Accreditation Board Orientation & Training

Eric Meinecke, CEBT
Co-Vice Chair, Training Chair
Accreditation Board
Objectives

- Overview of EBAA Accreditation Board
- Role of Inspectors
- The inspection process
- Forms
- Presentation of inspection findings to AB
- Q & A
To conduct site inspections of eye banks to ascertain an appropriate and current level of compliance with EBAA Medical Standards.

To advise eye banks in corrective actions to meet these standards.

To report in an advisory capacity to the Medical Advisory Board on accreditation issues which impact current standards.

To submit accreditation policies which advance eye banking to the Board of Directors.
AB members include eye bankers and physicians
AB meets twice a year (annual meeting and fall leadership meeting)
Business portion of meeting is open
Inspection discussions & voting portion of meeting is closed – only AB members attend
Confidentiality
Spring, fall and off-cycle inspections
Overview

- Co-Chairs and Co-Vice Chairs
- Forms Subcommittee
- Other subcommittees
- EBAA Director of Regulations & Standards
Role of Inspectors

- To assess level of eye bank’s compliance with EBAA Medical Standards.
- Team Approach – Surgeon & Eye Banker
- Eye banker typically is lead inspector (responsible for scheduling inspection, completion/submission of forms, and presentation of findings)
- Inspection teams assigned by co-chairs
- The eye bank may request reassignment of one of the inspectors within one calendar week from the date of notification.
Pre-Inspection

- Determine inspection date with eye bank’s Executive Director
- Confirmation letter (sample on EBAA website, next slide)
- Ensure delivery of PIQ and SOPs
- Coordinate dates, travel, lodging with co-inspector
- Develop an inspection schedule (2 consecutive days)
- Print all necessary forms (be sure you use most current forms from EBAA website – forms do change)
January 15, 2009

Mr. Cool, Executive Director
[EYE BANK NAME]
[EYE BANK ADDRESS]

VIA Email: [OF EXEC DIR]

Dear Mr. Cool:

This letter is to confirm our recent communications regarding your upcoming Eye Bank Association of America’s (EBAA) Site Inspection. I have been assigned as team leader for your inspection. My co-inspector is [CO-INSPECTOR NAME].

We will conduct your eye bank inspection on [DATE]. The medical director interview will be performed on [DATE], and the tour will be conducted on [DATE], whichever is most convenient for you. [MED DIR NAME] will take the majority of the time on the first day performing chart reviews. It is strongly recommended that fresh whole globes (not frozen) be used for the practical demonstration(s) to provide for the best possible outcome of the procedures.

Please forward one copy of your Policy and Procedure Manual and Pre-Inspection Documentation to each of us at the addresses below. We should receive your materials no later than [DATE]. See EBAA Accreditation Policy and Procedure C1.280, Submission of Pre-Inspection Documentation. Note: If your eye bank wishes to submit only an electronic version of your documents and/or your eye bank’s policy and procedure format does not follow the EBAA medical standards indexing system, please contact me immediately to discuss.

[LEAD-INSPECTOR NAME] [CO-INSPECTOR NAME] MD
[ADDRESS] [ADDRESS]

The EBAA Site Inspection forms are not mailed to you. Instead, they can be viewed and downloaded by all EBAA member eye banks through the EBAA website (via member log-in): http://www.restoresight.org.

Please contact me if you have any questions about this inspection. I look forward to visiting your bank.

Sincerely,

Lead Inspector
Phone [direct] [cell phone number] [email]

Cc: [NAME], Co-Inspector
    W. Barry Lux, MD, Co-Chair Accreditation Board
    Jim Quirk, CEBT, Co-Chair Accreditation Board
    Jennifer DeMatteo, EBAA Director of Regulations and Standards
Pre-Inspection Questionnaire (PIQ)

- Review PIQ
- Complete PIQ answer sheet (next slide)
- Compare observations with co-inspector via telephone or e-mail
PRE-INSPECTION QUESTIONNAIRE MANAGEMENT

**INTERROGATOR:***

**DATE:***

**RESPONDENT:***

**SITE NAME:***

**INSPECTION DATE:***

**INSPECTOR:***

**INSPECTION NUMBER:***

**SITE LOCATION:***

**SITE CONTACT:***

**SITE PHONE:***

**SITE EMAIL:***

**SITE WEB:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

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**ANSWER:***

**DATE:***

**SIGNATURE:***

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**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

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**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

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**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***

**PRE-INSPECTION QUESTIONNAIRE MANAGEMENT**

**QUESTION:***

**ANSWER:***

**DATE:***

**SIGNATURE:***
Pre-Inspection Questionnaire Answer Sheet

Instructions: After reviewing the answers submitted by the facility, indicate whether the information complies with ESHA Medical Standards in the space provided.

**Question 1**
- A. Relevant info for all XEROLOGY providers before first inspection?
- B. Acceptable info for providers of all OTHER SERVICES, i.e. validation, administrative procedures, etc.

**Question 2**
- C. 300, C. 910, C. 750
- A. Acceptable information for non-employees providing recovery, preservation and/or processing services.

**Question 3**
- C. 300
- A. Acceptable information provided for authorized staff.

**Question 4**
- C. 300
- A. Name of Medical Director

**Question 5**
- C. 300
- A. Correct facility or corning reference.

**Question 6**
- C. 300
- A. Name and qualifications of back-up Medical Director.

**Question 7**
- C. 300
- A. Documentation of Medical Director (DEPI)

**Question 8**
- C. 300
- A. Valid ESAO provided documentation of Medical Director's declarations, within the past three years, at a Medical Director's Symposium and a Medical Advisory Board Meeting.

**Question 9**
- C. 300
- A. Valid DEA certificate covering each year since last inspection.

**Question 10**
- B. 100
- A. Valid copy of FDA registration for each year since last inspection.

**Question 11**
- B. 100
- A. Valid copy of state and all applicable regulatory requirements for each year since last inspection.

**Question 12**
- B. 100
- A. Valid business license for each year since last inspection.

**Question 13**
- B. 100
- A. Facility does submit or at least (90 days).

**Question 14**
- A. Does the recording system provide for a unique ID for each surgical tissue or fraction processed?

**Question 15**
- A. Was the plan of closure worked out and identified problem solved correctly?

**Question 16**
- A. Was the plan of closure worked out and identified problem solved correctly?

**Question 17**
- A. Was the plan of closure worked out and identified problem solved correctly?

**Question 18**
- A. Was the plan of closure worked out and identified problem solved correctly?

**Question 19**
- A. Was the plan of closure worked out and identified problem solved correctly?

**Question 20**
- A. Was the plan of closure worked out and identified problem solved correctly?
If a citation is noted prior to the inspection and is corrected prior to the inspection, or on site during the inspection, it is still a deficiency that should be documented.
Review Policy & Procedure (P&P) manual as soon as possible after receiving. Be sure to remember to bring it to bank at time of inspection.

Suggestion: For easy reference, photocopy the Table of Contents and technical procedures which will be observed or discussed.
Review Policy/Procedure Manual

- Complete policies and procedures portion of the inspection questionnaire sheet
- Mark on questionnaire any missing procedures
- Compare observations with co-inspector prior to the site visit
### SITE INSPECTION QUESTIONNAIRE

**1. Organization of the Bank**

<table>
<thead>
<tr>
<th>Question</th>
<th>No.</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1.1</td>
<td></td>
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<td>1.1.1.2</td>
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<tr>
<td>1.1.1.3</td>
<td></td>
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</tr>
</tbody>
</table>

**2. Policies and Procedures Manual**

- [ ] 2.1.1.1 Policy statements and procedures are consistent with applicable regulations.
- [ ] 2.1.1.2 Policy statements and procedures are consistent with applicable regulations.
- [ ] 2.1.1.3 Policy statements and procedures are consistent with applicable regulations.

**3. Human Resources**

- [ ] 3.1.1.1 Employee performance appraisals are conducted annually.
- [ ] 3.1.1.2 Employee performance appraisals are conducted annually.
- [ ] 3.1.1.3 Employee performance appraisals are conducted annually.

**4. Operations**

- [ ] 4.1.1.1 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.
- [ ] 4.1.1.2 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.
- [ ] 4.1.1.3 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.

**5. IT and Information Security**

- [ ] 5.1.1.1 Cybersecurity policies and procedures are in place and implemented.
- [ ] 5.1.1.2 Cybersecurity policies and procedures are in place and implemented.
- [ ] 5.1.1.3 Cybersecurity policies and procedures are in place and implemented.

**6. Compliance**

- [ ] 6.1.1.1 Compliance training is provided to all employees on a regular basis.
- [ ] 6.1.1.2 Compliance training is provided to all employees on a regular basis.
- [ ] 6.1.1.3 Compliance training is provided to all employees on a regular basis.

**7. Risk Management**

- [ ] 7.1.1.1 Risk assessments are conducted on a regular basis.
- [ ] 7.1.1.2 Risk assessments are conducted on a regular basis.
- [ ] 7.1.1.3 Risk assessments are conducted on a regular basis.

---

**A. Policies and Procedures Manual continued:**

<table>
<thead>
<tr>
<th>Question</th>
<th>No.</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2.1.1</td>
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<td>1.2.1.2</td>
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<tr>
<td>1.2.1.3</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**B. Human Resources**

- [ ] 2.2.1.1 Employee performance appraisals are conducted annually.
- [ ] 2.2.1.2 Employee performance appraisals are conducted annually.
- [ ] 2.2.1.3 Employee performance appraisals are conducted annually.

**C. Operations**

- [ ] 3.2.1.1 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.
- [ ] 3.2.1.2 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.
- [ ] 3.2.1.3 Internal controls are in place to prevent fraud and ensure compliance with applicable regulations.

**D. IT and Information Security**

- [ ] 4.2.1.1 Cybersecurity policies and procedures are in place and implemented.
- [ ] 4.2.1.2 Cybersecurity policies and procedures are in place and implemented.
- [ ] 4.2.1.3 Cybersecurity policies and procedures are in place and implemented.

**E. Compliance**

- [ ] 5.2.1.1 Compliance training is provided to all employees on a regular basis.
- [ ] 5.2.1.2 Compliance training is provided to all employees on a regular basis.
- [ ] 5.2.1.3 Compliance training is provided to all employees on a regular basis.

**F. Risk Management**

- [ ] 6.2.1.1 Risk assessments are conducted on a regular basis.
- [ ] 6.2.1.2 Risk assessments are conducted on a regular basis.
- [ ] 6.2.1.3 Risk assessments are conducted on a regular basis.
You may notify the eye bank of the missing or erroneous components.

However, scoring of the inspection questionnaire should be based on the condition of the P&P manual when first presented.
Day of the Inspection

- Introductions
- Explain the Process
  - Interviews
  - Technical Proficiency
  - Laboratory Inspection
  - Records Review
  - Summation Conference
Organization of the inspection
- Meet with the director and key staff
  - Explain the inspection process
    - Voluntary peer review
    - Findings reported to AB who makes final determination
    - Opportunity for corrective actions
    - Opportunity for appeal
  - Schedule the day (detailed further)
    - Schedule interviews with key staff
    - Facility/Lab Inspection
    - Donor Chart Review
    - Review of Records
    - Practical Procedures (CEBT/Non-CEBT)
Identify any eye bank liaison for assistance

- Someone to retrieve needed documents and records
- Someone to show where in donor records needed items are located
Identify Your Space and Time Requirements

- Conference room or equivalent
- Lunch break
- Expected time of summation conference
Laboratory maintenance records
Donor files
Continuing education/training records
Sample forms/labels
Order of Events at Inspection

- Stick to your schedule as much as possible but flexibility is key! Keep eye bank informed of progress.
- Be respectful of eye bank operations and staff schedules.
Confirm availability ahead of time
Contingency plan for emergency
Determine the Medical Director’s involvement
Typically this interview is done by the MD inspector
Aseptic technique and surgical skills of CEBT (and non-CEBT if applicable)

Per the bank’s staffing list, determine the procedures to be observed and if a CEBT and non-CEBT need to be observed

Try to put technician at ease – inspections are stressful

Observe complete procedure

Have the eye bank’s written procedure in hand when you observe the procedure
Verify that all components of laboratory meet standards

- Common lab deficiencies
  - Lack of MSDS
  - No cleaning of high horizontal surfaces
  - Expired or co-mingling of sterile and non-sterile instruments

Use your observation skills!
Look for:

- Limited access
- Effective alarm system
- Emergency power backup if employed
- Cleanliness
<table>
<thead>
<tr>
<th>Record Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature recording graphs</td>
</tr>
<tr>
<td>Cleaning records</td>
</tr>
<tr>
<td>Autoclave records, if applicable</td>
</tr>
<tr>
<td>QA records</td>
</tr>
<tr>
<td>Adverse Reaction files</td>
</tr>
<tr>
<td>Technician training records</td>
</tr>
<tr>
<td>Tissue distribution records</td>
</tr>
<tr>
<td>Flow hood certification</td>
</tr>
<tr>
<td>Equipment maintenance records</td>
</tr>
<tr>
<td>Annual NIST temperature calibration</td>
</tr>
</tbody>
</table>

* or less as applicable
Randomly select 10% since last inspection or at least one record/month. At least 85% of these records shall have had at least one or more tissues transplanted.

Review a couple of non-transplant records and an import record (if applicable).

After reviewing each donor file check number off list

Carefully compare date/time of receipt of infectious disease testing results to eligibility determination to distribution
Review Donor Files

- Complete Record Review Form
- Confirm with co-inspector consistently missed fields
- Note improvements, if applicable
- If deficiency is found, copy a sample with identifying information redacted.
## Record Review Worksheet (2 pages)

The document appears to be a record review worksheet used for tracking and monitoring records. Each page contains a table with columns and rows, likely intended for data entry and review. The tables are structured to facilitate the organization and review of records in a systematic manner. The specific details and headings within the tables are not clearly visible due to the resolution of the image.
Donor/Recipient Record Review Summary

A. Donor Identification
   - Name, phone number, location/address

B. Donor Information
   1. Unique donor identifying a, e.g., donor's social security or medical record
   2. Name of donor bank, Tissue is requested
   3. Evidence of death and physical inspection of body
   4. Results of medical and/or laboratory examination of tissues, Social history interview, Rejection
   5. Indication of whether or not autopsy was performed
   6. Date and time of death
   7. Date and time of cooling of body
   8. Description of tissues
   9. Results of serologic tests performed
   10. Results of histologic examination
   11. National Tissue Donor Registry

C. Tissue Information
   1. Unique identifying number for each tissue graft
   2. Tissue type and results
   3. Evidence of rejection
   4. Evidence of surgical procedure performed
   5. Rejection of tissue
   6. Results of histologic examination
   7. Date of surgery
   8. Local site of surgery
   9. Type of surgery
   10. 30-12 month follow-up report

Comments:

Record Review Summary - 08/12 - November 2012
If Question/Dispute Develops Among Inspectors

- Discuss the issue privately
- Take time to read the relevant medical standard and focus on the *intent* of the standard
- Call a co-chair if necessary
If Eye Bank Disagrees with Inspector Comments

Inform them they may do one of three things:

- Provide corrective action
- Provide rationale for their disagreement prior to the AB meeting
- Do nothing
Summation

- Review Inspection Questionnaire with co-inspector
- Complete Summation Form
- List all potential threats and non-critical deficiencies – print legibly
- Photocopy for the eye bank – don’t indicate accreditation recommendation
SUMMATION CONFERENCE OUTLINE

1. The Site Inspection Summation Conference should take place at the conclusion of the inspection.
2. Inform the Executive Director and Medical Director of conference and its approximate time; let them know that they have the option of inviting other staff members.
3. Allow time for questions and feedback from eye bank staff.
4. Provide a photostat of the handwritten summation report to the eye bank (minus the last page). Begin with introduction; thank staff for assistance; provide positive statements about what you observed throughout.
5. State the purpose of the Dot Summation Conference, which is to give candid feedback on what you saw during the site inspection based on observed facts. State your role as a site inspector representing the EBAA Accreditation Board, emphasizing that you are providing documentation of observations and not personal comments or opinions. Make clear that the purpose of the conference is to provide informal feedback based on your comparison of observations to EBAA Medical Standards.
6. Emphasize that the site inspectors do not make the decision regarding accreditation. The Accreditation Board will make the decision after hearing the final report when they meet. Site inspection results are scored on a point system; this score is compared to the written report.
7. Feedback should be given for any potential threats and/or non-compliant items. Quote the applicable standard and what you observed that was not in compliance. Allow eye bank staff time to reply and if appropriate, to produce additional documentation to support a change in status. Emphasize any corrective actions, but should emphasize that the Accreditation Board will have the final say on whether they will be considered acceptable. Corrective actions must be reviewed by the lead inspector and the non-MD Accreditation Board co-chair within ten (10) working days of the inspection to be considered during the Accreditation Board meeting.
8. List the potential threats and other items not in compliance on the Summation Report. The co-inspectors should jointly complete the report and confer on the summation content. The lead inspector is responsible for ensuring the summation conference, with the co-inspector present.
9. Conclude the summation conference by summarizing the accreditation categories and where these are found in the EBAA Standards binder.
10. Thank all eye bank staff present. Inform the eye bank that a written report will be presented at the Accreditation Board’s upcoming meeting, the accreditation/non-accreditation status of the eye bank will be determined by the entire Accreditation Board through secret ballot. The identity of each bank will be revealed for all Accreditation Board members except the inspectors and Accreditation Board co-chairs. The eye bank will be notified immediately of the accreditation status, and a full written report with detailed recommendations will follow approximately thirty (30) working days later.
11. Reiterate that any recommendations made during the inspection are options of the Inspector(s) and not of the Accreditation Board.
12. For each eye bank inspected, submit only one summation form to the non-MD Accreditation Board Co-Chair signed by both inspectors.

EBAA Accreditation, Summation Conference Outline – Revised June 2009
Summation Conference

- Only one Summation Form completed
- Review with all staff in attendance
  - Discretion of Executive Director or Medical Director as far who attends the summation.
### EBAA Site Inspection Summary Report Form

#### Inspection Information:
- **Name of Eye Bank:**
  - [Field]
- **Date(s) of Inspection:**
  - [Field]
- **Name(s) of Inspector(s):**
  - [Field]
- **Date and time inspection started:**
  - [Field]
  - **Finished:**
  - [Field]

#### Names and titles of all eye bank staff members interviewed by the site inspectors:
1. [Name]
2. [Name]
3. [Name]
4. [Name]
5. [Name]
6. [Name]
7. [Name]
8. [Name]
9. [Name]
10. [Name]

#### Summary of non-compliant items found during inspection:
- **Non-compliant items found?**  [ ] Yes  [ ] No
- **Number of non-compliant items found:** [Field]
- **How many of these non-compliant items were potential threats?** [Field]
- **How many of these non-compliant items were repeat non-compliances from last inspection?** [Field]

### Itemization of non-compliant items (by potential threat/facett):
- **NC#** [ ] [Field]
- **P.I.** [ ] [Field]
- **Q.I.** [ ] [Field]
- **A.I.** [ ] [Field]
- **M.I.** [ ] [Field]
- **Med. Stf** [ ] [Field]
- **PTT** [ ] [Field]
- **Report** [ ] [Field]
- **CAPA?** [ ] [Field]
- **Compliant?** [ ] [Field]

### Accreditation Board Signatures:
- **Site Inspector:** [ ] [Field]
  - [Name] [ ] [Field] [Date]
- **Site Inspector:** [ ] [Field]
  - [Name] [ ] [Field] [Date]

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After receipt of the eye bank's corrective and preventive action plans, the inspectors recommend the following accreditation category:
- [ ] Three Year
- [ ] Two Year
- [ ] One Year
- [ ] Denied
The Summation Conference

Things to say:

- Thank bank for their hospitality
- Clarify that the AB will determine accreditation status
- Remind them that this is a peer review which they have asked to have performed
- Give them the Guidelines for CA and site inspection evaluation forms
Things **not** to say:

- Don’t offer a prediction what the AB will likely do
- Don’t accept verbal CA’s
- Don’t get into an argument
- Don’t refuse to remove a deficiency if they demonstrate compliance after you’ve written up the summation.
If disputes over results occur:

- If appropriate documentation is presented (not a corrective action), remove deficiency from list.

- If eye bank continues to dispute your finding remind them they may state their case in their corrective actions.
Discuss possible procedures for correcting deficiencies

- Take the opportunity to share experiences and suggest changes. However, be careful to be clear that what you may see as an appropriate corrective action may not be accepted by the AB.

- Clearly differentiate between recommended changes and deficiencies

- Obtain copies of documents, labels, or forms that demonstrate deficiencies
Guidelines for Corrective Actions

GUIDELINES FOR CORRECTIVE ACTIONS

The following guidelines should be followed by eye banks for submission of corrective actions following an EBAA inspection. Corrective actions must be submitted within ten (10) working days of the site visit to the non-MD Accreditation Board Co-chair and the Lead Inspector. Corrective actions submitted after ten (10) days may be considered at the discretion of the Board, upon written request to the Board by the eye bank.

Pre-Inspection Questionnaire: Submit adequate documentation for the following: outside agencies that perform services for the eye bank; qualifications of the medical director and supervising O.D.; and, proper phoria distance calculations.

Policy and Procedure Manual: The eye bank director and medical director must sign and date changes to the policy and procedures manual. If applicable, records that document compliance with new procedures must be submitted. Submit evidence that changes have been communicated to affected staff.

Director and Medical Director: Provide documentation signed by the director and/or medical director indicating notice of non-conformity deficiencies at the time of the site visit.

Laboratory: Submit purchase or work orders indicating work or equipment purchase necessary to bring the laboratory into compliance. Photos are helpful.

Failures in technician practical performance: For autopsy procedure, retain an outside consultant to review procedures; such as an operating room nurse. For autopsy or surgical procedure, a member of the Accreditation Board may be assigned to re-evaluate technician practical performance. It is strongly recommended that the medical director review technician performance prior to outside review. At the discretion of the co-chair, more than ten (10) working days may be allowed to make arrangements to correct this potential threat.

Record keeping: Copies of donor records that were determined to be deficient, but for which missing information has been found, should be submitted. Donate records that document complaints must accompany any changes in forms or procedures that were revised and implemented as corrective action following the site visit.

Quality assurance: Copies of documentation of review must accompany any changes in forms or policies and procedures, temperature charts or other evidence of compliance.

Prior to presentation to the Accreditation Board, corrective actions will be reviewed for acceptability by the non-MD co-chair and the Lead Inspector.

Non-Compliance Corrective Action Plan – Pilot forms

The Accreditation Board is piloting a new form for banks and inspectors to use for non-compliant items found during the site inspection. It is up to the inspectors to determine if they would like to use the form for the inspection. We ask the eye bank also use it if the inspectors use it and provide feedback to the Accreditation Co-Chairs on it.

EBAA Accreditation, Guidelines for Corrective Actions, Revised: June 2009
Summation Conference

- Post-inspection evaluation form mailed by eye bank to Accreditation Board Co-Chair
- Leave copies of P&P manuals sent to you
**Site Inspection Evaluation**

**SITE INSPECTION EVALUATION**

Please have the Director or Medical Director complete this form and return as indicated below.

1. Did the EBA provide adequate notice and instructions for your site inspection?  Yes  No

2. Did the site inspectors provide adequate pre-inspection information regarding his/her arrival and time requirements to the eye bank?  Yes  No

3. Did the site inspectors explain the objectives of the inspection?  Yes  No

4. Was the site inspection professionally conducted?  Yes  No

5. Does the eye bank feel the inspection was beneficial?  Yes  No

6. How would the eye bank rate the inspector(s) knowledge of Medical Standards and eye banking specifics?  (Please indicate by circling below)
   - 1 = Poor
   - 2 = Fair
   - 3 = Adequate
   - 4 = Good
   - 5 = Excellent

7. Did the inspector inform the eye bank that the decisions related to the inspection must be made by the Accreditation Committee assisted by competent grading of the inspection questionnaire?  Yes  No

8. Did the eye bank feel the inspection was relevant and fair?  Yes  No

   **Additional Comments:**

9. Please provide feedback on the Summation Conference/Exit Interview, i.e., did you feel it helpful, was it conducted in a professional manner?

---

**NAME & TITLE:**

**EYE BANK NAME:**

**EYE BANK ADDRESS:**

**DATES OF INSPECTION:**

**NAMES OF INSPECTORS:**

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Please send this form to the Co-Chair of the Accreditation Board:

Lisa K. Looking, Head & Eye Bank Opening, 9800:

Los Angeles Eye Bank of Delancey Valley, 881 N. 17th Street, Suite 300, Philadelphia, PA 19121

Revised July 2012
Pitfalls of an Inspection

- Treating an inspection as a social call
- Dinner plans before or after an inspection with eye bank staff
- Lunch outside of the eye bank with eye bank staff during the inspection
- Not allowing enough time
Team Leader’s Role- Post Insp.

- Collect all paper work from co-inspector
- Print legibly on the summation report
- Signature of both inspectors
- Send all inspection paperwork to AB co-chair as soon as possible following inspection
- Upon receipt, review CA’s with co-inspector
Inspection Paperwork Checklist

Inspection Paperwork Inspectors Submit to non-MD Accreditation Board Co-Chair

Eye Bank: __________________________________ City: __________________________ State: __________

Inspection Date: ________________ EID # ________________________________________

(Completed by Accreditation Board Co-Chair)

Parent Bank (circle one): Yes No
If Satellite bank, Name and Location of Parent Bank ________________________________

Lead Inspector: ______________________ Co-Instructor: ____________________________

DOCUMENTATION CHECKLIST
Inspectors Must Complete and Submit the Following Documents to:

Jim Quirk, CERT Co-Chair, Accreditation Board
President & Chief Operating Officer, Lions Eye Bank of Delaware Valley
401 N. 3rd Street, Suite 303, Philadelphia, PA 19123

☐ One original Pre-Inspection Questionnaire (PIQ) with supporting documentation for any items cited on Summation Report (both inspectors complete / sign only one form). (Should include the Pre-
Inspection Questionnaire materials completed by the Eye Bank if there was a deficiency related to the
completion or non-completion of the questionnaire.)

☐ One original Site Inspection Questionnaire (SIQ) with supporting documentation for any items cited on Summation Report (both inspectors complete / sign only one form) (Should include items such as
copies of policies / procedures, labels, forms, or other documents to support observed deficiencies.)

☐ Record Review Worksheet(s)

☐ Record Review Summary

☐ Technical Practical Performance Test for CERT (both inspectors if applicable)

☐ Technical Practical Performance Test for non-CERT (both inspectors if applicable)

☐ Summation Report (copy of the document given to bank)

Mail or email Expense Reimbursement Form and receipts to Bernard Dollars, bernard@trentaxight.org
in the EBAA office in Washington, DC within thirty (30) days. It is not necessary to send a copy to the
Accreditation Board Co-Chair.

Revised July 2012
Hello [Exec Dir Name]:

It was a pleasure to meet your staff and to inspect your bank last week [Inspection date]. Please thank your staff for all their help during the inspection. We hope the process was of value to you and your bank.

This email will serve as a follow up to your inspection. There were [X] official examination findings for your bank. As a reminder, per Accreditation Policies and Procedures, your bank has an opportunity, within [X] [working days] following the examination conference, to complete and submit any supplemental materials or corrective actions to your Lead Inspector (me) and the Accreditation Board Co-Chair (non-MD co-chair name) in order for your response to be considered by the Accreditation Board. Therefore your bank’s response is due by [due date]. Your response should be sent to both:

[Lead Inspector name, email, and mailing address]

and

[Non-MD co-chair name, email, and mailing address]

Another paragraph could be inserted here to clarify any outstanding questions or issues following the inspection.

I would like to make sure that the examination findings and potential corrective actions are very clear to you and your bank. I would also like to make you aware that the Accreditation Board may request additional corrective actions following the presentation of your bank’s findings at the AB meeting.

Should you have any questions, please call me at [Lead Inspector contact phone number].

Sincerely,

[Lead Inspector name]
Lead Inspector
c:
[Co-Instructor name], Co-Instructor
AB Co-Chairs
Submit reimbursement forms to EBAA promptly- 30 days

Include all receipts
## EBAA Request of Reimbursement of Site Visits

**Eye Bank Association of America**

### EBAA Request for Reimbursement

**Site Visit Inspections**

<table>
<thead>
<tr>
<th>Inspector Name:</th>
<th>Eye Bank(s) Inspected:</th>
<th>Return Date</th>
</tr>
</thead>
<tbody>
<tr>
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**Departure Date**

<table>
<thead>
<tr>
<th>Air Fare</th>
<th>Airport Parking</th>
<th>Automobile Charges</th>
<th>Car Rental</th>
<th>Taxi</th>
<th>Hotel (daily limit guideline $160)</th>
<th>Meals (daily limit guideline $53)</th>
<th>Other (itemize and attach receipts)</th>
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**TOTAL**

| $         |

**Inspector Signature:**

Please make check payable to:

Deliver check to the following address:

**Mail**

EBAA
Athena Finance
1015 18th St., NW 1015
Washington, DC 20006

**Email**

berritt@ects.com

**FAX**

202-426-6035 (Attn: Finance)

**Updated:** June 2013
Accreditation Board Meeting Presentation Guidelines

- Be as brief as possible! Be prepared!
- Group and prioritize deficiencies.
- Indicate what corrective action was submitted and if you believe it to be appropriate (including evidence of staff training/re-training if applicable)
- Recommend an accreditation status
Confidentiality is a hallmark of our accreditation process.

Confidentiality must be maintained at all times—be careful.

Only discuss names of eye banks to be inspected with co-inspector or Chair(s) of the Accreditation Board.
Presentation Guidelines

Do NOT name:

- Executive Director
- Medical Director
- Staff
Presentation Guidelines

Do NOT mention:

- Eye bank name or tissue volume
- Gender of ED or MD
- Relative longevity of staff
- City, State, or climate
- University/Hospital/Stand Alone
- Affiliations (Lions, OPO/Tissue, etc.)
Voting Guidelines

- Co-Inspectors should be prepared to offer their opinion regarding accreditation status.
- Consider carefully all the discussion regarding a bank and its deficiencies along with the EBAA provided scoring summary.
- Abstain from voting if:
  - You know the identity of the subject bank
  - You were not present for the entire discussion about the subject bank.
Read AB Policies and Procedures!
Co-Chairs:
Jim Quirk, CEBT
Lions Eye Bank of Delaware Valley
jquirk@lebdv.org
W. Barry Lee, MD
Eye Consultants of Atlanta
wblee@mac.com

Co-Vice Chairs:
Eric Meinecke, CEBT
Georgia Eye Bank
eric@georgiaeyebank.org
Shahzad Mian, MD
Kellogg Eye Center
smian@umich.edu

EBAA:
Jennifer DeMatteo
Director of Regulations & Standards
Eye Bank Association of America
jennifer@restoresight.org
EBAA 54th Annual Meeting
June 3-6, 2015
Loews Atlanta Hotel
Atlanta, Georgia

Thank you!