



Accreditation

Policies & Procedures

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Note: The numbers listed in this document do not correspond to EBAA Medical Standards.

A1.000 Introduction and Purpose

The Eye Bank Association of America (EBAA) accredits facilities that provide human eye tissue for surgical use, research and ophthalmic training. The EBAA has developed extensive medical standards (MS) and procedures for recovery, processing, storage, tissue evaluation, donor eligibility determination and distribution of human eye tissue for transplantation and research, as well as an on-site inspection program to accredit eye banks. These Accreditation Board procedures have been developed to assure consistently acceptable evaluation of eye banks. For a complete list of terms see the EBAA Medical Standards Glossary and the EBAA Constitution and Bylaws.

B1.000 General

The EBAA Accreditation Board is overseen by the Chair(s) of the Accreditation Board, individuals appointed by the EBAA Chairperson.

The EBAA Accreditation Board accredits establishments that perform any or all of the following functions:

Recovery

Processing

Storage

Distribution

Tissue Evaluation

Donor Eligibility Determination

C1.000 Site Inspection of Eye Banks

C1.100 Site Inspection Application

- a. Following notification from the EBAA office that a site inspection is to be scheduled, an eye bank has thirty (30) calendar days to submit a completed application form, along with the required fees to confirm its request to be inspected.

- b. Inspectors are assigned to each bank applying for the next inspection cycle. The EBAA will notify the bank of the assigned inspectors. The eye bank may request reassignment of one of the inspectors within one calendar week from the date of notification. The Team Leader for the inspection will determine the inspection date, within defined time parameters, in consultation with the eye bank applicant.
- c. The EBAA application is completed and fees are paid.
- d. If an eye bank is denied accreditation by the Accreditation Board, after receiving formal notice, an eye bank must submit a written request within thirty (30) calendar days, for an inspection to be considered for the proceeding round of inspections.
- e. Any eye bank that has not been previously inspected must submit a written request for inspection at least thirty (30) calendar days prior to the next EBAA meeting, in order to be considered for the next cycle of inspections.
- f. An eye bank must notify the EBAA in writing if it declines to be inspected (see Accreditation Policy C1.300, Deferral of Inspections).
- g. If an eye bank cancels or defers an existing, scheduled inspection, the bank is responsible for fees incurred.
- h. To apply for accreditation, an eye bank must verify that it has handled at least 25 surgical corneas within the past 12 months for each eye bank function for which it is seeking accreditation. Verification, to demonstrate proficiency and to maintain accreditation status (see Accreditation Policy D1.300, Provisional Accreditation), is demonstrated by documenting sufficient surgical tissue ID numbers (for each eye bank function for which the bank is seeking accreditation) on the application for inspection.
- i. An eye bank applying for accreditation / reaccreditation which operates entities physically separate from the parent bank shall be required to complete the appropriate section of the EBAA application (see Accreditation Policy C1.200, Inspection of Other Location(s) to Parent Banks).

C1.200 Inspection of Other Location(s) to Parent Banks

- a. Entities that perform any of the following activities on site for tissue intended for surgical use shall be considered satellites as defined EBAA MS Glossary, and shall be inspected as part of the accreditation process of the parent bank;
 - a. Processing (e.g. laboratory corneoscleral disc excisions, laboratory scleral preservation, preparation of lamellar tissue, preparation of tissue for LAK)

- b. Tissue Evaluation (i.e. slit lamp examination of the whole eye or excision corneoscleral disc, specular microscopy, pachymetry)
 - c. Donor Eligibility Determination (investigate and review medical/social history, laboratory information, obtain autopsy results, interview next of kin, family physician and maintain donor case records, etc.)
 - d. Storage (includes tissue awaiting placement or shipment and tissue that is quarantined or otherwise awaiting surgical eligibility determination)
 - e. Distribution (package and ship ocular tissue directly to consignees and maintain recipient case records)
- b. Entities that perform the following activities may be required to participate and/or provide laboratory information during the accreditation process of the parent bank;
 - a. Perform either whole eye enucleation or in situ corneoscleral disc excision
 - b. Store storage solution(s)
 - c. Store instruments
 - d. Sterilize instruments
- c. The determination of the need for and scope of an on site inspection is at the discretion of the Accreditation Board.

C1.300 Deferral of Inspections

Deferral of site inspection beyond the scheduled inspection cycle results in the automatic expiration of the eye bank's accreditation at the end of its accreditation period. A member eye bank will subsequently be listed as an Associate (unaccredited) Member, (EBAA Constitution & Bylaws, Article 2.1, Categories of Membership). A bank that defers inspection beyond the scheduled cycle shall not identify itself as an EBAA accredited bank.

C1.400 Submission of Pre-Inspection Documentation

- a. Along with the notice of inspectors assigned to the bank, the EBAA will make inspection related documents available (e.g. Site Inspection Preparation Guide, Inspection Questionnaire(s), etc.) to assist the bank with preparation for the inspection and completing the pre-inspection questionnaire.
- b. The eye bank to be inspected is responsible for timely submission of its Policies and Procedures Manual, Declaration of Compliance statement and the Pre-Inspection Questionnaire (and accompanying documentation) to the assigned inspectors at least twenty (20) working days prior to the scheduled inspection date.

- c. In order to facilitate review of the manual, the eye bank to be inspected must either tab their SOPs to correspond with each question in Section 2 of the Site Inspection Questionnaire or provide a separate document (crosswalk) that clearly explains where the inspectors can locate information pertaining to each question in Section 2 of the Site Inspection Questionnaire.

C1.500 Site Inspection

- a. The site inspection should include, but is not limited to, the following site inspection related duties:
- Review of the pre-inspection questionnaire materials including a review of the eye bank policies and procedures manual sent at least twenty (20) working days prior to the scheduled inspection date.
 - Interview of the Director in a private space.
 - Interview of the Medical Director, at a mutually agreed upon time, in a private space.
 - Interview of the Quality Assurance Director, or the person(s) responsible for these functions, in a private space.
 - Interview(s) of technical personnel in a private space.
 - Observation of a minimum of two (2) practical recovery or processing techniques as follows:
 1. If the establishment performs processing procedures other than those listed in 2-3 (prep for LAK, EK, DMEK, etc.) - at least ONE preparation of each processing procedure must be observed.
 2. If the establishment performs either laboratory corneoscleral disc excision or in-situ corneoscleral disc excision - at least ONE laboratory corneoscleral disc excision or in-situ corneoscleral disc excision must be observed, and TWO must be observed if the establishment does not perform any of the procedures listed above in 1.
 3. If the establishment does not perform any of the procedures listed above in 1-2, but performs some other type of processing (e.g. tissue transfer in the hood, removal of foreign body or excess tissue, rinsing of tissue to remove red blood cells), at least TWO of these procedures must be observed.
 4. At least ONE of the practical procedures required for the inspection must be performed by a CEBT, and at least ONE must

be performed by a non-CEBT. Non-CEBT technicians will not be expected to perform procedures that they have not been deemed qualified to perform independently by the Medical Director or Medical Director designee.

- Review of the eye bank laboratory and equipment.
 - Review of eye bank records, including but not limited to, donor/recipient records, laboratory environmental cleaning and monitoring records, laboratory equipment cleaning, monitoring and calibration/certification records, personnel orientation, training, continuing education records (including OSHA training records), Quality Assurance records, tissue distribution forms and records, Medical Director meeting minutes and technician oversight records, etc.
 - For noted non-compliant items, inspectors should provide hardcopy documentation of findings, where possible, and include them with your report to the appropriate Co-Chair.
- b. Questions on the Pre-Inspection Questionnaire and Site Inspection Questionnaire have been “tiered” according to the following definitions:
- Potential Threat (PT) - a citation that involves a potential threat to recipient and/or staff safety of sufficient seriousness to potentially move a bank to a 1 year status or denial
 - Significant Observation (SO) - a citation that while significant, does not meet the threshold for Potential Threat
 - Non-Conformance (NC) - a citation that while out of compliance, is of a lower significance than Potential Threat or Significant Observation.
- c. The Lead Inspector should complete and submit one copy of the Site Inspection Questionnaire, and the Donor / Recipient Record Review Summary form. Both inspectors should complete and submit the Record Review Worksheet and applicable technician practical performance test review form(s) to the appropriate Co-Chair. These documents should be reviewed for accuracy and completeness prior to submission.
- d. The inspection team should complete, sign, date and submit the eye bank inspection Summation Report to the appropriate Co-Chair.
- Inspectors should list only areas of non-compliance with Medical Standards on the Site Inspection Summary Form. Make copies of non-compliant items, e.g. temperature charts, incomplete forms, etc. as appropriate, to support their observations. Suggestions for improvement,

including references to deviation from the EBAA Procedures Manual, should not be documented on these forms unless they represent deviations from EBAA Medical Standards.

- All areas of non-compliance should be listed, including those that are corrected prior to, during, or after the site visit. This includes all problems with the Policies and Procedures Manual identified at the time of initial review.
- e. As part of the inspection process, the inspection team will hold a summation conference at the close of the inspection with key eye bank personnel to provide timely notice of inspection findings. During this conference, the eye bank has an opportunity to respond and to offer timely corrections. Otherwise supplemental materials or corrective actions must be received by the inspection Team Leader and the Accreditation Board Co-Chair with ten (10) working days following the summation conference for consideration by the Accreditation Board at the meeting where inspection results are presented.

C1.600 Corrective Actions

- a. Corrective actions for items found not in compliance during a site inspection shall be submitted to the Team Leader and to the Chair(s) of the Accreditation Board within ten (10) working days following the summation conference in order to be considered by the Board when the eye bank's inspection report is presented. It is at the Board's discretion to consider corrective actions submitted after ten (10) days. These corrective actions will not alter the percentage scores in each of the performance areas or tiers presented to the Board, but Board members may consider them in determining accreditation status (see Accreditation Policy D1.200, Accreditation Status).
- b. Inspectors should contact the Co-Chairs prior to the Board meeting if corrective actions submitted by the bank do not effectively address the cited areas of non-compliance, or if they seem to indicate a misunderstanding between the bank staff and the inspectors.
- c. Following presentation of the bank's inspection report, the Board may require that additional corrective actions be submitted within a defined time frame to address items that were found not in compliance during a site inspection.
- d. Failure to comply with the conditions of accreditation by submission of written corrective action plans and satisfactory documentation to the Accreditation Board within the defined time frames may result in an immediate loss of accreditation status, as determined by the Chairs of the Accreditation Board. **The burden for complying with time frames and deadline dates rests with the eye bank.**

Note: A loss (or change) of accreditation status will be documented on the official EBAA Accreditation List as soon as possible.

C1.700 Confidentiality and Public Health / Summary Suspension

If, during the course of an inspection, an inspector identifies a potential threat that has not been corrected or resolved satisfactorily, the inspector should immediately notify the eye bank of his/her findings, record the findings, and recommend steps to ameliorate the issue. In rare cases, where an inspection team believes that an eye bank fails to meet EBAA Standards to such a degree that the potential harm to recipients and/or employees is significant and immediate, the inspectors may recommend that the eye bank's accreditation be summarily suspended during the period between the date of the on-site inspection and the date the Accreditation Board meets to make a formal decision on the eye bank's accreditation status.

For example, if the issue warrants a recall of tissue, the bank is obliged to pursue all necessary steps to meet EBAA Medical Standards and/or any additional federal requirements. The inspector must report any problem of this magnitude to the Accreditation Board Co-Chair(s) and the bank, in turn, must make corrective actions available to the Chair(s).

Recommendations for summary suspension must be made by both members of the inspection team. When such a recommendation is made, EBAA staff will immediately convene a meeting or telephone conference with the inspectors and a subcommittee as defined in Accreditation Policy E1.100, Off-Cycle Subcommittee. The panel will discuss the matter with the inspection team and make a decision to summarily suspend, or not summarily suspend, the eye bank's accreditation status. A decision to summarily suspend must be unanimous, and such decisions are not subject to appeal. Eye banks that are summarily suspended will be so notified, and will have their accreditation status listed as "suspended" until the full Accreditation Board meets at its next scheduled time. An eye bank that has had its accreditation summarily suspended may not hold itself out to the public or to any third party as having EBAA accreditation during the period of the suspension.

The matter of confidentiality during the accreditation process cannot compromise the obligation of the inspector or the Association to take any reasonable action upon discovery of a problem that may be considered a potential threat or hazard to public health.

D1.000 Accreditation Results

D1.100 Accreditation Decisions

- a. Results of the site visit are determined by a majority decision of the Accreditation Board following a thorough review of the information and materials submitted by the eye bank and the inspection team.
- b. The identity of the eye bank is masked during the inspection team's presentation, Board discussion and vote.
- c. Deliberations of the Accreditation Board are confidential. Board members shall not discuss them with non-Accreditation Board members.
- d. Within thirty (30) calendar days following a determination of status, the Chair(s) of the Accreditation Board shall mail a written notification to the eye bank listing areas found not in compliance, initial scores from the site inspection questionnaire, other significant factors considered by the Accreditation Board in determining status, as well as deadlines for the submission of Corrective Action Plans and Corrective Actions, if required.
- e. Accreditation decisions take effect upon official notification of Board decisions (or others as defined by these Policies and Procedures), provided either at an EBAA meeting or through the mail, even when subsequent corrective actions are required. Failure to provide documentation of the implementation of corrective actions to the Board's satisfaction, within the required time frames, may result in loss of accreditation status.

D1.200 Accreditation Status

- a. The below are **guidelines only**. During the inspection team's presentation to the Accreditation Board and the ensuing discussion, the Board may consider other factors in determining accreditation status. These may include, but are not limited to:
 - Corrective actions submitted in the appropriate time frame prior to the meeting of the Accreditation Board (see Accreditation Policy C1.500).
 - Patterns of deficiencies (i.e., over time or by type).
 - Discussion and review of inspectors' specific findings.
 - Repeat deficiencies (deficiencies found on prior inspections for which corrective actions had been submitted which are again found to be out of compliance with EBAA Medical Standards).
- b. Accreditation is awarded on a time-limited basis by vote of the Accreditation Board. All banks awarded accreditation, regardless of the length of their accreditation status, have been found by the Accreditation Board to be in substantial compliance with EBAA Medical Standards. An eye bank that receives no citations following inspection will be recommended to receive maximum

accreditation status by motion and approval of the Accreditation Board. The following guidelines are used by the Board:

- **Three Year** - Acceptable compliance with EBAA Medical Standards in all tier levels (i.e. PT, SO and NC) and in all performance areas (i.e. pre-inspection questionnaire, policies and procedures, Executive Director, Medical Director, QA Director, technical personnel and procedures, lab and equipment, records) demonstrated during the site inspection and upon initial review of the policies and procedures. A score of at least 90% was achieved for each tier level and at least 90% in all performance areas. Follow-up/corrective actions required were relatively minor, and can be completed within the specified time frame(s). Duration of accreditation is three (3) years.
- **One Year** - Scoring does not meet the threshold for Three Year status, however a score of at least 85% was achieved for each tier level (i.e. PT, SO and NC), and no more than one performance area had a score below 85% (i.e. pre-inspection questionnaire, policies and procedures, Executive Director, Medical Director, QA Director, technical personnel and procedures, lab and equipment, records) during the site inspection and upon initial review of the policies and procedures. It is expected that deficiencies can be corrected through submission of written progress reports and corrective actions within a specified time frame(s). Duration of accreditation is one (1) year.

D1.300 Provisional Accreditation

- a. Provisional accreditation may be awarded when an eye bank has not provided documentation of the handling of at least twenty-five (25) surgical corneas for each function for which it is seeking accreditation during the previous year as required by EBAA MS B1.000, but has instituted an approved performance improvement and corrective action plan, as determined by the Accreditation Board. Eye banks are required to complete and submit statistical reporting to the EBAA per EBAA MS M1.600 in order to ensure proficiency and maintain accreditation. If a bank fails to submit required statistical reporting, it shall be placed in provisional accreditation until it meets this requirement and demonstrates that it has handled a sufficient supply of corneas. In addition, the eye bank must have achieved Accredited status during its most recent site inspection with no corrective actions outstanding. Provisional accreditation may be valid up to one (1) year following notification, as determined by the Accreditation Chair(s).
- b. Within thirty (30) calendar days of a discovery of noncompliance with EBAA MS B1.000, the EBAA office, in conjunction with the Chair(s) of the Accreditation Board, will send written notification to an affected bank of its move to provisional status due to its failure to meet the stated requirement.

- c. Within thirty (30) calendar days of a discovery of noncompliance with EBAA MS B1.000 #4, “Provisional Accreditation” may be granted based on the following mitigating factors:
 - 1. Accreditation Status - The eye bank was accredited at its most recent site inspection with no corrective actions.
 - 2. Immediate Corrective Action - The eye bank anticipated failure to meet the threshold and instituted a corrective action plan designed to remedy the failure and to maintain an acceptable level of continuing staff competency. The plan must be approved by the Chair(s) of the Accreditation Board in writing prior to publication of the Accreditation Status List.
 - 3. Demonstration of Increased Compliance - The eye bank submits interim reports that reflect satisfactory progress to the Accreditation Board every three months following notification of provisional accreditation. The bank must satisfactorily demonstrate improvement and an ability to meet the threshold.
- d. An eye bank on provisional status must demonstrate actual compliance with EBAA MS B1.000 to be reinstated as an accredited bank.
 - 1. The bank must be eligible for re-accreditation based on its most recent inspection and subsequent record.
 - 2. The EBAA Accreditation Board may conduct an off-cycle inspection, as necessary, to determine compliance and eligibility.
 - 3. Upon receipt of documented compliance and a satisfactory determination of compliance with EBAA MS, the bank is eligible for accreditation.
 - 4. Completion of the EBAA’s required statistical reporting.

D1.400 Non-Accreditation

A status of “unaccredited” will result when an eye bank has demonstrated significant non-compliance with EBAA Medical Standards, as in the following:

- a. Scheduled inspection results show:
 - 1. Scoring that does not meet the threshold for a One Year status, or
 - 2. Potential threats to recipient and employee safety, or

3. Noncompliance identified at a prior site inspection that was purportedly corrected is again found during this site inspection, or
- b. The bank's accreditation is withdrawn by the EBAA for other actionable reasons such as:
 1. Failure to comply with required corrective actions following a site inspection
 2. Failure to handle 25 surgical tissues for each function for which it is accredited within one year, absent an approved correction plan
 3. Results of an off-cycle inspection
 4. The bank declines to be inspected upon expiration of accreditation
 5. Noncompliance with EBAA Medical Standards identified during an inspection is determined to require immediate action.
- c. The bank voluntarily withdraws from accreditation.

An eye bank that has been denied accreditation shall be identified as an Associate (unaccredited) Member, (EBAA Constitution & Bylaws, Article 2.1, Categories of Membership). See Accreditation Policy, G1.000, Identification of Accreditation Status.

D1.500 Repeated Denials

An eye bank that fails two or more consecutive inspections, or two inspections within three inspection cycles, must demonstrate an acceptable level of compliance with Medical Standards prior to scheduling another inspection. The Accreditation Board Chair(s) will determine "acceptable compliance" based on the results of the bank's previous inspections and/or through submission of documentation that demonstrates the bank's compliance with Medical Standards. The Accreditation Board Chair(s) may take any actions appropriate to the situation, including but not limited to, reporting relevant information to state, federal and/or other regulatory agencies. The eye bank must assume increased costs attributable to the next inspection.

D1.600 At the Accreditation Board Meeting

D1.610 Inspectors' Presentations

- a. Do not mention any identifying characteristics of the bank, including location, personnel, size of the bank, scope of eye bank activities (i.e. limited or comprehensive), recent changes in governance, etc. If one of these items seems essential to your report, discuss it with the Co-Chairs prior to your presentation. Maintain strict confidentiality before, during and after AB meetings.
- b. Be brief and to the point. A detailed description of every area of non-compliance is not necessary, particularly for those that were easily and quickly corrected (e.g.

corrections to the P & P manual). These can be quickly reviewed on the presentation slide(s).

- c. Focus the discussion on items which:
 - are potential threats or repeat citations
 - are difficult to interpret
 - may continue to impact the bank's compliance with EBAA Medical Standards
 - the bank's staff disagreed with the inspector over the findings
- d. Be prepared to suggest an acceptable corrective action (e.g. further monitoring, chart review, etc.) for items that remain out of compliance with Medical Standards.
- e. Be objective. Site inspections are stressful. Banks are evaluated on compliance with EBAA Medical Standards, not demeanor or attitude of staff.
- f. Make a recommendation regarding accreditation status and length at the end of your report.

D1.620 Presentation of Inspection Reports of Inspectors' Home Bank

- a. The purpose of the following guidelines is to allow Board members to remain during discussion of inspection results from their home banks. This is to prevent inadvertent identification of the bank to Board members. These guidelines are also intended to ensure that the banks of Board members do not have an unfair advantage over other member eye banks during the presentation and discussion of inspection results.
- b. Routine Accreditation Board procedures shall be followed to mask the identity of banks during presentation and discussion of inspection results.
- c. Board members shall not participate in the discussion of the home banks' inspection nor in the determination of status and any required corrective actions.
- d. Board members shall abstain from the vote on accreditation status for their home banks. Each ballot includes an "abstain" box option.
- e. Board members shall not attempt to influence inspection results or accreditation status in any manner.

E1.000 Off-Cycle Site Inspection of Eye Banks

An off-cycle inspection, either full or targeted, may be initiated upon discovery of any of the following five conditions:

- a. A change in location (see Accreditation Policy E1.400, Eye Bank Laboratory Relocation).
- b. Any change in an eye bank that appears to be substantive, such as major reorganization that might affect continuity of care or raise concerns about the qualifications of personnel (see Accreditation Policy E1.500, Change in Governance / Mergers & Acquisitions).
- c. The eye bank is alleged, in a signed document, to have violated EBAA Medical Standards. This could include, but is not limited to, observations or findings documented by another regulatory agency (e.g. a Form 483 from the Food and Drug Administration, or other). The eye bank's response to such documents will also be considered.
- d. The Medical Review Subcommittee of the MAB determines that an eye bank has an unusually high number of adverse reactions.
- e. The eye bank, based on the judgment of the Accreditation Board Co-Chairs, has an unusual trend or pattern involving adverse reactions, deviation reports, recalls, market withdrawals or any other violation of Medical Standards.

These guidelines pertain to EBAA accredited eye banks. Under these guidelines, an eye bank must comply with notification requirements listed in EBAA Medical Standards B1.200, C1.300, C1.400, and C3.000, and with Accreditation Board Procedures. A review of change(s) may require, but is not limited to, requests for additional information or documentation, full or targeted off-cycle inspection or revocation of accreditation. An eye bank has the right to appeal the final results of an off-cycle inspection (see Accreditation Policy F1.000, Appeal of Accreditation Status).

E1.100 Off-Cycle Subcommittee

Off-cycle inspections are purely within the discretion of the EBAA. A subcommittee of the Accreditation Board will examine the circumstances and determine whether an off-cycle inspection is warranted. The decision to conduct an off-cycle inspection in a particular case is final and not subject to appeal. The subcommittee will determine if a full or targeted off-cycle inspection should be conducted.

The subcommittee may consist of three or more from the following representatives:

- Chair, Eye Bank Association of America
- Chair(s), Accreditation Board
- Vice-Chair(s), Accreditation Board
- Chair, Certification Board
- Chair, Medical Advisory Board
- Vice-Chair, Medical Advisory Board
- President/CEO of the Eye Bank Association of America (ex-officio)
- Past Chair(s) of the Accreditation Board

- Past Chair(s) of the Medical Advisory Board

The Off-Cycle Subcommittee will convene, at the earliest possible time, and will issue a decision on the findings of the site inspector(s) in writing to the bank within thirty (30) calendar days. To appeal the final decision of the Subcommittee, the eye bank may refer to appeal procedures (Accreditation Policy F1.000, Appeal of Accreditation Status).

E1.200 Full Off-Cycle Inspections

- A full off-cycle inspection may be conducted when the Accreditation Board subcommittee determines that conditions a) or b) exist as listed under Accreditation Policy E1.000, Off-Cycle Site Inspection of Eye Banks. At that time, the Accreditation Board's policies and procedures will apply, including EBAA policies regarding fees and expenses.
- The Accreditation Board Chair(s) will notify the eye bank in writing that a full off-cycle inspection has been requested, indicating the reason for the decision to conduct an off-cycle inspection. The eye bank will have four (4) weeks from the date of this notification to submit all application materials. If an eye bank fails to submit these materials by the deadline (or fails to pay any fees, when due), the Accreditation Board, at its sole discretion, may revoke or modify the eye bank's existing accreditation status, and any such modification or revocation shall not be subject to appeal.
- Once all application materials have been submitted, the EBAA will contact the eye bank to schedule the site visit. Eye banks will be given at least two (2) weeks between the date the application is submitted and the date of the inspection, in order to permit facilities to prepare for full inspection.

E1.300 Targeted Off-Cycle Inspections

- A targeted off-cycle inspection may be conducted when the Accreditation Board subcommittee determines that conditions c), d) or e) exist as listed under Accreditation Policy E1.000, Off-Cycle Site Inspection of Eye Banks. A limited inspection may be conducted, targeting only those areas in which the EBAA has received signed allegations of potential problems (E1.000 c), areas related to the subject matter of adverse reactions (E1.000 d), or unusual patterns or trends (E1.000 e).
- In cases involving targeted inspections, the eye bank will not be required to submit an application or complete any pre-inspection forms.
- An EBAA representative will contact the eye bank one (1) day in advance of the inspection, and will notify the eye bank Director of the following:

1. The time of the inspection,
 2. The reason for the inspection,
 3. Any documents and/or records to be made available to the inspection team;
and
 4. The personnel needed to be available for interview by the review team.
- d. Targeted inspections will **not** be rescheduled for any reason, including situations where relevant documents and/or personnel are unavailable. If key personnel are unavailable for any reason, the eye bank should make arrangements for telephone conferencing or take other steps to ensure that the inspection team has access to all relevant information.
 - e. Withholding any documents or records from the inspection team shall be grounds for immediate revocation of the eye bank's accreditation status, as will alteration or destruction of any documents or records during the one-day notice period.

E1.400 Eye Bank Laboratory Relocation

An eye bank must notify the Eye Bank Association of America when an eye bank laboratory relocates, expands, or has an addition of a satellite. For the purpose of retaining accreditation, an eye bank must adhere to the following:

- a. Prepare written notification of the laboratory relocation, expansion, or satellite addition to the EBAA office.
- b. The written notification must include information that demonstrates that the new laboratory meets the requirements of EBAA Medical Standards C3.000; the following points must be addressed in the notification letter:
 1. Documentation through photographs, floor plans/blue prints and written explanation that the new laboratory meets all of the following:
 - a. Sufficient space, equipment and storage to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timeliness and safety.
 - b. Limited access in which only activities directly related to eye banking are carried out.
 - c. Sink with drain and running water.
 - d. Adequate counter space for preparation of donor material.
 - e. Adequate stable electrical source and a sufficient number of grounded electrical outlets for operating laboratory equipment.
 2. Photographs or written description and/or manufacturer's information regarding changes in laboratory equipment including but limited to slit lamp,

specular microscope, refrigerator and alarm system, laminar flow hood, autoclave.

3. The certification / recertification of the processing environment, i.e. LFH, clean room, etc.
 4. Any documentation for service of any equipment that was moved.
- c. Written notification must be submitted to the EBAA within thirty (30) calendar days of the relocation of the laboratory.
 - d. Questions regarding this procedure should be directed to the Accreditation Board Chair(s).

E1.500 Change in Governance / Mergers & Acquisitions

EBAA Medical Standard C1.400 reads “An eye bank that undergoes a change in governance must notify the EBAA office (in writing) within thirty (30) days. Changes in governance include merger of eye banks, affiliation of two or more eye banks, affiliation of an eye bank with another non-eye bank organization (e.g. tissue banks, organ procurement organizations, hospitals, blood banks, etc.), a change in the name of the eye bank, or a change in required personnel, i.e., Director, Medical Director.”

Specific requirements to retain accreditation status after a change in governance include:

- a. Accreditation of eye banks that merge with non-accredited eye banks:
 1. The non-accredited bank must follow established procedures to achieve accreditation and
 2. A joint entity may be inspected at the discretion of the Accreditation Board Chair(s).
- b. Affiliation of one EBAA accredited eye bank with another EBAA accredited eye bank:
 1. The change is reported to the EBAA and the Accreditation Board within the required time limits.
 2. Required documentation is submitted within established time limits.
 3. The bank(s) under consideration do not have required outstanding corrective actions from the most recent site inspection(s).
 4. If one bank becomes a satellite facility as defined in EBAA MS Glossary, the satellite facility will generally be inspected on the same schedule as the parent bank, unless the accreditation history of the satellite facility indicates that an earlier inspection is warranted (e.g. incomplete required corrective actions, history of multiple or repeated deficiencies).

- c. Affiliation of an EBAA accredited eye bank (i.e. free-standing or within another organization) with a non-eye bank organization (e.g. tissue bank, OPO, hospital, blood bank):
 - 1. Eye bank continues as an intact operation within the new organization and continues to meet all EBAA Medical Standards.
 - 2. The change is reported to the EBAA within the required time limits.
 - 3. Required documentation is submitted within established time frames.
 - 4. The bank(s) under consideration does not have outstanding required corrective actions.
- d. Eye banks that have undergone changes in governance or a major reorganization (i.e. change in ownership or sponsorship of an eye bank that substantially affects the organizational structure, including its governance) may be required to reapply for EBAA accreditation as the new entity, including a change in operations that would qualify the bank as a limited member. An Off-Cycle Subcommittee, as specified in Accreditation Boards Policies E1.100, will be convened to determine if a change in status is necessary or if the new entity should be referred to the Constitution and Bylaws Committee as a new member applicant. Information reviewed by the Off-Cycle Subcommittee should include, but may not be limited to, the following:
 - 1. Name(s) of the parties involved in the merger/acquisition
 - a. Effective date of the merger/acquisition
 - b. The responsible (governing) entity
 - c. The accreditation status of the entities involved
 - d. Which entity's Policies and Procedures will be followed, including the effective date
 - e. How statistical reporting will be handled
 - 2. Any change of name for the entities
 - 3. Any change in required personnel (e.g. Director, Medical Director, CEBT in supervisory role, QA Director)
 - 4. Any changes to the facility, location or eye bank functions performed
 - a. Any changes in eye bank operations regarding Recovery, Processing, Storage, Distribution, Tissue Evaluation, or Donor Eligibility Determination may require submission of affected Policies and Procedures
 - 5. Any changes in regulatory registrations, licensures, etc. (e.g. FDA, State, Health Canada, Ministry of Health, etc.) will require documentation of any new registrations or licensures.

6. If the merger/acquisition involves a new entity not previously accredited:
 - a. Is the parent bank doing routine audits of the new entity
 - b. Photos and required documentation must be submitted

F1.000 Appeal of Accreditation Status

- a. An eye bank may appeal its accreditation status to the EBAA.
- b. An appeal for reconsideration of decisions by, or on behalf of, the Accreditation Board shall be submitted in writing to the Chair(s) of the Accreditation Board, either sent electronically or with five (5) copies to the President/CEO of the EBAA within thirty (30) calendar days of formal notification of status. This should include a letter outlining the appellant bank's intention to appeal, along with its basis for appeal, including supporting information. It is the responsibility of the appellant bank to mask all documentation and references to the eye bank and any other information that may be deemed confidential prior to submission to the EBAA office for distribution. It is the responsibility of the appellant bank to submit all documentation before an Appeals Committee will be formed; any incomplete documentation may result in further delays. If the Appeals Committee, in its discretion and by unanimous vote, concludes that an appeal is frivolous (for purpose of this provision, "frivolous" means that no reasonable person could conclude that the materials submitted by the eye bank provide a basis for modifying or overturning the decision of the Accreditation Board), then the Appeals Committee may require that the appellant bank pay some or all of the reasonable costs incurred by the Association (including, but not limited to, fees of the Association's counsel) relating to the appeal. The Appeals Committee is part of the accreditation process. It shall deliberate independently on appeals of the Accreditation Board's eye bank accreditation decisions.
- c. The Appeals Committee shall consist of at least three (3) of the following:
 1. Past Chair(s) of the Medical Advisory Board
 2. Past Chair(s) of the Accreditation Board
 3. Current Chair, Certification Board
 4. Past Chair(s), Certification Board
 5. Current Chair, Medical Advisory Board
 6. Vice Chair, Medical Advisory Board
 7. President/CEO of the EBAA (ex-officio)
- d. The Appeals Committee may be formed on the basis of availability, past service, and balance of physicians and non-physicians, if possible.
- e. The EBAA office shall forward all relevant information pertaining to the appeal to the Appeals Committee. It is the responsibility of the appellant bank to submit

masked documentation. The EBAA office cannot ensure the anonymity of any documentation submitted.

- f. The appeals process shall be conducted in private, except to the extent that disclosure is necessary to gather or adjudicate the facts. The appellant bank shall be listed on all EBAA materials with the status afforded it by the Accreditation Board. If the appellant bank's status changes, updated documentation shall be provided to the membership.
- g. The Appeals Committee shall meet in person or by conference call within a timely manner following receipt of all relevant materials from the appellant bank.
- h. All members shall be present to constitute a quorum. The members decide chairmanship of the Appeals Committee during each appeal.
- i. The Appeals Committee Chair may request additional information from the appellant bank via the EBAA office or, at the Committee's discretion, may interview individuals involved in the inspection process.
- j. One member of the Appeals Committee shall be appointed to prepare a response to the appellant bank. The response should follow the structure of the allegations set forth in the complaint/appeal. The Committee's decision shall be submitted to the EBAA office to be forwarded to the appellant bank and copied to the Accreditation Board Chair(s). All members of the Appeals Committee shall sign the decision.
- k. The decision of the Appeals Committee is final. The Accreditation Chair(s) shall not overturn the decision of the Appeals Committee.
- l. The appellant bank may submit a written request to the EBAA President/CEO for a conference with an appointed representative of the Appeals Committee, the EBAA President/CEO and the Accreditation Board Chair(s) to review the findings of the Appeals Committee. The conference is for purposes of explanation only and cannot revise the appeal.

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.

H1.000 Conclusion and Summary

This procedural summary contains information that outlines operations and procedures of the Accreditation Board of the EBAA. It is for general use by the EBAA membership. Accreditation Board Chair(s) may be contacted for additional information.