

Accreditation Board Meeting Agenda



CONFIDENTIAL – AB MEMBERS ONLY

Tuesday, November 10, 2020

20:00-22:00 ET

Via Videoconference

	Attachment	Presenter	Action?
1. Call to Order		Rhee	No
2. Approval of Minutes	A	Mavin	Yes
3. Old Business			
3a. Training Update		Brooks	No
3b. Forms Subcommittee Activity Report		Binnion	No
3c. Guidance on the Use of Video During Accreditation Inspections	B	Mavin/Ketcherside	Yes
3d. Notification of Accreditation Status Change	C	Stoeger	
4. New Business			No
4a. Hybrid Spring Inspections Feedback		Mavin/Rhee	Yes
4b. Defining the regularity of alarm testing (C3.200)	D	Mavin	
5. Late Additions		Mavin	Yes
6. Adjournment of Business Meeting		Rhee	Yes
7. Spring 2020 Inspection Cycle		Mavin	Yes
8. Adjournment		Rhee	

Reminders: Do not mention eye bank names, locations, size or affiliation of banks. Confidentiality must be maintained before, during and after all Accreditation Board meetings. AB members may cast a vote for banks they inspect. AB members are not permitted to vote if their own bank is presented or if they are not present during the inspection presentation.



ACCREDITATION BOARD MEETING MINUTES
June 18, 2020
Virtual Meeting

I. Call to Order

Dr. Chris Ketcherside called the meeting to order and welcomed Accreditation Board members and guests in the attendance.

Welcomed new AB members

The following members were present:

Christopher Ketcherside, MD	Co-Chair
Chris Stoeger, CEBT	Co-Chair
Kyle Mavin, CEBT	Co-Vice Chair, Training Chair
Michelle Rhee, MD	Co-Vice Chair
Beth Binnion, CEBT	Chair, Forms Subcommittee
Victoria Adler, RN, BSN, CEBT	
Alan Blake, CEBT	
Sara J. Botsay, CEBT	
Lisa Brooks, CEBT	
Jason Brosious, CEBT	
Ryan Cady, CEBT, CTBS	
Winston Chamberlain, MD	
Kevin Corcoran, CAE	President/CEO – EBAA
Maria Soledad Cortina, MD	
Curtis Coughlin, CEBT	
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards – EBAA
Marcella Dimond, CEBT	
Donna Drury, MBA, CEBT, CTBS	
Timothy Fischer, MHA, CEBT, CTBS	
Michael Geiss III, MD	
Brian Ha, MSc, CEBT	
Erik Hellier, CEBT	
Bennie Jeng, MD	
Adam Kaufman, MD	
Anup Kubal, MD	
Jennifer Li, MD	
Amy Lin, MD	
John Lohmeier, CEBT	

Linda Martin, CTBS	
Donna McDonald, CEBT	
Eric Meinecke, CEBT	
Shahzad Mian, MD	
Seth Michael Pantanelli, MD	
Brian Philippy, CEBT	
Jim Quirk, CEBT	
Sam Ramos, CEBT, CBTS	
Mijana Ridic, CEBT	
Adam Stockman, CEBT	
Bradley Tennant, CEBT	
Michael Titus, CEBT	
David Tremblay, MD	
Woodford Van Meter, MD	EBAA Chair
David Warner, MD	
Samuel C. Yiu, MD	
David Kennedy	Guest – Incoming AB
Jennifer Ling, MD	Guest – Incoming AB
Afshan Nanji, MD	Guest – Incoming AB
Andrea Bauknecht, CEBT	Guest – Incoming AB
Susan Hurlbert, CEBT	Guest – Incoming AB
Andrew Officer, CEBT	Guest – Incoming AB
Ankit Shah, MD	Guest – Incoming AB
Wesley Thompson, CEBT	Guest – Incoming AB
Heather Werner, MA, CEBT	Guest – Incoming AB
Tony Win'E, CEBT	Guest – Incoming AB

II. Approval of Minutes

Prior to the approval Chris Stoeger acknowledged the effort of the EBAA staff in regard to setting up the virtual meeting

Chris Stoeger requested approval of the minutes from the last meeting.

Action: Curt Coughlin, CEBT noted he was missing from the attendance list

A motion was made (Meinecke) and seconded (Brosious) to approve the minutes from the October 2019 meeting in San Francisco, CA.

Motion Passed.

III. Old Business

Accreditation Board Minutes, Virtual Meeting, June 2020

3A. Non-Member Accreditation and Stats Reporting – (Corcoran)

Kevin provided follow up information regarding a discussion item from last meeting in October. There were some inquiries regarding CorneaGen and the status of their EBAA Accreditation. It was noted that the CorneaGen locations that have active accreditations will remain so until they expire.

Kevin then reviewed the fee structure that the EBAA Board had set for both members and non-members. Members' fees will remain unchanged; \$500 application fee and \$3,500 inspection fee. However, in November 2019, the EBAA Board of Directors set the following fees for non-member entities:

Application fee	\$4,000
Accreditation fee	Net Ocular Revenue x .0045

This fee more fully reflects the value of EBAA accreditation to an eye bank and includes the association's overhead and operational costs, which are paid as part of a member eye bank's dues.

Kevin then discussed Statistical Reporting, he referenced Medical Standard C3.510 that states that an eye bank that obtains tissue from or distributes tissue to an unaccredited eye bank must document that the facility complies to EBAA Medical Standards, along with state and federal regulations. This requires a written agreement and regular scheduled audits performed by an EBAA accredited eye bank. The eye banks' SOPs should describe the audit plan, scope and frequency. These items will be reviewed during your accreditation inspection.

Kevin continued to discuss the aspect of statistical reporting. There was an issue that a processing/distributing eye bank refused to provide final disposition to the source eye bank, which prevented the source bank from submitting full and accurate statistical reports as required under Medical Standards . The issue was resolved but Kevin felt that this may become an issue again in the future. He encouraged source eye banks to include in their agreements a statement that the processing and/or distributing eye bank will provide final disposition of the tissue to the source eye bank.

Kevin concluded his report and invited any questions. Brian Philippp asked had any non-member eye banks requested accreditation since the implementation of the new policy; Kevin replied that none had. No further questions were asked.

3B. Training Update (Mavin)

No formal training updates were presented. Lisa Brooks was announced as the incoming Co-Vice Chair and will be taking on the training of the new AB members. Asked to anticipate an email inviting the new AB members to join a training session in the near future.

Dr. Rhee took the opportunity to report that Dr. Jeng will be the incoming physician Co-Vice Chair.

3C. Forms Subcommittee Activity Report (Binion)

Beth did not have a report to present.

3D. Scores and Scoring – (Stoeger)

Chris reported that although there were limited number of inspections that occurred, all the inspectors did utilize the updated SIQ (that totals the score as it is completed). There were not reports of any Accreditation Board Minutes, Virtual Meeting, June 2020

issues. Chris thanked Brian Philippy for developing the automated SIQ and encouraged everyone to continue to utilize the new SIQ.

3E. Use of video in lieu of being on site for training and inspections – Update (Ketcherside)

Dr. Ketcherside provided an update in regard use of video during inspection. A clip of the beta test video that was submitted by Kyle Mavin, Advancing Sight Network to the subcommittee prior to COVID pandemic was shown. Dr. Ketcherside stated that a decision was made to “speed things along” in regard to using this technology. The reasons for this were:

- Video has been used on a case-by-case basis already
- These trials have been successful
- Now more comfortable with this
- Being remote was never more important

The AB Chairs and video subcommittee have decided to put together a video use guidance document, which will be accessible through the EBAA website. A small group with guidance document experience has been formed. They will draft the document and submit it to the subcommittee for review and approval. The document then will be brought to the AB for final approval at the fall meeting. In the meantime, the use of vide will be approved on a case-by-case basis.

IV. New Business

4A Shifting of the Spring to Fall – Open Forum (Ketcherside)

Dr. Ketcherside explained that due to COVID-19 pandemic the AB Chairs made a decision to move the Spring Inspections (excluding those that were completed before COVID-19) to the Fall and then the Fall inspections into next Spring. Dr. Ketcherside then asked for any comments or questions in regard to this decision.

Erik Hellier made a comment in regard to the video that was shown during old business that he would like to see a more bird’s eye view to ensure the technician that is performing the procedure is maintaining sterility. Also noted that a 2nd camera view maybe considered.

Jennifer DeMateo did state that during the video there are clips that there were instructions given to the camera operator to zoom in and out and to change angles.

Dr. Warner asked if the video was going to be an option for future inspections will the eye bank have the ability to record (with the 2-camera view) be an option. Dr. Ketcherside stated that at this time the video option will be “live streaming”.

4B Loss of Accreditation Communication Plan (Stoeger)

Chris referenced Attachment B (of the AB packet) to policy G1.000 Identification of Accreditation Status. Chris explained that the policy is in place to notify the members of when the accreditation status does change for a bank. He stated that the notification is not very clear and would like to propose an addition be made to the policy as to when and how the notification should be performed. Chris noted that a timeline of 72 hours from time of status change should be used. Both eye bank members and Paton members should be notified (Chris stated that as a Paton member is an added value and should be treated as such allowing them to receive this communication). A template in regard to how the communication is to be worded was presented as well

Bank that loses their accreditation – *“As of DATE, EYE BANK NAME, is no longer accredited by the Eye Bank Association of America”*

Bank that is at a 3 year and is brought to a 1-year accreditation – *“As of DATE, EYE BANK NAME’s accreditation status was shortened to expire on DATE”*

Bank that gains their accreditation – *“As of DATE, EYE BANK NAME is accredited by the Eye Bank Association of America”*

Another additional statement was proposed is that the above templates may not be suitable for the communication needed therefore, the following statement was added to address that:

“Additional Information may be provided upon the advice and approval of the Accreditation Board Co-Chairs”

Chris then asked for questions from the AB. Eric Meineke stated that he was in support of this change but questioned if the notification of a bank’s accreditation being “shortened” is necessary. Asked for clarification as to the “why” this notification was found to be necessary. Chris Stoeger asked if Kevin Corcoran would like to respond. Kevin did state that this was discussed at length and the rationale was that providing the notification to the members of a change in accreditation status allows banks to communicate with the bank that is affected to discuss the reasons why the change occurred. Then the bank that has a working relationship can determine if the reason for the change warrants them to continue to work with them or not. Linda Martin then stated that she was in agreement with Eric’s comment in that if the eye bank did go through an off-cycle inspection and still met the standards to maintain their accreditation (although it is shortened) they are still accredited and therefore no notification should be done. Erik Hellier noted that there is an appeal process and if the eye bank in question was to perform that appeal process and was granted their full accreditation back how would that look? Chris Stoeger commented that as the proposal is currently written a follow up statement would be sent out informing that the accreditation was changed. Dr. Van Meter commented that there appears to be 2 issues being discussed, first that if a bank is accredited for 1 year or 3 years, they are accredited, and that notification should be that the bank is “accredited” not stating the length. Second issue is that if there is a denial of accreditation and an appeal is being performed, the eye bank’s accreditation status is denied until the appeal process has been completed. Dr. Van Meter continued to state that the EBAA should provide a status of all eye bank’s accreditation every 6 months. If there is a change in status, then a separate notification can go out at that time. Jennifer DeMatteo noted that per policy if a bank loses accreditation a notification is to go out. If the bank does go through the appeal process and they are granted accreditation, another status list is sent out showing the change in the bank’s status. Jennifer then provided some history behind why this policy change is being proposed. The past 2 years there have been 4 off-cycle for cause inspections, 1 lost accreditation, 2 maintained their accreditation but timeline was shortened, and 1 accreditation was suspended during investigation and then given back. Jennifer then stated that when the status list of banks is released it is up to the banks to determine if there were changes, therefore it is good to have these changes made to notify banks of changes. Beth Binion stated that historically it was noted that banks were accredited and not stating for how long but listing the inspection date. Beth recalled that that was due to a legal reason. Beth then stated that she agreed with Eric’s comment and that if a bank is accredited, they accredited and not have a notice go out when years of accreditation is changed. Lisa Brooks commented that from a quality view was there any concern of the status change. Lisa provided an example if there are audits scheduled every year or every two years, would this notification not help in that process? Chris Stoeger stated that if the bank did have a shortened

accreditation and then lost their accreditation, the EBAA would send a notification out and that would address the concern Lisa had shared. John Lohmeier stated he supported Eric and others in regard to not notifying the time frame of accreditation, “you are accredited or not accredited”. John made a second comment to consider the timing of the notification to be more in line with 1 to 2 months post AB meeting. This allows an appeal process to be completed (if necessary) without damaging the bank’s reputation. Chris Stoeger thanked everyone for the questions and conversation. He asked if there would be a proposed friendly amendment to make the statement broader. Chris pointed out that maybe the word “or shortened” and removing the whole statement of notifying when a bank’s accreditation is shortened. Jim Quirk made the motion and Eric Meineke second the motion. Chris then asked if there were any further discussions based on the friendly amendment. There were no more discussions therefore Chris put the proposed language (with friendly amendment) to a vote. Brian Ha requested to clarify what it is that the AB is voting on. Chris stated that the vote is to approve the additional language minus the friendly amendments. The motion did pass. Chris then proposed that a small subcommittee be formed to review the approved language to ensure it is written well. Then for this to stay under “old business” for the fall meeting, Erik Hellier and Kyle Mavin volunteered to help Chris review the proposed language. Dr. Ketcherside clarified that the current language has been approved and Chris Stoeger stated that the language will be implemented but if any further discussion can be made offline.

G1.000 Identification of Accreditation Status

- a. An accredited eye bank may identify itself as such and hold itself out to the public as EBAA accredited. A bank accredited for limited functions must so designate itself in a manner that does not imply accreditation for full service. If using the EBAA Accredited Logo, a bank must use the version that corresponds to the functions for which it is accredited and for the dates listed on its most recent accreditation certificate.
- b. A non-accredited eye bank shall not hold itself out either expressly, or indirectly, as an EBAA accredited eye bank. All materials that identify its accreditation status must be submitted to the EBAA for approval prior to distribution
- c. Eye banks provisionally accredited shall identify themselves as such
- d. A change in accreditation status from either accredited or non-accredited shall be communicated to eye banks and Paton members by the EBAA office as soon as practical, but no more than 72 hours from the date of the status change. Notification shall take place using the following template:

As of DATE, EYE BANK NAME is no longer accredited by the Eye Bank Association of America.

Or

As of DATE, EYE BANK NAME is accredited by the Eye Bank Association of America. Additional information may be provided upon the advice and approval of the Accreditation Board Co-Chairs.

V. Late Additions

No Late Additions were submitted.

VI. Adjournment of Business Meeting

Hearing no other questions or comments, Chris Ketcherside closed the business meeting and reminded those in attendance that the next section would be limited to AB members only.

VII. Closed Session / Spring 2020 Inspection Cycle – Reports of Findings

A. 4 Banks were inspected this round

The committee voted to award 3-year accreditation status to 1 bank with “No Findings” or 100%.

Inspectors presented observations on the other 3 banks.

The following was the result of the voting:

4 Banks received 3-year accreditation

Minutes submitted by AB Co-Vice Chair, Kyle Mavin, CEBT



Guidance on the Use of Video During Accreditation Inspections

COVID-19 has impacted our ability to conduct EBAA Accreditation Board inspections safely and effectively. Even prior to the pandemic, the use of video (in certain situations) has been effective in assisting both inspection teams and eye banks. This document is designed to provide guidance on how video (e.g. FaceTime, Zoom, Skype, Google Duo, etc.) can be used to assist with the inspection process. If you have questions or situations that this document does not address, you should contact the Accreditation Board co-chairs.

Accreditation inspections should not be conducted solely by video. Our robust process was designed to be an in-person (on-site) inspection, however, the use of video to supplement the on-site portion can be very helpful. The Lead Inspector should work with their co-inspector and the bank undergoing inspection to determine what elements will be done via video.

Here are some things that may help inspectors and eye banks regarding the use of video:

There must be two-way communication between inspector(s) and eye bank

During the video, the inspector(s) will need to communicate frequently with the person being interviewed/observed as well as with the person holding the camera/device. A strong and stable cellular/Wi-Fi connection is critical. A poor connection can quickly become frustrating for all involved. If there is a loss of internet connection, the inspector that is viewing should call the predetermined number to request the procedure to be stopped until internet connection is re-established. Make sure all devices being used have full battery charge or are plugged into a stable electrical source.

Videos must not be recorded

Inspection teams may only utilize live (real-time) video. Eye banks are not permitted to provide inspection teams with pre-recorded videos. Inspection teams and the eye bank being inspected will have to work closely together to schedule these live video interviews/demonstrations. The process being videoed must be performed independently by the eye bank staff member – no support or instruction is permitted during the video.

What makes for a great video experience?

Videos should be done with as little background noise as possible. Inspectors will pay very close attention in certain situations (e.g. watching a cornea excision) to detect any breach in aseptic/sterile technique or procedure deviation. The person controlling the video device at the eye bank, must be

familiar with the device and the application being used. They should also move the camera slowly so the inspection team can properly view. Inspectors will, at times, need to ask for a “closer look” and the person operating the camera needs to listen carefully and follow instructions promptly.

Videos may need to be followed-up with an in-person discussion/observation

Using video can be very helpful but not all situations and circumstances are suited to video observation. If an inspection team does not feel the video is effective or they see or hear something that needs clarification, the eye bank must be able, and willing, to show the inspection team when they go on-site.

Video observations and interviews should take as long as those done in person

Inspectors and eye banks should understand that the use of video is not intended to speed up the process. In some situations, using video may actually increase the time needed to observe/interview. Inspectors are not to ask those being interviewed/observed to skip steps. Inspectors should, as much as possible, refrain from stopping/interrupting the interview or observation.

Comprehensive 360-degree environmental readiness check to be performed

The technician performing the procedure or interviewee shall perform a 360-degree view of the space they occupy. This will ensure that there is no supportive staff or material being used.

Turn off notifications and alerts

Today’s mobile devices have notifications and alerts. These can be very handy but also can be disruptive. Notifications and alerts (on all devices) should be temporarily disabled when using video during inspections.

Lighting and sound are important considerations

Make sure there is proper lighting and good audio. If the quality of the video/audio is poor, the video should be stopped. Attempts can be made to improve video/audio quality but if those fail, the inspection team will have to wait for the on-site inspection.

G1.000 Identification of Accreditation Status

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- b. A non-accredited eye bank shall not hold itself out either expressly, or indirectly, as an EBAA accredited eye bank. All materials that identify its accreditation status must be submitted to the EBAA for approval prior to distribution
- c. Eye banks provisionally accredited shall identify themselves as such
- d. A change in accreditation status from either accredited or non-accredited shall be communicated to eye banks and Paton members by the EBAA office within 72 hours from notifying the bank of that status change. ~~as soon as practical, but no more than 72 hours from of the status change.~~ Banks will be given 48 hours from notification of status change to notify EBAA of an intent to appeal loss of Accreditation prior to notification of members. If notice of appeal is forthcoming within the 48-hour window, it will trigger additional consideration by EBAA and Co-Chairs related to member notification, not to exceed a further 72 hours. Upon the expiration of the 48 hour appeal period or the 72 hour reconsideration period, notification will be distributed to member eye banks and Paton members as appropriate depending on consideration of notification of appeal; such notification does not diminish the inspected bank's right to appeal as per Accreditation Policy F1.000.
- e. Notification shall take place using the following template:

As of DATE, EYE BANK NAME is no longer accredited by the Eye Bank Association of America.

Or

As of DATE, EYE BANK NAME is accredited by the Eye Bank Association of America.

Additional information may be provided upon the advice and approval of the Accreditation Board Co-Chairs.

From: [Jennifer DeMatteo](#)
To: [Jennifer DeMatteo](#)
Subject: FW: C3.200
Date: Thursday, November 5, 2020 12:17:33 PM

From: Erik Hellier <ehellier@eversightvision.org>
Date: Tuesday, October 27, 2020 at 12:04
To: Kyle Mavin <kmavin@advancingsight.org>
Subject: C3.200

Kyle,

On a recent inspection I noticed something in the Medical Standards that I believe needs to be reviewed. The eye bank I inspected only performed an alarm test on their refrigerators once a year. I found this to be concerning and originally cited them for not performing the test at a sufficient interval. Upon further review of the Medical Standards, I realized that they were technically in compliance even though the timeframe between testing seemed quite long. C3.200, paragraph 2 states "Testing of the alarm system must be performed and documented on a regular basis.", but does not define what a regular basis is. In the previous paragraph it states that "The refrigerator's continuous temperature recorder must be calibrated against an NIST standard thermometer (or for eye banks outside the U.S.A., a standard thermometer as defined by their countries' regulatory agencies) at least once a year.". Based on this, I can easily see how an eye bank would determine annually to be a reasonable timeframe. Under the current standards, an eye bank could do the alarm test every 10 years and still ,technically, be in compliance. I feel that we should re-evaluate this section and propose a minimum interval for alarm testing be included in the Medical Standards. I recommend that we propose to change the standard to read "Testing of the alarm system must be performed and documented on *at least a quarterly* basis".

Thank you for your consideration.

Sincerely,

Erik

Erik Hellier, MBA, CEBT

Global Development Director

[Schedule a meeting with me](#)

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