



**ACCREDITATION BOARD MEETING MINUTES**  
**June 6<sup>th</sup>, 2024**  
**Annual Meeting**

**I. Call to Order**

Lisa Brooks, CEBT called the meeting to order and welcomed the Accreditation Board members and guests in attendance.

The following members were present:

Lisa Brooks, CEBT, CTBS	Accreditation Board Co-Chair
Bennie Jeng, MD	Accreditation Board Co-Chair
Marcy Dimond, CEBT, CTBS	AB Co-Vice Chair, Training Chair
Amy Lin, MD	AB Co-Vice Chair
Victoria Adler, RN, BSN, CEBT	
Andreea Bauknecht, CEBT	
Jason Brosious, RN, MSN, CEBT, CTBS	
William Buras, CEBT	
Winston Chamberlain, MD, PhD	
Kevin Corcoran, CAE	President/CEO – EBAA
Maria Soledad Cortina, MD	
Curtis Coughlin, CEBT	
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards – EBAA
Wayne Dietz, CEBT	
Donna Drury, MBA, CEBT, CTBS	
Erik Hellier, CEBT	
Susan Hulbert, CEBT	
Chris Johns, CEBT, CTBS	
Adam Kaufman, MD	
Sara Kerr, CEBT	
Christopher Ketcherside, MD	
Ellen Koo, MD	
Jennifer Li, MD	EBAA Chair
John Lohmeier, CEBT	
Thomas Mauger, MD	
Eric Meinecke, CEBT	
Shahzad Mian, MD	
Afshan Nanji, MD, MPH	
Lara Newman, MD	
Andrew Officer, CEBT	
Juan Pawirosetiko, CEBT	

Brian Philippy, CEBT  
Jim Quirk, CEBT  
Samuel Ramos, CEBT, CTBS  
Adam Stockman, CEBT  
Michael Titus, CEBT

## II. Approval of Minutes

A. Lisa Brooks requested an approval of the minutes from last meeting.

**ACTION:** A motion was made by Eric Meinecke, seconded by Erik Hellier to approve the minutes from the November 2<sup>nd</sup>, 2023, meeting. – **Motion Passed.**

## III. Old Business

A. **AB Training Update (Dimond)** No updates or training this cycle.

### Forms Subcommittee (Meinecke)

Changes to the following forms were updated as approved at the Fall meeting to L1.100 of the Medical Standards as well as PIQ/SIQ Worksheet, item 7-B as follows:

*L1.100 In special circumstances, like approved research programs, the Medical Advisory Board (MAB) may waive certain label and tissue report form requirements. Approval for omission must be obtained in advance from the MAB and surgeons receiving study tissues must consent in advance to any masking of standard required data.*

*Tissue distributed for transplant use shall be accompanied by a tissue report form and may include additional forms to address all requirements. The tissue report, including pertinent additional forms, shall contain the following:*

*9. Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, storage, evaluation, donor eligibility determination and distribution. Steps performed after release of a whole cornea for transplant use (e.g., processing, distribution) may be documented on additional forms (e.g., "processing form," "disclosure of eye banking functions form," importing eye bank revised/supplemental Tissue Report Form, or other documents).*

### **PIQ/SIQ Worksheet, Item 7-B**

*Name and EBAA accreditation status (including accredited functions) of each establishment that performs any of the following steps in the preparation of tissue (as shown on Tissue Report Form and/or other additional forms): recovery, processing, tissue storage, evaluation, donor eligibility determination, and final distribution.*

Eric has requested the ability to step down as the forms chair. We thank him for his service to the committee. The Co-chairs will initiate a search for a replacement. Please notify the Co-Chairs via email if you are interested in serving in this roll.

## **B. Training Subcommittee -Proposed change to C2.000 (Officer)**

Andrew Officer reviewed the following recommended changes to C2.00 and affected C1.200, Glossary and PIQ 2-C as written:

Andrew Officer presented proposed changes to the medical standards from the Accreditation Board's Subcommittee on Training. The proposed changes were to C1.200, C2.000, and the glossary.

### **C1.200 Medical Director**

The eye bank must have a Medical Director. When the Medical Director is not available, a back- up Medical Director shall be designated who is capable of fulfilling the responsibilities of the Medical Director on an interim basis.

The Medical Director and a back-up Medical Director must be an ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research, or teaching in cornea and/or external disease. If the Medical Director has not served a corneal fellowship, then the eye bank must have and document a consulting relationship with an ophthalmologist who has.

Any physician who provides verification of competency **determination by observation of for staff performing tissue recovery, and preservations, and/or processing** shall attend the Medical Directors' Symposium at the annual meeting of the EBAA at least once every three years and a Medical Advisory Board meeting once every three years. A newly appointed Medical Director shall attend a Medical Directors' Symposium and a Medical Advisory Board Meeting within one year of appointment, unless a Co- Medical Director has fulfilled the requirement. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

**For the purposes of this standard, "technician" refers to any individual performing eye bank functions (e.g., recovery, processing, tissue evaluation, donor eligibility determination, storage, and final distribution).**

The Medical Director shall oversee and provide advice on all medical aspects of the eye bank operations. These include but are not limited to:

1. Formulation, approval, and implementation of medical policies and procedures.
2. Participation in training and oversight of technical staff with regard to eye bank functions.

3. Participation in establishment and operation of a quality assurance program, including but not limited to policy development and approval, process validation, adverse reaction investigation, donor chart auditing, and development of corrective and preventive action plans.
4. Responsibility for verification of competency for tissue recovery and preservation by personnel applying for CEBT certification. Proficiency assessment of personnel applying for CEBT certification.
5. Initial and annual competency determination *by observation* of all staff designated to train tissue recovery, preservation, and processing procedures.
6. Initial and annual competency determination *by observation or verification* of all staff designated to train the functions of tissue evaluation and surgical suitability determination.
7. Initial and annual competency determination *by observation or verification* of all staff designated to release tissue for surgical use (e.g., final donor eligibility determination by Medical Director Designee).
8. When there is no trainer designated for a function, the Medical Director may serve as the trainer.

Medical Director responsibilities of competency determination are also outlined in EBAA Medical Standard C2.000 (table).

An eye bank's Medical Director must observe the designated staff trainer or trainers performing the following procedures as applicable on an annual basis:

1. In-situ corneoscleral disc excision or laboratory corneoscleral disc removal from whole eye
2. Posterior lamellar processing procedure that utilizes a microkeratome
3. At least one type of laser-shaped processing procedure
4. Each manual dissection processing procedure(s) for EK and ALK (i.e., DSEK or DMEK)

If an eye bank Medical Director has not designated any individuals as staff trainers he/she must observe each technician they have qualified to perform any of the above procedures on an annual basis.

The Medical Director may delegate responsibility for eye bank functions to qualified eye bank personnel; however, the Medical Director shall ensure that the eye bank operates in compliance with the EBAA Medical Standards. Ultimate responsibility for the suitability of each tissue for the transplantation in patients rests with the transplanting eye surgeon.

An eye bank has three months to replace a Medical Director who has resigned.

### **C2.000 Training, Certification and Competency Reviews of Personnel Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.**

An eye bank or other establishment performing eye banking functions must provide a formal orientation program for each new employee and the employee's participation must be documented. For the purposes of this standard, "technician" refers to any individual

performing eye bank functions (e.g., recovery, processing, tissue evaluation, donor eligibility determination, storage, and final distribution).

An eye bank or other establishment performing eye banking functions must also establish a comprehensive and well-defined training program outlining specific job-related tasks that each employee is being trained to perform. This comprehensive training program shall include the implementation and documentation of annual competency reviews of the skills and job-related knowledge of all eye bank employees performing eye banking functions. The person responsible for this training program must be a CEBT or an individual who has been qualified by a CEBT who is part of the organization’s comprehensive quality program.

Eye bank technicians may independently perform only those activities for which they are qualified and authorized by competency assessment. A competency assessment evaluates or determines an individual’s ability to perform a specific task according to procedure. A competency assessment is completed before the individual performs the task independently and at least annually thereafter. **Determination of competency**  
**Competency determination** for eye banking functions is the responsibility of the Medical Director or trainer(s) designated and determined competent by the Medical Director to serve as trainer of a function. Competency determination may be accomplished by observation or verification. Observation and verification are defined in the EBAA Medical Standards Glossary. This training program shall contain documentation indicating when each employee is released to perform their job-related tasks independently. **Competency and training records shall be maintained for a minimum of 10 years.**

Eye bank technicians seeking to receive EBAA certification or become recertified must meet the criteria set forth in the EBAA document Criteria for Certification and Recertification of Eye Bank Technicians.

All EBAA accredited eye banks must have one CEBT attend an EBAA sponsored skills workshop once every three years.

<b>Initial and Annual Competency Responsibilities</b>		
<b>Procedure</b>	<b>Trainer</b>	<b>Non-Trainer</b>
<b>Recovery</b>	<b>Observation by Medical Director</b>	<b>Observation by Trainer</b>
<b>Preservation</b>	<b>Observation by Medical Director</b>	<b>Observation by Trainer</b>
<b>Processing</b>	<b>Observation by Medical Director</b>	<b>Observation by Trainer</b>
<b>Tissue Evaluation</b>	<b>Observation or Verification by Medical Director</b>	<b>Observation or Verification by Trainer</b>
<b>Surgical Suitability Determination</b>	<b>Observation or Verification by Medical Director</b>	<b>Observation or Verification by Trainer</b>

Donor Eligibility Determination	Observation or Verification by Medical Director	Observation or Verification by Medical Director
<ul style="list-style-type: none"> <li>If a procedure has optional steps (e.g., DMEK processing procedure has optional step for pre-load), a single competency assessment with all optional steps performed shall represent competency assessment of all variations of the procedure.</li> <li>Trainers may not determine competency of other trainers.</li> </ul>		

**EBA Medical Standards Glossary**

Competency Assessment – A competency assessment evaluates or determines an individual’s ability to perform a specific task according to procedure.

Competency Determination – Determining competency either by observation, verification, or both.

Observation of Competency – The act of viewing a procedure or mock procedure to assess the technician’s competency to independently perform the procedure. Observation of competency is one of two methods for assessing competency.

Verification of Competency – The act of reviewing evidence of skilled execution of tasks related to the eye bank function performed to assess the technician’s competency to independently perform the p one of two methods for assessing competency.

**Action:** A motion was made by Michael Titus, seconded by William Burris to approve the recommended change as written. - **Motion Passed.**

**C. Processing Subcommittee – Proposed changes to C1.400 (Meinecke)**

The Processing Subcommittee chaired by Kyle Mavin recommended the following changes to C1.400. Lisa Brooks called for a motion to accept the changes as written.

Eric Meinecke presented the Processing Subcommittee Report. Eric directed AB members to the changes in red to C1.400 Change of Governance, the new table (C1.410 Processing Activity), the glossary text in red for Processing, and Lamellar/Segmental Additive Keratoplasty.

## C1.400 Change in Governance

An eye bank that undergoes a change in governance must notify the EBAA office, in writing, within 30 days. Some examples of changes in governance include a merger of eye banks, affiliation of two or more eye banks, affiliation of an eye bank with another non-eye bank organization (e.g., tissue banks, organ procurement organizations, hospitals, blood banks, etc.), a change in the name of the eye bank, a change in required personnel, i.e. Director, Medical Director, or **a change in processing activity**.  
(Refer to Accreditation Policies and Procedures E1.500.)

**C1.410 Processing Activity is defined as Basic (Level I) and Advanced (Level II) in the following table:**

	<b>Basic (Level I)</b>	<b>Advanced (Level II)</b>
<b>Cornea</b>	Rim Trim	DSAEK/ALK
	Tissue Rinse	DMEK
	Media Transfer	Preload DSAEK/DMEK
	Corneal Marking (PKP)	Laser Assisted Keratoplasty
	Long-Term Preservation	Irradiation/Sterilization
	Media Additive	LSAK
<b>Sclera</b>	Long-Term Preservation	Irradiation/Sterilization
<b>Whole Eye</b>	Transfer	
	Rinse	
	C-S Rim Removal	

### Glossary Terms:

**Processing.** Any activity performed on the eye tissue, other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution, such as: testing for microorganisms; preparation, sterilization, steps to inactivate or remove adventitious agents; preservation for storage; manipulation/sizing and removal from storage. Any manipulation of the ocular tissue intended for transplant that involves opening a previously sealed container after recovery.

***Specific processing activities are categorized as Basic (Level I) or Advanced (Level II) according to the matrix in C1.410 Processing Activities.***

***Lamellar/Segmental Additive Keratoplasty (LSAK). Donor Tissue corneal segments or lamellae derived from any layer of the cornea intended for onlay, inlay or underlay keratoplasty procedures.***

**Action:** A motion was made by Erik Meineke, seconded by Alan Blake to approve the recommended change as written. - **Motion Passed.**

**D. MD Subcommittee – Proposed changes to PP C1.500 (Brooks)**

The Medical Director Subcommittee presented a recommended change to C1.500 which would require the Medical Director to be conducted in person at the eye bank during an accreditation inspection, unless pre-authorized for an alternative arrangement has been obtained.

**Action:** No action taken, Subcommittee will have further discussion and the item will be moved to Old Business to be followed up on at the Fall Meeting.

**IV. New Business**

**A. New Process for AB Subcommittee Formation (Brooks)**

Lisa Brooks shared that a new process will be utilized going forward for the formation of AB Subcommittees. Calls for participation will be sent following the AB meeting to board members who may respond to Jennifer or the Co-Chairs if they are interested in participating via email.

**B. Proposed changes to PIQ/SIQ (Meinecke) (Attachment E)**

A proposed change to the PIQ/SIQ worksheet was made by Vicki Adler to require age criteria in their policies and procedures for any eye banking functions.

The PIQ requires the donor's age to be on the tissue report form, per medical standards.

The final Tissue Report Form and the Package Insert is the responsibility of the bank that performs Final Distribution (FD), so Section 1: Pre-Inspection Materials of the PIQ/SIQ worksheet only applies to banks that perform FD.

The Policy and Procedure (P&P) section (Q23) currently only requires age for Recovery and Donor Eligibility (DE) functions. Banks that perform any of the functions should have donor age exclusion criteria.

Director (Q80) is specifically related to tissue distribution and thus is appropriate to only ask a Director of a bank that performs FD. Similarly Medical Director (Q97) is specifically related to distribution and thus is appropriate to ask a Medical Director of a bank that performs FD.

Section 8: Records (Q197) - Banks that perform any of the eye bank functions should have the donor's age or date of birth in their records.

The table below shows the current PIQ and SIQ age questions by eye bank functions. The proposed change would make age exclusion criteria apply in the P&P section for all functions, and the age or date of birth of the donor should be in the records for all functions.





**Action:** A motion was made by Adam Stockman, seconded by Jason Brosius to approve the recommended change as written. - **Motion Passed.**

#### **D. Accreditation Modernization (Corcoran)**

Kevin Corcoran provided an update from the Accreditation Modernization Subcommittee. The intent of the change is to shift some of the administrative review to the EBAA so that the site inspectors can focus on more operational functions. The following changes have been approved and recommended by the EBAA Board of Directors;

- The EBAA plans to hire an Administrative Inspector to assist in the review of the application, forms and documents submitted by the bank for accreditation.
  - This will likely be a contract inspector or two contract inspectors who have knowledge in eye banking.
  - The position will be an EBAA employee via a contract relationship.
- The Inspection cycle will move to a year-round inspection cycle, similar to the AATB inspection schedule.
  - Under this model the AB will meet annually in person primarily to review and approve items typically covered in the open portion of the current model.
  - The AB members would meet virtually four times a year to review and vote on inspections.
- Virtual training will be enhanced to develop consistency among inspectors and attendance will be mandatory annually for inspectors.
- The EBAA will be moving to a virtual (cloud) system for document management. This will be a living portal allowing for annual uploads of a bank's documents. The funding for this system will come from a major gift (\$600K) that was given to EBAA in the previous year.
- Lastly the number of charts reviewed during an inspection will be adjusted based on the size of the bank. The AB board has been asked to find an appropriate system to determine the scope.

**Action:** A motion was made by Alan Blake, seconded by Erik Hellier to approve the recommended changes. - **Motion Passed.**

#### **V. Late Additions – No Late Additions**

#### **VI. Adjournment of Business Meeting**

**Action:** A motion was made by Brian Philippy, seconded by Sam Ramos to adjourn, and move to the closed session. - **Motion Passed.**

#### **VII. Closed Session**

Inspectors presented observations of all 18 banks.

The following was the result of the voting:

18 Banks received 3-year accreditation.

1 Bank deferred inspection and is now considered non-accredited.

No bank was denied accreditation.

Minutes submitted by AB Co-Vice Chair, Marcy Dimond, CEBT, CTBS