



American Association of Tissue Banks

Newsletter

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Board Approves Standard Requiring Pre-Processing Cultures

At a meeting held on April 10, the Board of Governors approved a standard that will require that a pre-processing culture must be obtained for all human tissues intended for transplantation with the exception of skin. For skin, the current standard D5.610 will apply. The new standard, which will be listed under K2.210 Pre-Sterilization/Pre-Disinfection Cultures, will include the exception for skin. The new standard will take effect on July 12, 2002. The revised standard reads as follows: *(Continued on page 2)*

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New Standards Edition Available

The tenth (2002) edition of *AATB Standards* is now available. This newly published edition contains the recently added standard requiring pre-processing cultures, K2.210 Pre-Sterilization/Pre-Disinfection Cultures (*effective July 12, 2002*), and the addition in the definitions section of the term, "Services to Donor Families," and the accompanying standard D2.600 Service to Donor Families. Finally, the sentence, "Compliance with Standards by all parties shall be required and documented," is deleted from B1.500 Multi-Facility Tissue Banking. These are the major changes; there are also minor typographical-error corrections. Ordering information can be obtained by calling the AATB Executive Office or by downloading an order form from the AATB Website at www.aatb.org.

HHS Premieres New TV Donor Documentary

On April 9, 2002, Secretary of Health and Human Services (HHS) unveiled a TV documentary entitled, *No Greater Love*, about organ donation and transplantation. The film also highlights the value of tissue donation and transplantation. The one-hour PBS show is intended to raise awareness about the need for and the benefits of donation. Featured in the story is a fireman who received a transplant after having been on the waiting list for a liver transplant for two years. According to HHS, the need for organ transplants is currently three times the number of donations available. Said Secretary Thompson, "It's not enough just to sign the organ and tissue donor card or note it on your driver's license; you must share the decision with your loved ones. If everyone did that, there wouldn't be any need for an organ donor waiting list. PBS has exclusive rights to the show for two years and information about when it will be shown in various cities can be obtained by contacting the local PBS affiliate. Robert Rigney and Jeanné Mowc represented AATB at the premier.

Banks Honored for 911 Support

President Doppelt and CEO Rigney awarded certificates to the following accredited banks honoring their efforts to provide personnel, allograft skin for transplantation, materials and supplies to hospitals and physicians in the care of survivors of the disasters of September 11, 2001. Several AATB skin banks provided grafts and various other support for survivors at both the World Trade Center in New York and the Pentagon in Washington. Banks were recognized at the 6th Annual Spring Meeting and included American Red Cross, Community Tissue Services, Intermountain Tissue Center, LifeCell Corporation, LifeLink Tissue Bank, LifeNet, Musculoskeletal Transplant Foundation, Northwest Tissue Center, Ohio Valley Tissue & Skin Center, and Transplant Services Center, University of Texas Southwest Medical Center.

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- Established a joint liaison committee with AOPO.
- Submitted comments in response to the FDA's proposed rule on "Current Good Tissue Practices for Manufacturers of Human Cellular and Tissue-Based Products."
- Issued a statement in response to the Office of the Inspector General's January 5, 2001 release of two reports, "Oversight of Tissue Banking," and "Informed Consent in Tissue Donation: Expectations and Realities." In addition, the Association invited Russ Herford, the lead investigator on the OIG reports, to speak at the AATB 5th Annual Spring Meeting.
- Attended the April 17, 2001 announcement of HHS' new national initiative to encourage organ, tissue, and marrow donations.
- Expanded AATB's National Tissue Network to include skin banks. The Association recruited skin banks and informed more than 150 burn surgeons of the Network, encouraging them to contact it if they faced shortages of skin for their burn patients.
- Approved and implemented a new standard requiring post-donation services for donor families.
- Prepared a side-by-side comparison of AATB Standards and FDA's proposed CGTP regulations.

Variance Approved

On February 19, 2002, AATB's Board of Governors approved a request for a variance to AATB standard D4.360, Repeat Testing of Living Donors, from Rubinoff Bone and Tissue Bank (Rubinoff), Toronto, Ontario, Canada. Standard D4.360 requires that "all cells and/or tissue from surgical bone donors that can be stored and still retain suitability for use shall be quarantined for a minimum of 180 days following donation, after which time the donors shall be retested for antibodies to HIV-1, HIV-2, HCV, and HBc; cells and/or tissue shall be released only if the test results are non-reactive." In its request, Rubinoff indicated that the Lobator process it uses is the only Class IV medical device validated and approved by the Health Protection Branch, Bureau of Biologics at Health Canada to kill HIV-1/2, HIV-1/0, HBV, HCV, HTLV, Syphilis, CMV, CPV, and human pathogenic vegetative bacteria.

Rubinoff requested a variance to the required 180-day quarantine period because its process destroys the viruses, and therefore, makes re-testing unnecessary. The variance is applicable only to bone from living donors who have completed all the testing requirements and the bone has been processed in the Lobator process. In addition, the bone cannot be distributed outside of Canada. This variance shall remain in effect as long as the applicable standard exists and is valid only for tissue being retrieved, processed, stored, and/or distributed from Rubinoff in Canada.

Banks Accredited

The following banks have recently been accredited:

Alabama Tissue Center, Inc., Birmingham, Alabama
For Processing, Storage and Distribution of Cardiovascular Tissue

American Red Cross Tissue Services, North Central Area, Eagan, Minnesota
For Retrieval and Storage of Skin, Musculoskeletal and Cardiovascular Tissue

Andrology Laboratory and Sperm Bank, Cleveland, Ohio
For Retrieval, Processing, Storage and Distribution of Reproductive Tissue

Community Tissue Services, Fort Worth, Texas
For Retrieval, Storage and Distribution of Skin and Musculoskeletal Tissue, and Retrieval of Cardiovascular Tissue

Comprehensive Tissue Centre, Edmonton, Alberta, Canada
For Retrieval, Processing, Storage and Distribution of Skin, Cardiovascular and Musculoskeletal Tissue

Doheny Eye and Tissue Transplant Bank, Los Angeles, California
For Retrieval of Skin, Cardiovascular and Musculoskeletal Tissue

Indiana Organ Procurement Organization, Indianapolis
For Retrieval of Skin, Cardiovascular and Musculoskeletal Tissue

LifeLink Tissue Bank, Tampa, Florida
For Retrieval, Processing, Storage and Distribution of Skin and Musculoskeletal Tissue, and Retrieval of Cardiovascular Tissue

Lost Mountain Tissue Bank, Inc., Kennesaw, Georgia
For Retrieval, Processing, Storage and Distribution of Musculoskeletal Tissue

Northern California Transplant Bank, San Jose
For Retrieval and Storage of Musculoskeletal Tissue, and Retrieval of Skin and Cardiovascular Tissue

Tissue Banks International National Processing Center, San Rafael, California
For Processing, Storage and Distribution of Musculoskeletal Tissue

Transplant Services Center, Dallas, Texas
For Retrieval, Processing, Storage and Distribution of Skin and Musculoskeletal Tissue, and Retrieval of Cardiovascular Tissue