



ACCREDITATION BOARD MEETING AGENDA

CONFIDENTIAL – AB MEMBERS ONLY

Tuesday, June 15, 2021

20:00 – 22:00 ET

Via Videoconference

	Attachment	Presenter	Action?
1. Call to Order		Rhee	
2. Approval of Minutes	A	Mavin	Yes
3. Old Business		Mavin	
3a Training Update		Brooks	
3b. Forms Subcommittee Activity Report		Binnion	Yes
3c. Propose change to C3.200 Medical Standard	B	Hellier	Yes
4. New Business			
4a. Proposed CAPA Guidance Document	C	Tennant	Yes
4b. New Online Accreditation application	D	DeMatteo	No
4c. Upcoming Inspections – Hybrid or Not?		Rhee/Mavin	Yes

4d. New Forms Committee Chair

Mavin

Yes

Call for volunteers

5. Late Additions

6. Adjournment of Business Meeting

7. Spring 2021 Inspection Cycle (Closed Session)

8. Adjournment



ACCREDITATION BOARD MEETING MINUTES
November 10, 2020
via Videoconference

I. Call to Order

Dr. Michelle Rhee called the meeting to order and welcomed Accreditation Board members and guests in the attendance.

The following members were present:

Michelle Rhee, MD	Co-Chair
Kyle Mavin, CEBT, CTBS	Co-Chair
Lisa Brooks, CEBT, CTBS	Co-Vice Chair, Training Chair
Bennie Jeng, MD	Co-Vice Chair
Victoria Adler, RN, BSN, CEBT	
Andreea Bauknecht, CEBT	
Gregg Berdy, MD	
Beth Binnion, CEBT	Chair, Forms Subcommittee
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
David DeRose, MD	
Marcella Dimond, CEBT	
Donna Drury, MBA, CEBT, CTBS	
Sean Edelstein, MD	
Timothy Fischer, MHA, CEBT, CTBS	
Brian Ha, MSc, CEBT	
Erik Hellier, CEBT	
Christopher T. Hood, MD	
James Matthew Huffman, MD	
Susan Hurlbert, CEBT	
Adam Kaufman, MD	

David Kennedy, MD
Christopher Ketcherside, MD
Anup Kubal, MD
Ginny Kullman, MD
William Barry Lee, MD
Jennifer Li, MD
Amy Lin, MD
Jennifer Ling, MD
John Lohmeier, CEBT
Linda Martin, CTBS
Thomas Mauger, MD
Donna McDonald, CEBT
Eric Meinecke, CEBT
Shahzad Mian, MD
Afshan Nanji, MD, MPH
Michael Nordlund, MD, PhD
Andrew Officer, CEBT
Seth Pantanelli, MD
Brian Philippy, CEBT
Jim Quirk, CEBT
Sam Ramos, CEBT, CBTS
Christopher Sales, MD, MPH
Ankit Shah, MD
Adam Stockman, CEBT
Chris Stoeger, MBA, CEBT, CTBS
Bradley Tennant, CEBT
Wesley Thompson, CEBT
Michael Titus, CEBT
David Tremblay, MD
David Warner, MD
Evan J. Warner, MD
Heather M. Werner, MA, CEBT
Troy Win'E, CEBT
Samuel C. Yiu, MD

II. Approval of Minutes

Kyle Mavin requested approval of the minutes from the last meeting.

Action: A motion was made (Fischer) and seconded (Jeng) to approve the minutes from the June

Motion Passed.

III. Old Business

A. Training Updates (Brooks)

Lisa provided information regarding changes to the AB new member presentation. She shared a new member guidance document will be created and the current presentation will be revised. It is anticipated these will be complete by year's end and available prior to the next inspection cycle.

B. Forms Subcommittee Activity Report (Binion)

Beth noted there was small correction to the SIQ form. A finding heading had been inadvertently added to the form. The heading caused some confusion was removed to eliminate confusion to inspectors.

C. Guidance on the Use of Video During Accreditation Inspections (Ketcherside)

Dr. Ketcherside reviewed the guidance document as a final draft for using video during an inspection. Dr. Ketcherside opened the floor for discussion. Kyle noted that several inspectors did use video this cycle. Dr. Warner asked about the ability to detect a breach of aseptic technique. Dr. Jeng stated he had no issues with the procedure during his inspection. He also noted that he was able to provide commands for the videographer to follow and was able to obtain a good visual of the room. Dr. Rhee mirrored Dr. Jeng's experience and noted there is a lot of versatility with current technology. Dr. Rhee thanked Dr. Ketcherside, Dr. Mian, and Chris Stoeger for their forethought to address the use of video during an inspection. Kyle opened the floor for a motion to approve the document. A motion to approve was made by Jason Brosious. A second motion was made by Beth Binnion. Vote passed 100%.

D. Notification of Accreditation Status Change (Stoeger)

Chris provided history to G1.000(d) changes and noted that it was approved during last AB meeting. The changes allow an eye bank 48 hours to appeal their status change. If an appeal is submitted for consideration the EBAA and its Co-Chairs have 72 hours to reconsider the status change and determine if notifications are warranted. Chris recognized the wordiness of the language but noted it was done to capture all the timelines. Brad Tennant agreed it is wordy and recommended a change to business days. Chris stated by leaving it at hours vs days it provides all parties the due course to review. Kevin Corcoran noted that we are talking about an eye bank's accreditation status change it is important to be explicit in the wording to provide a clear process to follow. Brad commented that eye banks are given ten (10) business days to submit corrective actions to an inspection and in his opinion, it would be better if eye banks are given a number of business days to respond. Kyle opened the floor for a motion to approve the wording. A motion to approve was made by David Kennedy. A second motion was made by Erik Hellier. Vote passed 91%. Wording will be presented to the MAB.

IV. New Business

A. Hybrid Spring Inspections Feedback (Mavin)

Kyle discussed the hybrid inspection process that was implemented due to the pandemic. Kyle and Dr. Rhee identified eye bankers willing to travel and physicians that were willing to participate virtually. Kyle thanked all the inspectors that accepted the challenge and for a job well done. Kyle

and Dr. Rhee met with the inspectors post-inspection to discuss the pros and cons of a hybrid inspection.

Dr. Rhee shared the feedback from the physicians stating their portion of the inspection went really well. The physicians participated virtually due to their inability to travel. The physicians had the ability to review charts remotely. In addition, the Medical Director interviews were performed remotely with a video platform. This option gave flexibility to the physicians to schedule their interviews. Dr. Rhee noted these options could be considered for future inspections with the possibility of the physician to be on site one day versus two days. Kyle agreed with Dr. Rhee's feedback presentation. Kyle did note the importance of a working camera and good internet access during the interview to ensure integrity during. Kyle and Dr. Rhee are considering the possibility of using a hybrid platform in the future, beyond the pandemic. Overall, the hybrid inspections were well received.

Jennifer DeMatteo referenced the guidance document that states a 360-degree room review is required prior to performing a virtual interview. Jennifer shared a negative feedback related to poor visualization during the DMEK competency. Kyle suggested that eye banks reach out to the EBAA for recommendations for devices that can correct this issue

B. Defining the Regularity of Alarm Testing – C3.200 (Hellier)

Erik submitted a request to define “regular basis” under C3.200 (recommended quarterly). Kyle opened the floor for discussion. A discussion followed among the AB members as to whether a change is necessary and if yes how to define “regular basis”. Brad suggested a small sub-committee to review. Kyle called for a sub-committee to review and make recommendations for change. Sub-committee members: Jason Brosious, Erik Hellier, John Lohmeier, Winston Chamberlain, and Barry Lee. Erik Hellier was tasked with taking the lead. Eric Meinecke to request withdrawal of this item from Thursday's MAB agenda.

V. Late Additions – No Late Additions

VI. Adjournment of Business Meeting

Michelle Rhee closed the business meeting and reminded AB members to stay on the line for the closed session. Genevieve cleared open session and provided clearance to proceed with closed session.

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

A. 9 Banks were inspected this round

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

Inspectors presented observations of all 9 banks.

The following was the result of the voting:

9 Banks received 3-year accreditation

0 Bank received 1-year accreditation

0 Bank was denied accreditation

Minutes submitted by AB Co-Vice Chair, Lisa Brooks, CEBT, CTBS

ATTACHMENT B

From: Erik Hellier

Sent: Monday, February 22, 2021 1:41 PM

To: Kyle Mavin <kmavin@advancingsight.org>; Michelle Rhee, MD <mrhee@ebsr.org>; Jennifer DeMatteo <Jennifer@restoresight.org>

Cc: Winston Chamberlain <chamberw@ohsu.edu>; William LEE <wblee@mac.com>; John Lohmeier <jlohmeier@corneas.org>; jbroscious (jbroscious@coleb.org) <jbroscious@coleb.org>

Subject: Refrigerator sub-committee recommendation

Hi Kyle and Dr. Rhee,

The refrigerator sub-committee met and discussed identifying a timeframe to testing the alarm system as mentioned in the previous AB meeting. Here are the recommendations we wish to submit:

Change standard C3.200, paragraph 2 from "Testing of the alarm system must be performed and documented on a regular basis." to "Testing of the alarm system must be performed and documented on a regular basis in accordance with manufacturer recommendations, but to be done no less frequently than annually."

Additionally, add a question to the SIQ stating "Does the alarm system function properly". This question can be verified by having the eye bank perform a high or low alarm test during the inspection. The inspector should make sure the alarm is triggered and any call out is initiated. If the eye bank has a call tree then it is unnecessary to have the alarm system go through the entire call tree. Having it trigger one call out will show that the alarm system is functioning.

Thank you for your time and consideration of the matter. Please let us know if you need anything else from the group.

Have a great day.

Erik Hellier, MBA, CEBT

Background:

There is no clear documentation regarding the request for submission of corrective actions following AB meetings. AB Co-chairs change frequently, usually every two years, and have not been provided any guidance on writing letters to inspected banks requiring further corrective submission(s) post AB meetings. The document below is intended to be a guidance document and can be a living and breathing one. The hope through the promulgation of these guidelines, is to achieve consistency between inspections and requirements, and to aid AB Co-chairs in writing letters to inspected banks requiring submission of further corrective actions. In time perhaps, the document could and should be an aid to all EBAA member banks as to the guidelines and requirements.

The below guidance has been reviewed by the special AB subcommittee consisting of former AB Co-chairs-Dr. Chris Ketcherside, Dr. Woodford Van Meter, Jim Quirk, Beth Binnion, Chris Stoeger, Eric Meinecke and Chaired by Bradley Tennant. The guidance has also been reviewed by Kevin Corcoran, Jennifer DeMatteo and current AB Co-chairs-Dr. Michelle Rhee & Kyle Mavin. The guidance is recommended for review and approval by the full AB.

Routine Practice for AB Co-chairs

Guidelines for the Submission of Corrective Actions Post-AB Meetings:

1. Deficient/non-compliant policies & procedures,
 - i) Bank revises/updates P&P
 - ii) ED & MD review and approve revision(s)
 - iii) Eye Bank staff review P&P revision(s) and document his/her understanding
 - iv) Eye Bank staff are trained on P&P revisions, if applicable
 - v) Eye Bank submits all of the above information to the AB Co-chairs
2. Eye Bank Director Interview Response(s) are incorrect,
 - i) ED authors letter, on eye bank letterhead, to AB Co-chairs that addresses deficiency and his/her understanding as to the desired/correct response and signs/dates
 - ii) Letter is submitted to the AB Co-chairs
3. Medical Director Interview Response(s) are incorrect,
 - i) MD and/or ED authors letter, on eye bank letterhead, to AB Co-chairs that addresses deficiency and his/her understanding as to the desired/correct response and signs/dates letter. Letter is signed by the MD & ED.
 - ii) Letter is submitted to the AB Co-chairs
4. QA Director Interview Response(s) are incorrect,
 - i) QA Director authors letter, on eye bank letterhead, to AB Co-chairs that addresses deficiency and his/her understanding as to the desired/correct response and signs/dates the letter. Letter is signed by the QA Dir. & ED.
 - ii) Letter is submitted to the AB Co-chairs

5. Technical Personnel & Procedures Deficiencies, interview response(s) are incorrect,
 - i) Technical Director/personnel authors letter, on eye bank letterhead, that addresses deficiency and his/her understanding as to the desired/correct response and signs/dates the letter. Letter is signed by the TD/personnel & ED.
 - ii) Letter is submitted to the AB Co-chairs
6. TP & PD cont.-Technician(s) fail aseptic technique portion of practical exam,
 - i) Technician(s) are observed by an OR nurse or MD performing the aseptic technique portion of the practical exam utilizing AB form(s).
 - ii) OR nurse or MD documents (signs/dates) technician(s) passing of the aseptic technique portion of the practical exam
 - iii) Above documentation is submitted to the AB Co-chairs
7. TP & PD cont.-Technician(s) fail surgical technique portion of practical exam,
 - i) Technicians are observed by the MD performing the surgical technique portion of the practical exam utilizing AB form(s).
 - ii) MD documents (signs/dates) technician(s) passing of the surgical technique portion of the practical exam
 - iii) Above documentation is submitted to AB Co-chairs
 - iv) AB Co-chairs assign an AB member(s) to observe technician(s) performing the surgical technique portion of the practical exam
 - v) AB member submits documentation of the technician(s) passing of the surgical technique portion of the practical exam to the AB Co-chairs
8. TP & PD cont.-Technician(s) fails to package tissue according to P&P & Medical Standards,
 - i) Technician(s) & ED author letter, on eye bank letterhead, that addresses deficiency and his/her understanding as to the desired/correct response and sign/dates the letter. Letter is signed by TD/personnel & ED.
 - ii) Letter is submitted to the AB Co-chairs
 - iii) AB Co-chairs assign an AB member, if needed, to observe technician(s) performing the tissue packaging procedure.
 - iv) AB member submits documentation of the technician(s) passing of the tissue packaging procedure to the AB Co-chairs
9. **Laboratory & Equipment-CA submission requirements pending sub-committee work on refrigerator alarm testing, should also consider development of criteria regarding performance of procedures in an acceptable environment**
10. Eye Bank Records-Deficient Medical Director oversight in operations and training of technical staff,
 - i) ED & MD author letter, on eye bank letterhead, that addresses deficiency and his/her understanding as to the desired/correct oversight response(s) and signs/dates the letter. Letter is signed by the ED & MD.
 - ii) Letter is submitted to AB Co-chairs.

- iii) Affected P&P's, if applicable, are revised/updated and are reviewed and approved by the ED, MD. Staff document review and understanding of P&P revisions and are trained, if applicable, on P&P revisions. Staff training is also documented.
 - iv) Items/documentation required in iii are sent to the AB Co-chairs.
11. Eye Bank Records cont.-Deficient lab, equipment cleaning & equipment testing records,
- i) Eye bank prepares and submits three- or six-months compliant documentation of required cleaning(s) & testing(s) to the AB Co-chairs.
12. Eye Bank Records cont.-Deficient QA monitoring records,
- i) Eye bank prepares and submits three- or six-months compliant documentation of required QA monitoring records to the AB Co-chairs
13. Eye Bank Records cont.-Deficient donor and or recipient records,
- i) Eye Bank submits the next ten, consecutive donor/recipient charts/records documenting compliance of the deficient items/information to the AB Co-chairs.
14. Eye Bank Records cont.-Deficient post-operative outcomes information solicitation,
- i) Eye bank prepares and submits documentation of post-operative outcomes information solicitation, as dictated by its P&P and next solicitation schedule, to the AB Co-chairs.

Additional Notes:

- The AB can take any necessary action(s) it deems necessary in determining an eye bank's accreditation status based upon required follow-up, or lack thereof, from an inspected bank.
- Corrective actions submitted to the inspectors/inspection team, prior to AB meetings, and found to be in compliance with EBAA Medical Standards, does not need to be requested post AB meetings.

ATTACHMENT D

TO: Accreditation Board Members
FROM: Jennifer DeMatteo
DATE: June 8, 2021
RE: **Online Accreditation Application Video**

Please watch this short video demonstrating the new online accreditation application prior to the Accreditation Board Meeting.

<https://www.dropbox.com/sh/feimr8iainazk7s/AAA-oyxUZJBpiW3Xgln0j8eja?dl=0>