Good Human Organ, Tissue and Cell Practice

1. An organ bank shall formulate a quality plan and ensure that such plan is effectively implemented.

   The quality plan mentioned in the preceding paragraph shall contain at least the following particulars:

   (1) Proper organizational and personnel education and training programs, and requirements for personnel experience and continuing education;

   (2) The operating procedures for establishing, maintaining and updating the quality plan as well as record production and retention;

   (3) The setup of facilities and premises, and quality assurance measures;

   (4) Temperature and humidity control, ventilation and air filtering, cleaning and sterilization of work area and equipment, maintenance of control equipment for sterile operating environment, monitoring of environmental organisms, and other cleaning and hygiene activities relating to environmental control and monitoring;

(5) Instruments or equipment for the screening of organ donors and the harvesting, processing, testing and storage of human organs, tissues and cells (collectively referred to as “organs” hereunder), the operating procedures for their cleaning, sterilization, calibration and maintenance, and requirements for the frequency of such activities;

(6) Measures for the quality assurance of materials, supplies and reagents;

(7) Development, implementation, control and monitoring of donor screening assays;

(8) Process control relating to the organ harvesting, processing, testing, storage, labeling, packing, and delivery procedures, changes thereof and validation check to ensure that the organs are not contaminated and to prevent the spread of contagious disease. The validation check protocol when the organ processing procedure cannot be checked through subsequent examination and testing;

(9) Labeling requirements;

(10) Determination and maintenance of temperature range in the organ storage and processing process and effective period by type of organ, processing procedure (including sterilization validation procedure and preservation method), storage conditions and packing;

(11) Operating procedures for the acceptance, harvesting, delivery, destruction and disposal of organs;

(12) Transport conditions for all types of organs, design and production of packing and transport containers sufficient to ensure the functions and integrity of the organ, and validation check measures;

(13) Measures for preserving completely the data of organ donors and recipients, records on donor suitability reviews, and leak prevention;

(14) Mechanism for tracking organ transfer; and

(15) Creation of complaint file, and corrective and preventive action procedure.

The quality plan shall be reviewed at least once a year and

revised if deemed necessary. Records on the implementation and audit of the quality plan shall be produced and retained for at least ten (10) years.

2. The organ bank shall have proper space, structure, compartmentation, and control mechanism, and be equipped with adequate lighting, ventilation, water supply, drainage, cleaning and sanitation facilities.
3. Materials, supplies and reagents of the organ bank used for donor screening and the harvesting, processing, testing and storage of organ shall be checked to make sure they conform to specifications and shall not be put to use before the checking is completed. If the organ bank produces its own reagents, the related manufacturing process shall be validated or checked batch-by-batch.

The term “specifications” mentioned in the preceding paragraph refer to requirements set out to prevent increase in the risk of introduction, propagation or spread of contagious diseases due to organ contamination or impaired functions or integrity of organ.

The check mentioned in Paragraph 1 hereof may be conducted by the suppliers.

4. The retention period for records on the acquisition, preservation and transfer of an organ shall be extended for at least ten (10) years from the date the recipient undergoes organ implantation, transplantation, transfusion, or transfer, or from the date on which the organ is used to manufacture other products. Where an organ has been harvested, implanted, transplanted, transfused or transferred, or has been used to manufacture other products prior to the implementation of these Regulations and the date of occurrence is not certain, the organ bank shall retain the aforementioned records for at least another ten (10) years from the date these Regulations are promulgated.

5. An organ bank shall establish and maintain the methods for tracking the organ donor screening as well as the harvesting, processing, testing, storage, labeling, packing and delivery of organ, and produce records thereon. Such records shall contain information on the donor to the final disposition of

the organ. Where other institutions are engaged to carry out some of the processes mentioned in the preceding paragraph, such institutions should establish and maintain the methods for tracking the processes they have handled.

An organ bank should establish a two-way safety tracking mechanism with the organ-receiving institutions.