

Medical Advisory Board Meeting Minutes

June 27, 2025

Dr. Shahzad Mian called the meeting to order at 2:00pm PST. The following Board members were in attendance:

Shahzad Mian, MD	MAB Chair
Christopher Ketcherside, MD	MAB Vice Chair
Kristen McCoy, CEBT, CTBS	MAB Secretary
Anthony Aldave, MD	
Patrick Becker, CEBT	Technical Procedures Manual Subcommittee Chair
Lisa Brooks, CEBT, CTBS	
Jason Brosious, RN, CEBT, CTBS	
Winston Chamberlain, MD, PhD	
Jamie Collier, MA, CEBT	
Kevin Corcoran, CAE	President & CEO
Maria Cortina, MD	
Andrea Crosson, CEBT	
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards, Ex-Officio
Marcella Dimond, CEBT, CTBS	Accreditation Board Co-Chair
Sander Dubovy, MD	
Sean Edelstein, MD	
Asim Farooq, MD	Policy & Position Research Subcommittee Chair, Ex-Officio
Melissa Greenwald, MD	AATB Liaison
Christopher Johns, MBA, CETB, CTBS	
Stephen Kaufman, MD, PHD	
Amy Lin, MD	Accreditation Board Co-Chair
John Lohmeier, CEBT	
Kristin Mathes, MS, MA	
Rachel Peltier, CEBT, PhD	Certification Board Chair
Brian Philippy, CEBT	
Jim Quirk, CEBT	EBAA Chair
Edwin Roberts, MPA, CEBT	
Ingrid Schunder, CEBT	Technician Education Committee Chair
Shannon Schweitzer, MBA, CEBT	
Chris Stoeger, MBA, CEBT, CTBS	
Michael Titus, CEBT	
Michael Tramber, MBA, CEBT, CTBS	
Concetta Triglia, CEBT	
Elmer Tu, MD	Medical Review Subcommittee Chair, Ex-Officio
Woodford Van Meter, MD	
David Verdier, MD	
Jim Wagner, CEBT, CTBS	

Minutes

MOTION: A motion was made and seconded to approve the minutes from the October 2024 meeting.

Discussion:

Correction to the call to order: Dr. ~~Winston Chamberlain~~ Shahzad Mian called the meeting to order at 1:00pm.

All approved, no nays – Motion Passed

Medical Review Subcommittee

Dr. Elmer Tu presented the Medical Review Subcommittee Report.

Dr. Tu reviewed the adverse reaction report as presented in the board packet. Adverse reactions have remained stable for the last several years. The number of adverse events jumped in 2016 and 2017 and the number of early regrafts, and primary failures have remained stable. Of the 3 transplant types DMEK is up slightly and PKP and DSAEK remain stable.

Infections continue to occur however at a low rate, with DMEK slightly higher than DSAEK. Overall, the number of infections, specifically fungal endophthalmitis or keratitis, have gone down significantly and have remained low since 2017.

As a reminder, the FDA is independently contacting eye banks and surgeons following infection-related MedWatch reports. It is important that both surgeons and eye banks provide consistent, accurate information to avoid misinformation.

Amphotericin B Supplementation

Dr. Tu presented data on Amphotericin B supplementation

A large eye bank presented data at ASCRS 2025 on 53,000 grafts (2021–2024). Findings showed a statistically significant increase in primary graft failure (PGF) and early regrafts in PKP tissue with Amphotericin B supplementation. EK tissue showed a similar trend, though not statistically significant. Notably, Amphotericin B supplementation was associated with a statistically significant reduction in post-op infection rates.

Discussion There was discussion about whether the observed graft failure rate is clinically significant, given the small sample size and limited follow-up (8–12 weeks post-transplant). Long-term outcomes, including late regrafts or failures, remain unknown. The infections reported in the study were fungal infections. This data allows surgeons to weigh risks and benefits individually. Additionally, EBAA has added *Candida auris*—a fungus resistant to amphotericin B—to OARRS for tracking.

Rabies Transmission

Dr. Tu presented a recent case of Rabies transmission.

Rabies Transmission Case – CDC Notification (1/28/25):

CDC reported a potential rabies transmission in a kidney recipient who showed acute neurologic

decline and hydrophobia before passing. Rabies was confirmed via PCR on 2/2/25. Kidneys and corneas were recovered from the donor. Cause of death included anoxic brain injury and underlying conditions. Notably, the donor had been scratched by a skunk six weeks prior, with no follow-up or quarantine.

Corneal tissue was used in two DMEK procedures (12/16/24) and one gamma-irradiated CTAK (1/27/25). All grafts were explanted; recipients received post-exposure prophylaxis.

CDC lab analysis confirmed a partial rabies genome in donor corneal cells matching the variant found in the kidney recipient, consistent with silver-haired bat rabies.

Dr. Asim Farooq presented additional information on Rabies and proposed language for the medical standards.

MOTION: A motion was made and seconded to revise the language in the medical standards to:

"Donors with suspected rabies, as well as persons who were bitten or scratched within the last **6 12 months** by an animal suspected to be infected with rabies, or whose condition is otherwise unknown, should be deferred."

26 approved, 2 nays – Motion Passed

Policy and Position Review Subcommittee

Dr. Asim Farooq presented the Policy and Position Review Subcommittee (PPRS) Report.

The PPRS updated COVID-19 Guidance in March 2025.

- Specific COVID-19 screening questions are no longer required.
- Donors should continue to be screened for active infection and signs of sepsis.
- Ocular tissue from donors with pending COVID-19 results may be released for surgical use at the medical director's discretion, based on clinical assessment.

PPRS has been working on a manuscript, which is close to submission, on positive HTLV, CMV, and EBV. There was some concern about positive HTLV, CMV, and EBV being reported on tissue information forms. The subcommittee performed an extensive literature review which showed no cases of transmission via ocular tissue. Current EBAA guidance states that positive test results for HTLV, CMV, or EBV are not a deferral for ocular tissue. Based on these results the PPRS is not recommending a change to the EBAA medical standards.

Accreditation Board

Marcella Dimond presented the Accreditation Board Report.

During the Spring inspection cycle, 10 banks were inspected. 8 banks received a 3-year accreditation, 1 eye bank received a 1-year accreditation and 1 eye bank was deferred.

Certification Board

Rachel Peltier, PhD presented the Certification Board Report.

Starting Fall 2025, two certification tracks will be available:

Certified Eye Banker – Technical (CEBT): For technical professionals; includes practical performance competency verification.

Certified Eye Banker (CEB): For non-technical professionals; does not require a practical component.

- Candidates may now fulfill the practical requirement with one of three procedures: Corneal Excision, DSAEK, or DMEK.
- A single 250-question exam will be used for both certifications. CEB candidates will not be evaluated on technical proficiency.
- There will be no changes to the recertification process; both CEB and CEBT will follow the same 3-year recertification cycle.
- CEBs may apply to become CEBTs after their first recertification. Early transition requests may be considered after one year under special circumstances.
- There will be no changes to the EBAA Medical Standards; all references to CEBT remain unchanged.

Fall 2025 exam window will be October 11–25. The application deadline is September 3; early rates end August 15.

During the Fall 2024 and Spring 2025 exam cycles 25 new CEBTs were certified.

Technician Education Committee

Ingrid Schunder presented the Technician Education Committee Report.

The Technician Education Seminar (TES) was held virtually in January and February and welcomed 60 attendees from 12 countries. The course featured approximately 30 on-demand presentations and 3 live workshops.

The Committee hosted the following webinars and community chat discussions:

- November: Keratoconus – Overview, Current Treatments and Future Therapies
- December: Community Chat - Corneal Tissue Processing: Ask the Processors
- March: Ocular and Tissue Donation: Working Together to Enhance Lives – hosted with AATB
- April: Community Chat - Corneal Tissue Processing: Ask the Processors Round 2!
- May: Answering the Call: Navigating the Role of the AOC

Upcoming Webinars include:

- July 31: Gender Identification in Decedent Care and Medicolegal Investigation
- August 14: DMEK 2.0 – Beyond the Basics
- September 10: Community Chat: Ocular Tissue Allocation and Distribution

Educational Resources: Ongoing development of technical sessions, skills videos, and procedural content available on eyeLEARN.

Annual Meeting Presentations: Featured interactive sessions and workshops, including DSAEK 2.0, corneal tissue evaluation, and collaborations with medicolegal entities.

Thanks to industry partners (Haag-Streit, Konan, MedLogics, Moria) and eye banks for equipment and tissue donations. Special recognition to donors and families for enabling educational experiences.

Technician Procedures Manual Subcommittee

Patrick Becker gave the Technical Procedures Manual Subcommittee Report.

The procedures manual subcommittee proposed the following changes to the Procedure Manual:

1. Mergers, Acquisitions and Dissolutions – Consider adding to Procedures manual C1.400 or MS C1.400 Change in governance.
 - The addition of the language was tabled. A subcommittee will be formed to discuss and present final verbiage to the MAB at the fall meeting. Language should be compared to existing language in the accreditation and Medical Standards.
 2. B1.000 - Accreditation - 3-Year accreditation MS/PM discrepancy –
 - Skipped
 3. C2.000, Point 11 in page 7 of Procedures Manual discrepant from page 11 in Medical Standards based on new trainer requirements.
 - a. Update point 11 in C2.000 (page 7) add “or Designated Trainer”
11. The Medical Director **or Designated Trainer** must designate in writing all non-EBAA certified technicians who are qualified and authorized to perform eye bank laboratory procedures.
4. C3.100 Eye Bank Laboratory - Glossary, add QPE, Qualified Processing Environment
 - Glossary in Medical standards must have the same definition of QPE in the glossary (Quality Assurance Subcommittee is simultaneously working on this)

#7: Qualified Processing Environment (QPE) - ISO 5/Class 100 laminar airflow hood, operating room or a clean room which meets the eye banks quality control criteria. Refer to EBAA Medical Standards E1.200.

Discussion: add operating room as a QPE

5. C3.100, point 14 (page 11) - Add Reference
 - **EBAA Medical Standards C3.150**
6. E1.000 - Recovery, Open-Container Processing and Preservation

Update Title to: E1.000 Recovery, ~~Open-Container~~ Processing, and Preservation

7. E1.120, Enucleation, point 11 (page 61) Gloving
 - a. Add re-gloving rationale to E1.100 point 11

If the technician compromises their surgical gloves in step 10, or at any other point, either intentionally or unintentionally, they must re-glove or remove outer gloves. If the technician does not compromise their gloves in step 10, they may proceed without re-gloving or removing outer gloves only if doing one of the following:

- a. maintaining sterility of the uncompromised glove, or;
- b. waiting to compromise their gloves and apply the recommended solution until after the second eye is enucleated

8. E1.200, Update title and point 1
 - a. Replace with: Processing shall be performed in a Qualified Processing Environment (QPE)

E1.200 ~~Open-Container~~ processing

1. ~~Open container~~ Processing must be performed in: a) a laminar flow hood or biosafety cabinet which meets ISO Class 5 Standards, b) in an accredited operating room, or c) in ~~another~~ a Qualified Processing Environment (QPE) See C3,100: Glossary. ~~documents annually to have less than 25 colony forming units per 90mm settle plate per one hour exposure.~~

9. E1.400 Long Term Preservation - add Ethanol

- a. Insert Ethanol, between 1. Cryopreservation and 2. Glycerin (will become number 3.)

Procedure:

2. Ethanol

- Tissue preserved in ethanol is to be held for a minimum of 5 days (120 hours) from time of processing before releasing for transplant.
- Donor tissue may be preserved in ethanol for a period of time validated by the eye bank, not to exceed the expiration date of the medium or container.
- Ethyl alcohol concentration is to be minimum 70%, by volume.
- If selecting USP (United States Pharmacopeia) grade, ethanol *concentration* is minimum 95% and a maximum impurity allowance of 0.5% by weight.
- Another purity / grading option is to subject the ethanol to 0.2 micron filtration, providing 'filter sterilization'.

Rationale:

- If an eye bank elects to use ethanol preservation, a detailed policy and procedure shall be included in the eye bank's written policies and procedures manual.

Discussion: in the 4th bullet under procedure add the word concentration after ethanol

10. J1.000, point 4 b - FIN(P)

- a. Procedures manual J1.000 Point 4 B (page 168)- "if applicable" needs to be deleted to match the new FIN (P) requirement for all processed tissues regardless of the source/distributing eye bank.

B. ISBT 128 tissue identifiers. ISBT tissue identifiers include Donation Identification Number (DIN), Product Code, and Processing Facility Information Code. ~~(if applicable)~~

Discussion: Change the preservation to storage to be consistent with ISBT

MOTION: A motion was made and seconded to approve the above changes to the procedure manual. Number 1 was excluded, and discussion items were added to the above changes.

All approved, no nays – Motion Passed

The procedures committee will be revising the procedures manual to identify process improvements and opportunities. The revised procedures manual will be presented at the fall meeting.

Discussion: Change preservation to storage to be consistent with ISBT

Old Business

Kristin Mathes presented a Sepsis Work Group update

Sepsis Guidance and Workflow Discussion:

- In 2024, multiple eye banks received FDA 483 citations due to inconsistent interpretation of the 2007 sepsis guidance. Concerns were raised about tissue safety.
- A Sepsis Work Group was formed during the 2024 MAB meeting to develop a consistent evaluation tool for sepsis across eye banks.
- The group reviewed FDA warning letters and infection cases but found no correlation between reported infections and donor records.
- Initial efforts to create a universal tool were paused pending new FDA guidance documents, which were released in January 2025 and then rescinded. Revised versions are now open for public comment (due July 7).
- A workflow tool was developed based on the 2007 guidance, incorporating input from multiple eye banks and reviewed by a physician-led work group. It is intended as a guidance document, not a medical standard.
- The tool outlines steps for evaluating potential sepsis, including:
 - Deferral if sepsis is confirmed with no alternative explanation.
 - Further review and consultation if sepsis is suspected but not confirmed.
 - Use of a treating physician or knowledgeable healthcare professional for additional medical history.

- Additional recommendations include:
 - Work to provide guidance on documentation
 - Providing training on effective communication with hospital staff
 - Sharing language to support efficient physician consults

New Business

Wayne Dietz presented a request from the QA committee to add a nonvoting seat on the MAB.

MOTION: A motion was made and seconded to approve the QA committee to have a nonvoting seat on the MAB.

All approved, no nays

Jennifer DeMatteo presented updates to the Guide for ISBT 128 in North America Eye Banks.

This guide was last updated in 2017 and is part of the procedure's manual. There are several updates which are presented in the board packet.

MOTION: A motion was made and seconded to approve the updates as presented in the MAB Agenda packet to the Guide for ISBT 128 in North American Eye Banks.

All approved, no nays

Late Additions

No late additions

MOTION: A motion was made and seconded to adjourn the Medical Advisory Board Meeting at 1538 PST.

All approved, no nays