of Health, respectively.

ARTICLE 3. The application of these Regulations is the responsibility of the Secretariat. The governments of the Federal Entities, under the terms of the Coordination Agreements they sign with said Secretariat, may participate in the provision of the services to which these Regulations refer.

ARTICLE 4.- It is the responsibility of the Secretariat to issue the technical standards to which the disposal of organs, tissues and their components and derivatives, products and corpses of human beings, including those of embryos and fetuses, will be subject throughout the national territory.

The Secretariat is also responsible for issuing the instructions, circulars and forms that may be required for the application of this regulation.

ARTICLE 5.- The Secretariat will promote, encourage and develop study programs and research related to the disposition of organs, tissues and their components and derivatives,

products and corpses of human beings, particularly with regard to transplants, transfusions and other therapeutic procedures.

ARTICLE 6.- For the purposes of this Regulation, the following definitions apply:

I.- Apheresis: The procedure that aims to separate blood components from a single donor of human blood, by direct centrifugation or with continuous or discontinuous flow machines;

II.- Organ and Tissue Bank: Any authorized establishment whose primary purpose is the procurement of organs and tissues for their preservation and therapeutic supply;

III.- Blood Bank: The establishment authorized to obtain, collect, analyze, fractionate, preserve, apply and provide human blood; as well as to analyze, preserve, apply and provide its components;

IV.- Plasma Bank: The establishment authorized to fractionate blood obtained from authorized Blood Banks through the apheresis procedure, and for the preservation of the resulting plasma;

V.- Corpse: The human body in which the loss of life has been verified;

VI.- Blood components: The specific fractions obtained through the apheresis procedure;

VII.- Cell concentrates: The cells obtained from the blood within its expiration date;

VIII.- Blood derivatives: Products obtained from blood through an industrial process, that have therapeutic, diagnostic, preventive or research applications;

IX.- Final destination: The permanent preservation, burial or disintegration under sanitary conditions permitted by the Law and this Regulation, of organs, tissues and their components and derivatives, products and corpses of human beings, including embryos and fetuses;

X.- Disposing Party: The person who authorizes, in accordance with the Law and these Regulations, the disposal of organs, tissues, products and corpses;

XI.- Disposal of organs, tissues and corpses and their products: The set of activities relating to the obtaining, preservation, preparation, use, supply and final destination of organs, tissues and their components and derivatives, products and corpses, including those of embryos and fetuses, for therapeutic, teaching or research purposes;

XII.- Donor of Human Blood: The person who freely supplies their blood in any of the following forms:

A) To a patient at the request of the attending physician or the hospital establishment, or

B) Responding to a general call and without taking into account which person it may be intended for, or else used for obtaining blood components and derivatives;

XIII.- Embryo: The product of conception up to the thirteenth week of gestation;

XIV.- Fetus: The product of conception from the thirteenth week of gestation until its expulsion from the mother's womb;

XV.- Obtaining blood: Activities related to the extraction of human blood;

XVI.- Organ: Morphological entity composed of the grouping of different tissues that come together to performance of the same physiological work;

XVII.- Human Plasma: The specific component separated from the blood cells;

XVIII.- Product: Any tissue or substance excreted or expelled by the human body as a result of normal physiological processes. The placenta and skin appendages shall be considered as products;

XIX.- Blood Collection Station: Mobile or fixed establishment that has the necessary elements exclusively to extract blood from human blood donors and that operates under the responsibility of an authorized Blood Bank;

XX.- Recipient: The person to whom an organ or tissue will be transplanted or has been transplanted or transfused with blood or its components through therapeutic procedures;

XXI.- Blood: The blood tissue with all its elements;

XXII.- Transfusable human blood: The blood tissue collected in containers with anticoagulants, under conditions that allow its use during the validity period, according to the anticoagulant used;

XXIII.- Transfusion Service: The establishment authorized for the handling, storage and application of human blood and its components, obtained from a blood bank;

XXIV.- Tissue: A morphological entity composed of a group of cells of the same nature, regularly arranged and performing the same function. Blood will be considered a tissue;

XXV.- Therapeutics: The branch of medicine that establishes the applicable principles and medications or means for the rational treatment of diseases, and

XXVI.- Transfusion: Procedure through which blood or any of its components is supplied components to a human being, solely for therapeutic purposes.

ARTICLE 7.- The following shall be considered the final destination of organs, tissues, products and corpses of human beings:

I.- The burial;

II.- Incineration;

III.- Inclusion in acrylic and other plastic substances;

IV.- Permanent preservation through paraffin-based treatment;

V.- The permanent preservation of skeletons for teaching purposes;

VI.- Permanent embalming for purposes analogous to those of the previous section;

VII.- The permanent preservation of organs and tissues using fixative substances for teaching purposes, and

VIII.- Others that have as their purpose the permanent conservation or disintegration under sanitary conditions, as authorized by the Secretariat.

ARTICLE 8.- It is the responsibility of the Secretariat to control, program, coordinate, supervise and evaluate the activities referred to in this Regulation, organize and operate services and monitor their operation, within the framework of the National Health System, taking into consideration that in case of conflict between individual interests and those of society, the two of the latter will prevail, in the terms of the Law and of this regulation.

ARTICLE 9.- Under no circumstances may organs, tissues, products and corpses be disposed of in against the will of the original provider.

CHAPTER II
Of the Providers

ARTICLE 10.- In accordance with the Law and these Regulations, the providers may be original and secondary.

ARTICLE 11.- The original disposing party is the person with respect to his or her own body and the products thereof.

ARTICLE 12.- The original donor may at any time revoke the consent he has given for the purpose of disposing of his organs, tissues, products or his own corpse, without any liability on his part.

If the original provider has not revoked their consent during their lifetime, the revocation made by the secondary providers referred to in the following article will not be valid.

ARTICLE 13.- The following shall be secondary grantors, in the following order of preference:

I.- The spouse, the concubine, the concubine, the ascendants, descendants and the collateral relatives up to the second degree of the original disposing party;

II.- The competent health authority;

III.- The Public Ministry, in relation to the organs, tissues and corpses of human beings that are find themselves under their responsibility due to the exercise of their functions;

IV.- The judicial authority;

V.- The legal representatives of minors and incapacitated persons, only in relation to the disposal of corpses;

VI.- Educational institutions with respect to the organs, tissues and corpses that are provided to them for research or teaching, once the claim period has expired without a claim having been made, and

VII.- Those also to whom the applicable general provisions confer such character, with the conditions and requirements indicated therein.

ARTICLE 14.- The secondary donors referred to in the previous article may give their consent for the disposal of the corpse, organs and tissues, as well as products of the original donor, in accordance with the Law and this Regulation.

In accordance with the law itself, in cases where the competent authority orders the autopsy, no authorization or consent will be required for the disposal of organs and tissues, and it must be subject to the technical standards that are issued.

ARTICLE 15.- The preference among the secondary disposing parties referred to in section I of article 13, shall be defined in accordance with the rules of kinship established by the Civil Code for the Federal District in common matters and for the entire Republic in federal matters.

ARTICLE 16.- In the case of living donor transplants, the original donor from whom the transplants are taken organs and tissues must:

I.- Be over eighteen years of age and under sixty;

II.- Have an updated and favorable medical report on your state of health, including the psychiatric aspect;

III.- To be compatible with the recipient, in accordance with the medical tests performed;

IV.- Having received complete information about the risks of the operation and the consequences of the organ removal, if applicable, as well as the likelihood of success for the recipient, and

V.- Having expressed their will in writing, free from physical or moral coercion, granted before two suitable witnesses or before a notary.

In the case of bone marrow transplants, the Ministry may, where appropriate, exempt the original donor from the requirement referred to in section I of this article. For this purpose, the studies and therapeutic diagnoses that the Ministry determines must be submitted to it, and, where applicable, the consent of the donor's legal representatives, who must also be provided with the information referred to in section IV of this article.

CHAPTER III
On the Disposition of Organs, Tissues and Products

SECTION ONE
Common Provisions

ARTICLE 17.- The selection of the original donor and the recipient of organs or tissues for transplantation or transfusion will always be done by prescription and under medical control, in the terms established by the Secretariat.

In the case of transplants, a section performed by a single doctor will not be admissible.

ARTICLE 18.- The procedures for the preservation of organs and tissues for therapeutic purposes,
They will be established in the technical standards issued by the Secretariat.

ARTICLE 19.- The public prosecutor may authorize the disposal of organs, tissues or products from the corpses of known persons or those that have been claimed and that are at his disposal, in accordance with the technical standards issued for this purpose by the Secretariat and provided that not
there is a contrary provision, by testamentary title, of the original disposing party and the consent of the secondary disposing parties referred to in sections I and V of article 13 of this Regulation is obtained.

To carry out acts of disposal of organs and tissues in any of the cases contemplated in the preceding paragraph for therapeutic purposes, a prior written request is required, made in accordance with the provisions of this Regulation and the technical standards issued by the Secretariat.

ARTICLE 20.- Health establishments, with prior authorization from the Secretariat, may install and maintain, for therapeutic purposes, organ and tissue banks, whose operation will be governed by the provisions of the Law, this Regulation and by the technical standards issued by the aforementioned agency.

SECOND SECTION
On the Disposition of Organs and Tissues for Therapeutic Purposes

ARTICLE 21.- The disposal of organs and tissues for therapeutic purposes will be free of charge.

ARTICLE 22.- The trade of organs or tissues detached or sectioned by
surgical intervention, accident or illegal act.

ARTICLE 23.- The transplantation of a single, non-regenerative organ, essential for the preservation of life, may only be performed by obtaining it from a cadaver. For the purposes of these Regulations, the eyes shall be considered as a single organ.

ARTICLE 24.- The document in which the original provider expresses his will for the
The disposition of their organs and tissues for transplantation purposes must contain:

I.- Full name of the original provider;

II.- Domicile;

III.- Age;

IV.- Sex;

V.- Civil Status;

VI.- Occupation;

VII.- Name and address of the spouse, partner or concubine, if any;

VIII.- If single, name and address of the parents or, if these are absent, of one of his closest relatives;

IX.- The statement that of his own free will and on a gratuitous basis, he consents to the disposal of the organ or tissue in question, expressing whether this disposal will be understood to be made between living persons or for after his death;

X.- Clear and precise identification of the organ or tissue to be transplanted;

XI.- The name of the recipient of the organ or tissue, in the case of a living donor transplant, or the conditions that allow the recipient to be identified if the provision is for after their death;

XII.- The indication of having received satisfactory information about the consequences of the removal of the organ or tissue;

XIII.- Name, signature and address of the witnesses when it is a private document;

XIV.- Place and date of issue, and

XV.- Signature or digital fingerprint of the provider.

ARTICLE 25.- The recipient of an organ or tissue must meet the following requirements:

I.- Having a condition that can be effectively treated through transplantation;

II.- Not to have other diseases that predictably interfere with the success of the transplant;

III.- To have a state of physical and mental health capable of tolerating the transplant and its evolution;

IV.- Having expressed their will in writing, once informed of the purpose of the intervention, of their risks and the probabilities of success, and

V.- Be compatible with the original donor from whom the organ or tissue is to be taken.

ARTICLE 26.- The written document expressing the will referred to in section IV of article The above must contain:

I.- Full name of the recipient;

II.- Domicile;

III.- Age;

IV.- Sex;

V.- Civil Status;

VI.- Occupation;

VII.- Name and address of the spouse, partner or concubine, if any;

VIII.- If single, name and address of the parents or, if these are absent, of one of his closest relatives;

IX.- The precise statement that of his own free will he consents to the performance of the transplant, and that he was sufficiently informed of the object and type of the intervention and of the probabilities of therapeutic success;

X.- Signature or digital fingerprint of the recipient;

XI.- Place and date of issue, and

XII.- Name, signature and address of the witnesses if it is a private document.

ARTICLE 27.- When, due to the recipient's minority, incapacity, or physical impossibility, the recipient cannot express their will for the transplant, the intervention may be consented to by the persons referred to in section I of article 13 of these Regulations, or by the legal representatives of minors or incapacitated persons, provided that they have previously received complete information on the probabilities of therapeutic success.

The authorization referred to in the previous paragraph must meet the requirements set forth in Article 26, in addition to indicating the existing link with the recipient.

In case of urgency for the performance of the transplant, consent may be given by the first person mentioned in section I of article 13 of these Regulations who is present and, in the absence of this, by the Internal Transplant Committee of the hospital institution in question.

ARTICLE 28.- In the case of transplants of organs or tissues obtained from a corpse, this will meet the following conditions prior to death:

I.- To have reached a physiological age suitable for transplantation purposes;

II.- Not having suffered the deleterious effect of prolonged agony;

III.- Not having suffered from malignant tumors with a risk of metastasis to the organ used, and

IV.- Not having presented serious infections and other ailments that could, in medical judgment, affect the recipient or compromise the success of the transplant.

ARTICLE 29.- The obtaining, storage, preservation, preparation and use of organs, tissues, their components and products of living human beings, or of corpses, for therapeutic, scientific research or teaching purposes, may only be done in institutions authorized for this purpose.

ARTICLE 30.- Organ, tissue and component banks may be of:

I.- Eyes;

II.- Livers;

III.- Pituitary gland;

IV.- Bones and cartilage;

V.- Bone marrow;

VI.- Pancreas;

VII.- Parathyroid;

VIII.- Skin;

IX.- Kidneys;

X.- Blood and its components;

XI.- Plasma;

XII.- Blood vessels, and

XIII.- Any others that the Secretariat may authorize.

The banks may consist of one or more types of organs or tissues referred to in the fractions previous ones, the type of bank in question must be stated in the corresponding documentation.

ARTICLE 31.- Those responsible for organ and tissue banks will facilitate transplant procedures and, to that end, will perform the following functions:

I.- Participate in the selection of original providers;

II.- Obtaining and storing organs and tissues;

III.- Preservation and storage;

IV.- Distribution, and

V.- Other similar ones to the above as determined by the Secretariat.

They will also be able to carry out scientific research and teaching activities related to its functions, as well as staff training activities.

ARTICLE 32.- Organ and tissue banks must operate in coordination with one or more health establishments in the public, social or private sectors.

ARTICLE 33.- The requirements for services, organization, operation and sanitary engineering of organ and tissue banks will be set by the Secretariat through technical standards and instructions or circulars, which will be published in the Sanitary Gazette.

ARTICLE 34.- Institutions that perform transplants must have an Internal Committee of Transplants, whose responsibilities will be as follows:

I.- Verify that transplants are performed in accordance with the requirements established by the Law, this Regulation and the technical standards;

II.- Verify that transplants are performed with maximum safety and in accordance with principles of medical ethics;

III.- Make the selection of original donors and recipients for transplantation;

IV.- Provide the necessary information to the recipients, donors and family members in relation to these therapeutic procedures, and

V.- Promote the updating of personnel involved in performing transplants.

The Committees referred to in this article will be composed of medical personnel specialized in transplantation and in an interdisciplinary manner, under the responsibility of the institution, and their composition must be approved by the Secretariat.

ARTICLE 35.- When, by virtue of advances in science, transplantation is useless or does not fall under the case of Article 321 of the Law; the Secretariat may declare this by publishing this resolution in the Health Gazette, organ and tissue banks and hospital institutions must refrain from carrying out operations related to the transplant subject to the resolution.

ARTICLE 36.- The Secretariat shall be in charge of the National Transplant and Transfusion Registries, whose functions shall be:

I.- Coordinate the distribution of organs and tissues throughout the national territory;

II.- Establish and implement procedures to facilitate, throughout the national territory, the obtaining of organs and tissues of human beings;

III.- Keep a record of original donors of organs and tissues and of donors of human blood;

IV.- To study, understand and provide information on all aspects related to the arrangement of organs and tissues of human beings;

V.- Send to blood banks, plasma banks and transfusion services, the control samples referred to in Article 44 of these Regulations, and

VI.- Other similar ones to the above that the Secretariat may indicate.

ARTICLE 37.- Establishments that carry out acts of disposal of organs and tissues for therapeutic purposes, shall submit a report of their activities to the National Transplant and Transfusion Registries, referred to in the previous article, in the terms, form and periodicity indicated by the Secretariat.

SECTION THREE
Regarding the Disposal of Blood and its Components

ARTICLE 38.- In the case of blood donation, it is not necessary for the donor to express their written will.

ARTICLE 39.- Blood may under no circumstances be the object of commercial acts.

ARTICLE 40.- Blood banks must have the following services:

I.- Waiting room;

II.- Medical examinations;

III.- Clinical laboratory;

IV.- Obtaining the blood;

V.- Subdivision and conservation;

VI.- Application of blood or one or more of its components;

VII.- Administrative control and supply, and

VIII.- Adequate sanitary facilities.

Plasma banks will exclusively offer the services referred to in sections III, V, VII and VIII of this article.

Transfusion services will include the services referred to in sections II, III, V, VI, VII and VIII of this article.

ARTICLE 41.- The requirements for services, organization, operation and sanitary engineering of blood and plasma banks, as well as transfusion services, will be set by the Secretariat through technical standards and instructions or circulars, published in the Sanitary Gazette.

ARTICLE 42.- The material for obtaining and preserving, as well as for the application of blood or blood components and derivatives, must be disposable and meet the quality control conditions established by the Secretariat in the technical standards it issues.

ARTICLE 43.- Blood banks must have reagents for performing the following analyses:

I.- Dosage of hemoglobin or hematocrit, or both;

II.- Identification of blood groups;

III.- Blood compatibility;

IV.- Detection of syphilis;

V.- Detection of hepatitis transmissible by blood transfusion;

VI.- Detection of human immunodeficiency virus (HIV) or its antibodies, and

VII.- Other reagents that the Secretariat determines in the technical standards it issues.

Transfusion services must have the reagents referred to in sections I, II, III and VII of this article.

ARTICLE 44.- For quality control, blood banks, plasma banks and transfusion services will provide the Secretariat with the necessary facilities for taking control samples during the collection and separation of blood components and preservation thereof.

ARTICLE 45.- The owner and the doctor responsible for organ and tissue banks and blood and plasma banks, as well as transfusion services, will have, jointly, the civil and administrative responsibility for the activities carried out in said establishments.

ARTICLE 46. The Ministry shall establish the expiration date for blood and its components to ensure they are in optimal condition for use. The physician responsible for the blood banks or services referred to in this section shall discard them when they are no longer in optimal condition, even if their expiration date has not yet passed.

ARTICLE 47.- The physicians responsible for a blood or plasma bank and the services of transfusion, will meet the requirements established by this Regulation.

ARTICLE 48.- The physician in charge of a Blood Bank shall perform or supervise the next activities:

I.- To count the blood and components obtained from it.

II.- Record the quantities drawn from each donor of human blood and the dates of extractions, in the control book authorized by the Secretariat;

III.- Perform the following medical examination and laboratory tests on donors of human blood:

A).- ABO Blood Group in erythrocytes and serum;

B).- Rh° (D) antigen;

C) Hemoglobin, hematocrit, or both;

D) Test for the detection of syphilis;

E).- Test for the detection of hepatitis transmissible by blood transfusion;

F) Protein dosage in cases of plasmapheresis, and

G) Test for the detection of the Human Immunodeficiency Virus (HIV) or its antibodies.

IV.- Verify that the provider of human blood meets the required conditions so that blood is obtained from him;

V.- To guide those who provide human blood regarding the advisability of blood extractions blood tests should be spaced at least 45 days apart;

VI.- Send periodic reports of blood and blood component receipts and disbursements to the Secretariat, under the terms established by the corresponding technical standards;

VII.- Give immediate notice to the Secretariat when you cease to be responsible for the establishment;

VIII.- Notify the Secretariat immediately of the detection of the Immunodeficiency Virus Human or antibodies against it, and

IX.- Report any act of blood trafficking to the health authority.

Physicians responsible for plasma banks and transfusion services must perform and supervise the activities contained in sections I, VI and VII.

ARTICLE 49.- Hospitals, sanatoriums, clinics, maternity wards and in general hospital establishments of the Public, Social and Private Sectors, must have at their disposal an authorized blood bank or transfusion service.

ARTICLE 50.- Every industrial establishment that obtains blood derivatives must obtain it through an authorized blood bank or plasma bank.

ARTICLE 51.- Medical care establishments that require donors of human blood must perform a medical examination and laboratory tests on them as indicated by the applicable technical standards.

ARTICLE 52. The directors of health institutions and attending physicians shall notify the Ministry of Health of any cases of diseases suspected of having been transmitted through transfusion of blood or its components and derivatives. When Acquired Immunodeficiency Syndrome occurs in a patient who has received blood, its components, or derivatives, the notification referred to in this article must be made immediately, providing all available information regarding the source of the transfused blood.

ARTICLE 53.- The preparation, storage and labeling of blood and its components shall comply with the requirements of this Regulation and the technical standards and instructions issued by the Secretariat.

ARTICLE 54.- Transfusions must be carried out after typing the recipient of the ABO and RH° (D) groups and with the respective compatibility tests.

The transfusion must be carried out by medical and nursing staff acting under the supervision of the responsible physician and performed in accordance with the technical standards issued by the Secretariat.

Blood transfusions will only be performed for therapeutic purposes, in accordance with the technical standards issued by the Ministry. Transfusions of blood or blood components to the donor of the same blood are prohibited, except when therapeutically necessary and the transfusion is performed in a hospital setting.

ARTICLE 55.- A pilot sample will be taken from each unit of blood or its fractions and will be kept for a minimum of 24 hours after it has been transfused.

FOURTH SECTION
Product Disposal

ARTICLE 56.- For the purposes of this Regulation, in addition to those indicated in section XVIII of article 6 of the same regulation, excreta and germ cells will be considered as products of the human body.

Products derived from human beings, except germ cells, may be used as raw materials for industrial purposes, in accordance with the health regulations governing the process in question.

The arrangement of germ cells will be carried out in accordance with the regulations. techniques issued for this purpose by the Secretariat.

ARTICLE 57.- Health establishments may allocate, for scientific or industrial uses, the placentas they obtain, either through some consideration or free of charge, provided that they are handled in accordance with the technical standards issued by the Secretariat.

CHAPTER IV
Regarding the Disposition of Corpses

ARTICLE 58.- The Secretariat shall issue the technical standards related to the conditions for the handling, use, preservation and disposal of corpses.

ARTICLE 59.- The disposal of corpses for research or teaching purposes may only be done after certification of the loss of life in accordance with the provisions of article 317 of the Law.

ARTICLE 60.- The disposal of corpses of unknown persons shall be subject to what is indicated by the Public Ministry, in accordance with the applicable legal provisions, this Regulation and the technical standards issued for this purpose by the Secretariat.

ARTICLE 61.- In the case of corpses of known persons in which the Public Ministry or the judicial authority has ordered the practice of the autopsy, their use for research or teaching purposes will be carried out in accordance with the provisions of this Regulation and the corresponding technical standards; if the use is for transplantation purposes, the provisions of article 325 of the Law will also apply and a written request from the interested institution or organ and tissue bank will be required, as well as informing the health authority.

ARTICLE 62.- For the performance of any act of disposal of corpses, it must be previously obtained the death certificate, which will be issued once the death has been verified and its causes determined, by medical professionals or by persons authorized by the competent health authority.

ARTICLE 63.- The burial or cremation of corpses may only be carried out with the authorization of the person in charge or Judge of the corresponding Civil Registry, who will ensure the death and its causes, and will require the presentation of the death certificate.

ARTICLE 64.- In the event that corpses are to remain without burial or cremation for longer than indicated in article 339 of the Law, they must be preserved in accordance with the procedures referred to in the following article.

ARTICLE 65.- The following are considered accepted procedures for the preservation of corpses;

I.- Refrigeration in closed chambers at temperatures below zero degrees Celsius;

II.- Embalming, by means of intravascular injection of antiseptic solutions;

III.- Total immersion of the corpse in closed containers containing antiseptic solutions, and

IV.- Any others that the Secretariat may determine, taking into account scientific advances on the subject.

ARTICLE 66.- The sanitary control of cemeteries will be the responsibility of the competent health authorities, in accordance with the applicable legal provisions and the technical standards that the Secretariat is responsible for issuing.

ARTICLE 67.- Corpses that are inhumane shall remain in the pits, at a minimum:

I.- Six years for persons over fifteen years of age at the time of their death, and

II.- Five years for persons under fifteen years of age at the time of their death.

After the above deadlines have passed, the remains will be considered as aggregates.

ARTICLE 68.- Embalming certificates must conform to the models issued by the Secretariat, which will be published in the Health Gazette.

ARTICLE 69.- The transfer of corpses by air, land or sea, shall be done in compartments isolated from those intended for passengers and goods, and in accordance with the technical standards issued by the Secretariat.

ARTICLE 70.- The following will be required for the practice of necropsies:

I.- Order of the Public Prosecutor, the judicial authority or the health authority;

II.- Authorization of the original provider, or

III.- Authorization of the secondary donors in the order of preference established in this Regulation, when the autopsy is intended to be carried out in scientific or hospital institutions and provided that there is no contrary provision of the original donor.

ARTICLE 71.- Only the following techniques and procedures for the preservation of corpses may be applied:

I.- Doctors with a legally issued and registered degree from the competent educational authorities:

II.- Embalming technicians or assistants who have diplomas legally issued and registered by the competent educational authorities, and

III.- Other persons expressly authorized by the Secretariat.

ARTICLE 72.- Establishments that apply techniques and procedures for the preservation of corpses may only carry out those that have been expressly authorized to them, according to their installed capacity and the respective health needs.

ARTICLE 73.- The general provisions on corpses shall be applied, where appropriate, to those of embryos and fetuses.

CHAPTER V
From Research and Teaching

ARTICLE 74.- For the purposes of this Regulation, educational institutions shall be designated as those that are dedicated to research or teaching and for which they use organs, tissues and their derivatives, products and corpses of human beings including those of embryos and fetuses.

ARTICLE 75.- Clinical research and teaching in the field of transplantation may only be carried out under the terms of article 346 of the Law, when the information sought cannot be obtained by another means.

method, and must be based on previous experimentation carried out on animals, in laboratories or on other scientific facts.

ARTICLE 76.- Clinical research and teaching in the field of transplants may only be carried out by professionals and in medical institutions that have express authorization and under the supervision of the Secretariat.

ARTICLE 77.- Teaching and research on transplants with cadavers may only be done in medical schools and faculties or in medical institutions where teaching is given on this subject.

ARTICLE 78.- Educational institutions will inform the Secretariat of their needs for corpses and report on what they have in their possession, so that the Secretariat can determine how to distribute the existing ones.

ARTICLE 79.- For the use of corpses or parts thereof, of known persons for research or teaching purposes, permission of the original disposing party is required, granted before the notary public or in a private document, issued before two suitable witnesses.

ARTICLE 80.- The document in which the original provider expresses his will for his
If a cadaver is used for research or teaching, it must contain:

I.- Full name of the original provider;

II.- Domicile;

III.- Age;

IV.- Sex;

V.- Marital status;

VI.- Occupation;

VII.- Name and address of the spouse, partner or concubine, if any;

VIII.- Name and address of the parents and, if deceased, mention of this fact;

IX.- In the event of not having a spouse, partner, or parents, the indication of the name and address of one of their closest relatives;

X.- The statement that of his own free will and gratuitous title he orders that his corpse be employed for research or teaching;

XI.- The name of the educational institution that will benefit from the body;

XII.- The indication of having received satisfactory information regarding the employment that will be given to his corpse and, where applicable, its final destination;

XIII.- The name, address and signature of the witnesses when it is a private document, and

XIV.- Date, place and signature of the original provider.

ARTICLE 81. The secondary testators referred to in sections I and V of Article 13 of these Regulations, and in the order of preference established therein, may consent to a corpse being used for research or teaching when the original testator did not do so during their lifetime and provided there is no testamentary provision to the contrary. For this purpose, they must grant their authorization in writing, before a notary public or two suitable witnesses. This document must contain the requirements referred to in sections I through VI and X through XIV of Article 80 of these Regulations, understood to apply to secondary testators.

ARTICLE 82.- When educational institutions obtain corpses from the Public Ministry for research or teaching purposes, the following must be observed:

I.- It may only receive corpses of unknown persons;

II.- When collecting the body, they must issue a receipt, which must contain the requirements established by the Secretariat, and

III.- The following documents must be obtained:

A).- The authorization of the deposit, in favor of the institution, signed by the agent of the Ministry Public with whom the proceedings are conducted;

B) The death certificate, and

C) A copy of the document, in which the Public Prosecutor informs of the depository in the institution to the Judge or person in charge of the Civil Registry who must draw up the death certificate.

Once the body has been received, it must be transported in a vehicle authorized for such service.

ARTICLE 83. For the purposes of Article 334 of the Law, a detailed record shall be drawn up with a description of the organ or tissue in question and the data necessary for its identification. In addition, it shall be stated whether incineration is ordered or whether it is to be preserved or sent for research or teaching purposes. The record shall be supplemented by the incineration certificate, a declaration of preservation, or a receipt in the case of sending.

ARTICLE 84.- Educational institutions shall be obliged to hand over the corpses they have received for research or teaching, even after the deposit period has ended, when requested by the competent authority or there is a claim from the secondary disposer, provided that the final destination of the corpse has not been given.

ARTICLE 85.- In the case of a claim for any corpse that is found in any institution For educational purposes to be used in research or teaching, the following procedure will be observed:

I.- The claimant shall submit, to the respective institution, a written request containing:

A).- Full name;

B).- Address;

C) General Identification Data;

D).- Quality with which he/she claims;

E).- General identification data of the corpse;

F) Date of the claim, and

G).- Claimant's signature.

II.- The application must be accompanied by the documents on which the applicant bases his claim, as follows: as with those who prove their identity;

III.- The claimant must verify the identity of the corpse he/she is claiming;

IV.- Once the body has been delivered, the claimant will issue the corresponding receipt signed before two witnesses, and

V.- The claimant will receive, along with the body, the corresponding embalming certificate, which must contain:

A).- Identification of the embalmed corpse;

B) Technique used in conservation, and

C).- Identification data of the person issuing the document.

Claim procedures will always be free of charge.

ARTICLE 86.- Educational institutions that receive corpses for research or teaching will carry out the necessary procedures before the Civil Registry authorities and other competent authorities.

ARTICLE 87. Corpses or parts thereof that can no longer be used for research or teaching shall be cremated or preserved, after notifying the competent health authority. The procedures and expenses incurred shall be borne by the disposing educational institutions.

ARTICLE 88. Educational institutions shall be responsible for the proper and ethical use of cadavers. Only the number of cadavers expressly authorized by the Ministry may be released annually, and for the use of a greater number, the respective institution must submit a request stating the reasons justifying it.

CHAPTER VI
Regarding Authorizations

ARTICLE 89.- The Secretariat shall issue, after compliance with the corresponding requirements, the licenses, permits and health control cards referred to in this Regulation.

ARTICLE 90.- The following require a Sanitary License:

I.- Public, social and private medical establishments that perform transplants;

II.- Organ and tissue banks, blood banks and plasma banks;

III.- Transfusion services;

IV.- Establishments dedicated to the obtaining, handling and supply of products of the human body;

V. Educational institutions that have corpses for research or teaching purposes, and

VI.- Vehicles used for the transport of corpses or their parts.

ARTICLE 91. The establishments referred to in section I of the preceding article, in addition to complying with the requirements established in these Regulations, must also meet the requirements set forth in the Regulations for the Provision of Health Services in the Area of Medical Care. The Ministry will issue a single license certifying that these establishments have met the requirements set forth in the aforementioned Regulations.

ARTICLE 92.- The establishments mentioned in section I of article 90 of this Regulation must meet the following requirements:

I. Possess the medical or surgical specialty corresponding to the transplants to be performed, with independence from other healthcare activities they provide;

II. Have a clinical pathology laboratory;

III. Have a pathology laboratory or access to one;

IV. Have a blood bank or transfusion service capable of providing blood units and blood components in the quantity and quality required for the type of transplant they perform;

V. Have a recovery room;

VI. Have an intensive care unit;

VII. Have medical personnel specialized in the type of transplants they perform, and other personnel professional, technician and support health assistant with experience in the area;

VIII. To have adequate medicines, medical and surgical equipment and instruments, and

IX. Any others specified in this Regulation and other applicable legal provisions.

Establishments that exclusively perform corneal transplants must meet only the requirements set out in sections I, II, III, V, VII, VIII and IX.

ARTICLE 93.- Organ and tissue banks, blood and plasma banks, as well as the transfusion services mentioned in sections II and III of article 90 of this Regulation, must meet the following requirements:

I.- Regarding the staff:

A) That it is sufficient and suitable, for which their level of preparation will be taken into account in relation with the functions he/she performs;

B) That they have programs for the continuous updating of their knowledge, and

C) That they have adequate procedures for the permanent control and periodic evaluation of their performance.

II.- Have a professional responsible for the services;

III.- In the case of organ and tissue banks, the following services must be available:

A).- Obtaining, preparing, storing and preserving;

B).- Supply;

C).- Information;

D) Administrative control, and

E) Adequate sanitary facilities.

IV.- In the case of blood and plasma banks, as well as transfusion services, they must to have the services referred to in Article 40 of these Regulations, and

V.- Any others indicated in this Regulation and the technical standards issued by the Secretariat.

ARTICLE 94.- The establishments indicated in section IV of article 90 must meet the following requirements:

I.- To have a staff trained for the handling and supply of human body products;

II.- Have adequate equipment and instruments;

III.- Have adequate sanitary facilities;

IV.- To have a professional responsible for the service, and

V.- Any others indicated in this Regulation and the technical standards.

ARTICLE 95.- The educational institutions mentioned in section V of article 90 of this Regulation, must comply with the following requirements:

I.- To have amphitheaters equipped with adequate systems that guarantee the good preservation of the corpses and with a ventilation system that effectively eliminates the odors caused by them;

II.- To have a system for the storage and security of corpses or parts thereof;

III.- To have, at least, one vehicle suitable for the transport of corpses or parts thereof;

IV.- To have adequate materials, equipment and personnel for the application of conservation techniques, and

V.- Any others that this Regulation may indicate.

ARTICLE 96.- The vehicles mentioned in section VI of article 90 of this Regulation must meet the following requirements:

I.- That its use is exclusive for the transfer of corpses or their parts;

II.- Be permanently ***(sic DOF 20-02-1985)*** clean and disinfected;

III.- Have a compartment where the corpse or part of it is deposited, which must be completely isolated from the rest of the vehicle and closed to the outside and, if it has windows, these must have opaque glass, and

IV.- The others indicated in this Regulation and the technical standards issued by the Secretariat.

ARTICLE 97. To obtain the health licenses indicated in Article 90 of these Regulations, the applicant must submit an application signed by the owner or legal representative of the establishment, service, institution, or vehicle. The application must be accompanied by the necessary documents and information that demonstrate compliance with the requirements set forth in Articles 92, 93, 94, 95, and 96 of these Regulations, as well as any other administrative information determined by the Secretariat.

ARTICLE 98.- The health licenses referred to in this Regulation shall be granted for a period of time minimum of two years and its validity will begin from the date of its issuance.

The term of health licenses may be extended for a period equal to their original validity, provided that the requirements established in the Law, these Regulations, and other applicable provisions continue to be met. The corresponding application must be submitted to the Secretariat at least thirty days prior to the license's expiration date.

ARTICLE 99.- Licenses may be reviewed by the Secretariat at any time.

ARTICLE 100.- The following require a health permit:

I.- Those responsible for establishments and institutions that carry out acts of disposal of organs, tissues and their components and derivatives, products and corpses;

II.- The entry into or exit from the national territory of organs, tissues, corpses and arid remains of human beings;

III.- The entry into or exit from the national territory of blood, its components and derivatives;

IV.- The transfer of corpses and cremated remains from one Federal Entity to another;

V.- Embalming;

VI.- The burial or cremation of corpses during the first twelve hours after death and after forty-eight hours after it occurred;

VII.- Exhumation before the deadlines established in Article 67 of these Regulations;

VIII.- (Repealed)

IX.- The obtaining, preservation, use, preparation, supply and export or import of products of human beings for the performance of industrial procedures;

X.- The register book kept by educational institutions that use corpses for the purposes of research or teaching, and

XI.- The register book kept by blood banks, plasma banks and transfusion services.

ARTICLE 101.- Those responsible referred to in section I of the previous article must meet the following requirements:

I.- Possess a professional degree as a medical surgeon, and

II.- Have experience in the activity or service to which the establishment is dedicated.

ARTICLE 102.- To obtain the sanitary permit referred to in section II of article 100 of these Regulations, the following requirements must be met:

I.- In the case of organs and tissues:

A).- Certification from a doctor with a legally issued degree, of the circumstances prior to the death of the person from whose corpse the organs or tissues that are intended to be admitted were extracted;

B) Constitutive documentation of the educational or medical care institution that performs the hospitalization and information about the organ or tissue donation process, and

C) Information on the recipient of the organs or tissues, if applicable, or the destination that will be given to them.

II.- In the case of corpses:

A) Presentation of the death certificate and record and proof of embalming, translated to Spanish, where applicable, certified by the Mexican consular authorities;

B) Presentation of the international transfer permit granted by the health authority of the country where the death occurred, translated, if applicable, into Spanish, certified by the Mexican consular authorities, and

C) Any others established by International Treaties and Conventions and other applicable provisions.

III.- In the case of arid remains:

A) Certification from the health authority of the country of origin, translated, if applicable, into Spanish, and certified by the Mexican consular authority, regarding the conditions and characteristics of the blood products, and

B).- Constitutive documentation of the educational institution or medical care establishment that carries out the hospitalization and information of the one that will use the blood products.

ARTICLE 103.- The Secretariat will grant the entry or exit permit referred to in the section III of article 100 provided that the following requirements are met:

I.- Certification from the health authority of the country of origin, translated, if applicable, into Spanish, certified by the Mexican consular authority, regarding the conditions and characteristics of the blood, its components or derivatives.

II.- Constitutive documentation of the educational institution or medical care establishment that perform the hospitalization, and information on who will use the blood, its components or derivatives.

The export of blood products from the national territory will be authorized by the Secretariat only when the requirements for these products in the country are met, except in cases of emergency that will be determined by the Secretariat.

ARTICLE 104.- To obtain the sanitary permit referred to in section IV of Article 100 of these Regulations, the following requirements must be met:

I.- In the case of corpses:

A).- Presentation of the death certificate;

B).- Proof of embalming, if applicable, in accordance with the technical standards issued by the Secretariat;

C) Information on the air, sea or land route that will be used, and

D) Information on the final destination of the body.

II.- In the case of dry remains:

A).- Proof of burial;

B) Information on the air, sea or land route that will be used, and

C).- Specification of the destination of the aggregate remains.

ARTICLE 105.- The permit referred to in section V of article 100 of this Regulation, in the case of embalming of corpses after twelve hours of death, may be processed by the secondary disposing party, his legal representative or whoever demonstrates legal interest, presenting the corresponding death certificate.

ARTICLE 106.- To obtain a permit for the embalming of a corpse, within twelve hours after death, the secondary disposers referred to in sections I and V of Article 13 of these Regulations must present the following to the competent health authorities:

I.- Written request from one of the aforementioned parties, indicating the reason for requesting embalming;

II.- Death certificate issued by a physician with a legally issued degree, and

III.- Submission of documents that prove the applicant's status and the reasons for the application.

ARTICLE 107.- Once the health permit to embalm a corpse has been granted, the Secretariat will appoint an official doctor to supervise the application of the preservation technique used and report on the procedure.

The doctor referred to in the previous paragraph must also verify the death certificate.
to embalm the corpse.

ARTICLE 108.- The health authority will grant permission in the case of section VI of article 100 of this Regulation, to carry out burials during the first twelve hours after the death occurs, when the doctor who certifies the death recommends urgent burial as a protective measure of public health, expressing the causes of such measure.

In all other cases, the reasons and circumstances that exist in each situation will be assessed, in order to to allow or deny the burial permit under the terms referred to in the preceding paragraph.

Once the permit has been issued, the relevant Civil Registry official will be notified.

ARTICLE 109.- Burial or cremation will only be permitted after forty-eight hours from the time of death, when the embalming or preservation of the corpse has been authorized and carried out.

ARTICLE 110.- In order for the health authority to issue the exhumation permit referred to in section VII of article 100 of these Regulations, the interested parties must comply with the following requirements:

I.- Submit the death certificate and proof of burial, and

II.- State the reasons for the exhumation and the final destination of the remains.

ARTICLE 111.- The permit referred to in the previous article will not be issued when the exhumation is requested only for subsequent reburial or cremation, except in cases of extreme necessity, at the discretion of the Secretariat.

ARTICLE 112.- (Repealed)

ARTICLE 113.- To obtain the sanitary permit mentioned in section IX of article 100 of this Regulation, interested parties shall inform the Secretariat about the procedures that are intended to be developed for this purpose, mentioning the sanitary conditions in which the product in question will be handled and the way in which they intend to obtain them.

The Secretariat will only grant the permit referred to in the previous paragraph when the use of the products does not pose risks to people's health.

ARTICLE 114.- To obtain the permit referred to in sections X and XI of article 100 of this Regulation, interested parties must comply with the requirements indicated in the instructions issued by the Secretariat.

ARTICLE 115. To obtain the health permits indicated in Article 100 of these Regulations, an application signed by the interested party must be submitted. The application must be accompanied by the necessary documents and information that demonstrate compliance with the requirements set forth in these Regulations, as well as any other administrative information determined by the Secretariat.

ARTICLE 116.- The Secretariat may require a health control card from persons who carry out or intervene in any of the acts of disposal of organs, tissues and their derivatives, products and corpses, when there is a risk of spreading any disease.

ARTICLE 117.- The Secretariat will issue the forms according to which interested parties must request the authorizations referred to in this Regulation, which will be published in the Official Gazette of the Federation.

ARTICLE 118.- It will not be necessary to request new health authorizations in the following cases:

I.- When there is a change of representative, in the case of a legal entity;

II.- When the person in charge of the establishment in question changes or is dismissed;

III.- When there is an increase in resources, or

IV.- When the modifications are to improve the organization.

In the aforementioned cases, it will suffice to notify the Secretariat within fifteen days of the date on which they occur. Failure to provide such notification will subject the authorization holder to the penalty stipulated in section IV of article 122 of these Regulations.

ARTICLE 119.- The health permit referred to in section I of article 100 of these Regulations shall be granted for a minimum period of two years. Its validity shall begin on the date of issuance of the permit.

The term of the permit referred to in section I of article 100 mentioned above may be extended for a period equal to its original validity, provided that the requirements established in the Law, these Regulations, and other applicable provisions continue to be met. The corresponding application must be submitted to the Secretariat at least thirty days prior to the permit's expiration date.

ARTICLE 120.- The permits referred to in ***this*** Regulation may be reviewed by the Secretariat at any time.

ARTICLE 121.- The Secretariat shall have a period of forty-five business days to resolve the application for a health license or permit, counted from the date of submission of the application, or from the date on which the applicant is provided with the clarifications or additional information expressly required. If the resolution is not issued within the indicated period, the requested license or permit shall be considered granted.

CHAPTER VII
Revocation of Authorizations

ARTICLE 122.- The Secretariat may revoke the authorizations granted in accordance with this Regulation had granted, in the following cases:

I.- When, due to supervening causes, it is verified that the activities, products or services, constitute risks or damages to health;

II.- When the exercise of the activity exceeds the limits set in the authorization;

III.- Because the authorization is used for a purpose other than that specified;

IV.- For serious non-compliance with the provisions of the Law, these Regulations or others applicable provisions;

V.- For repeated refusal to comply with the orders issued by the Secretariat in accordance with the Law, of this Regulation and other applicable provisions;

VI.- When the data or documents provided by the interested party are found to be false served as a basis for the Secretariat to grant the corresponding authorization;

VII. When the interested party does not comply with the terms, conditions or requirements under which the authorization has been granted, or makes improper use of it;

VIII.- When persons, transport, objects or products cease to meet the conditions or requirements under which the authorizations were granted;

IX. When requested by the interested party, and

X.- In other cases as determined by the Secretariat, in accordance with the Law and these Regulations.

ARTICLE 123.- When the banks of organs, tissues and their components definitively cease to provide their services, the authorizations granted will become moot and will cause their revocation.

In these cases, the Secretariat must be notified within ten business days following the date in which the services are definitively discontinued, attaching the respective authorizations.

ARTICLE 124.- When organ, tissue and component banks temporarily suspend their services, they must notify the Secretariat within five business days following the event, informing the reasons for the suspension and its duration.

A suspension exceeding sixty calendar days will be considered definitive; however, the The Secretariat may grant a longer period when there are reasons that, in its opinion, justify it.

The resumption of service must be notified to the Secretariat within five business days following the resumption.

CHAPTER VIII
Surveillance and Inspection

ARTICLE 125.- The Secretariat is responsible for monitoring compliance with these Regulations and other provisions that may be issued.

ARTICLE 126.- The health surveillance referred to in the previous article shall be carried out in accordance with the Seventeenth Title of the Law.

ARTICLE 127. During the inspection, and if the Ministry deems it necessary, control samples of the organs, tissues, and products referred to in these Regulations may be obtained for analysis in the Ministry's laboratories or those expressly authorized by it. Likewise, the aforementioned analyses may be ordered and carried out on the premises of the inspected establishment, when circumstances permit. A detailed account of the control samples obtained shall be recorded in the minutes drawn up for that purpose, in accordance with the formalities established in the Sole Chapter of Title Seventeen of the Law.

CHAPTER IX
Security Measures

ARTICLE 128.- The application of security measures regarding the disposal of organs, tissues and their derivatives, products and corpses, shall be subject to the provisions of Chapters I and III of Title Eighteen of the Law and to the provisions of this Regulation.

ARTICLE 129.- The Secretariat shall issue the following security measures:

I.- The suspension of work or services:

II.- The securing and destruction of objects, products or substances;

III.- The prohibition of acts of use, and

IV.- Other health-related measures that can prevent or continue to cause risks or damage to health.

CHAPTER X
Administrative Sanctions

ARTICLE 130.- Violations of the provisions of this Regulation will be sanctioned administratively by the Secretariat, without prejudice to the penalties that may apply when they constitute crimes.

ARTICLE 131.- Violation of the provisions contained in articles 37, 44, 46, 51, 52, 55, 62, 83, 84, 86, and 87 of this Regulation will be sanctioned in accordance with article 419 of the Law.

ARTICLE 132.- Violation of the provisions contained in articles 16 section V, 34, 50, 63, 67, 70, 72, 75, 76, 77 and 82, section I of this Regulation will be sanctioned in accordance with article 420 of the Law.

ARTICLE 133.- Violation of the provisions contained in articles 9, 21, 22, 23, 29, 35 and 39 of this Regulation shall be sanctioned in accordance with article 421 of the Law.

ARTICLE 134.- Infractions not provided for in this chapter will be sanctioned in accordance with the terms of article 422 of the Law.

CHAPTER XI
Procedure for Applying Sanctions and Security Measures

ARTICLE 135.- The procedures for the application of security measures and sanctions are They will comply with the provisions of the Law.

CHAPTER XII
From the Appeal for Nonconformity

ARTICLE 136.- Against acts and resolutions of the Secretariat, which, due to the application of this Regulation, end an instance or resolve a file, the interested parties may file the appeal of nonconformity and its processing will conform to Chapter IV of Title Eighteen of the Law.

TRANSITIONAL

ARTICLE ONE.- This Regulation shall enter into force on the day following its publication in the Official Gazette of the Federation.

ARTICLE TWO.- The administrative acts and procedures related to the subject matter of this Regulation, which were initiated under the validity of the Regulations mentioned in the Third Transitory Article, will be processed and resolved in accordance with the provisions thereof.

ARTICLE THREE.- The Federal Regulations for the Disposal of Organs, Tissues and Cadavers of Human Beings, of August 16, 1976, published in
The Official Gazette of the Federation on October 25 of the same year; the Regulations for Blood Banks, Transfusion Services and Blood Products, of October 4, 1961, published in the Official Gazette of the Federation on November 8 of the same year; and the Federal Regulations for Cemeteries, Burials, Exhumations, Preservation and Transfer of Corpses of February 28, 1928, published in the Official Gazette of the Federation on March 12 of the same year. Likewise, all other administrative provisions that conflict with these Regulations are repealed.

Given at the Residence of the Federal Executive Power in Mexico City, Federal District, on the eighteenth day of February, nineteen hundred and eighty-five.- **Miguel de la Madrid** H.-Signature.-
The Secretary of Health, **Guillermo Soberón Acevedo.-** Signature.

TRANSITIONAL ARTICLES OF REFORM DECREES

Errata to the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Corpses of Human Beings, published on February 20, 1985.

Published in the Official Gazette of the Federation on July 9, 1985

DECREE reforming the indicated Articles of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Corpses of Human Beings, to read as indicated.

Published in the Official Gazette of the Federation on November 26, 1987

ARTICLE ONE.- Articles 1, 4, 5, 6, 7, 9, 12, 14, 16, 19, 21, 23, 27, 29, 30, 31, 32, 33, 36, 39, 40, 42, 43, 48, 51, 52, 53, 54, 56, 61, 90, 92, 93, 94, 96, 100, 102, 103, 104, 119, 123 and 124 of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings are amended to read as follows:

…….

ARTICLE TWO.- The name of Section Three of Chapter III is modified
Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings, to read as follows:

…….

ARTICLE THREE.- The last paragraph of article 25, the last paragraph of article 93, section VIII of article 100 and 112 of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Corpses of Human Beings are repealed.

TRANSITIONAL

FIRST.- This Decree shall enter into force on the day following its publication in the **Official Gazette of the Federation.**

SECOND.- All provisions that conflict with this Decree are hereby repealed.

Given at the residence of the Federal Executive Power on the twenty-fourth day of November 1987.- **Miguel de la Madrid H.-** Signature, The Secretary of Health, **Guillermo Soberón Acevedo.-** Signature.

DECREE amending Article 92 of the Regulations of the General Health Law regarding Sanitary Control of the Disposal of Organs, Tissues and Corpses of Human Beings.

Published in the Official Gazette of the Federation on January 27, 2012

SOLE ARTICLE.- Article 92 of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings is **AMENDED** to read as follows:

.....

TRANSITIONAL

FIRST.- This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

SECOND.- Those procedures for requesting a health license, whose resolution is pending at the time of the entry into force of this Decree, will be resolved in accordance with the legal provisions in force at the time of their presentation.

Given at the Residence of the Federal Executive Power, in Mexico City, Federal District, on the Eighteenth day of January, two thousand twelve.- **Felipe de Jesús Calderón Hinojosa.-** Signature.- The Secretary of Health, **Salomón Chertorivski Woldenberg.-** Signature.

REGULATIONS of the General Health Law on Transplants.

Published in the Official Gazette of the Federation on March 26, 2014

TRANSITIONAL

FIRST. This Regulation shall enter into force on the day following its publication in the Journal Official of the Federation.

SECOND. The provisions of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings, which refer to the donation, disposal and transplantation of organs, tissues and cells, other than blood and its components, hematopoietic progenitor cells or stem cells, as well as those provisions that oppose this Regulation, are repealed.

Consequently, Sections Three and Four of Chapter III; Chapter IV, and Chapter V of the Regulations of the General Health Law on Sanitary Control of the Disposal of Organs, Tissues and Cadavers of Human Beings remain in force, as well as the other provisions of the same regulation, which are necessary for the application of said Sections and Chapters mentioned above.

THIRD. The Agreement establishing the guidelines for the allocation and distribution of organs and tissues from human cadavers for transplantation, published in the Official Gazette of the Federation on April 23, 2009, is hereby repealed.

FOURTH. The Agreement delegating to the Head of the Federal Commission for Protection against Sanitary Risks the handling of the procedure indicated, published in the Official Gazette of the Federation on June 16, 2011, is hereby repealed.

FIFTH. The National Transplant Center will have a period of ninety working days, counted from the entry into force of this Regulation, for the issuance of the forms referred to in articles 8 and 11 of this regulation.

SIXTH. The administrative procedures and processes related to the purpose of this Regulation that are in process at the time of its entry into force, will be resolved in accordance with the provisions in force on the date on which said procedures and processes began.

SEVENTH. The expenses generated as a result of the entry into force of this Regulation shall be covered by the budget approved for the Ministry of Health, therefore it will not require additional budget increases and its regularizable budget for the current fiscal year will not be increased.

Given at the Residence of the Federal Executive, in Mexico City, Federal District, on the twenty-first of March, two thousand and fourteen.- **Enrique Peña Nieto.-** Signature.- The Secretary of Health, **María de las Mercedes Martha Juan López.-** Signature.