Accreditation Board - PIQ / SIQ with Applicable Eye Bank Functions
AB Meeting, November 2017

When the AB first started doing inspections of limited banks, it was up to the inspectors to determine which questions on the PIQ and SIQ applied to that particular bank. This sometimes resulted in disagreements between the inspectors and the banks. I believe it was Jackie Malling that took the SIQ and created an internal AB form that outlined which Eye Bank Functions were felt to be applicable for each question. This was a document solely for the AB Co-Chairs and inspectors, and was never disseminated to the general EBAA membership. I don't believe it was ever brought to the AB or officially approved. Also, this was never done for the PIQ.

The document has been reviewed and updated by the Forms Subcommittee, and the PIQ has been added. AB Co-Chair Eric Meinecke and Jennifer DeMatteo also reviewed it and the document has been finalized for presentation at the November 2017 AB meeting.

The AB Co-Chairs and I would like to stress that this is a *Guidance Document only* and that the indicated "Applicable Functions" are not to be seen as set in stone. Each bank has its own unique situation and inspectors should still review all questions for applicability. As always, if an inspector or a bank is uncertain if a particular question applies, they should consult the AB Co-Chairs.

Respectfully submitted,

Beth Binnion, CEBT
AB Forms Subcommittee Chair

Pre-Inspection Questionnaire Answer Sheet w/ Functions

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

			Yes	No	N/A	Tier PT/SO	Applicable Functions
Question 1							
D1.200	a.	Acceptable info for all INFECTIOUS DISEASE TESTING providers utilized since last inspection?					DE
C3.300, C3.510, C3.700	b.	Acceptable information for providers of ALL OTHER SERVICES; (i.e. sterilization, biohazardous waste disposal according to state and federal regulations; eye banking functions provided by another eye bank or entity) utilized since last inspection?					ALL
C1.300, C2.000	c.	Acceptable information for non-employees providing recovery, preservation and/or processing services?					ALL
Question 2							
C1.100-C1.300		Completed information provided for authorized staff?					ALL
Question 3							
C1.200	a.	Name of Medical Director?					ALL
C1.200	b.	Qualifications of Medical Director?					ALL
C1.200	c.	Name and qualifications of back-up Medical Director?					ALL
C1.300	d.	Documentation of Medical Director CEBT?					ALL
Question 4							
C1.200	a.	Valid EBAA provided documentation of Medical Director attendance, within the past three years, at a Medical Directors' Symposium and a Medical Advisory Board Meeting?				SO	ALL
C1.300	b.	Valid CEBT certificate covering each year since last inspection?					ALL
B1.000	c.	Valid copy of FDA registration for each year since last inspection?					ALL
B1.000	d.	Valid copy of state and/or all other applicable regulatory requirements for each year since last inspection?					ALL
C3.200	e.	Valid annual certificate for Processing Environment(s) per MS E1.200 for each year since last site inspection?					P
J1.000	f.	Sample labels submitted for all tissue distributed?					FD
B1.000	g.	Documentation of ICCBBA registration for FIN.					P, DE, FD
Question 5							
J1.000		Does the numbering system provide for a unique ISBT 128 Tissue Identifier for each surgical tissue or fraction thereof?					P, DE, FD
Question 6							
D1.200		Was the plasma dilution worksheet/algorithm problem solved correctly?				SO	DE
Question 7							
M1.300-M1.500		Attached sample forms used to record donor and recipient information?					ALL
Question 8							
B1.200		If the eye bank was inspected by an official agency and received any written documentation of observations, findings or results (including, but not limited to, FDA 483), was a copy sent to the EBAA office within ten (10) business days of receipt?				SO	ALL
Question 9							
		Was the eye bank's manual and "Declaration of Compliance with Governmental Regulations" received at least 20 working days prior to the scheduled inspection?				SO	ALL
Question 10							
		For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions were answered "NO".) Please indicate any items which were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

KEY: R - Recovery P - Processing S - Storage TE - Tissue Evaluation
DE - Donor Eligibility Determination FD - Final Distribution

SITE INSPECTION QUESTIONNAIRE

I. Organization of Eye Bank

A. Policies and Procedures Manual - ***These questions should be answered following review of the eye bank's policies and procedures manual***

Does the Policies and Procedures Manual contain a policy and/or procedure (as applicable) for the following that meets EBAA Medical Standards:

			Yes	No	N/A	Tier PT/SO	Applicable Functions
B1.200	1	Reporting requirements following inspections by official agencies?					ALL
C2.000	2	An orientation program for new employees performing eye bank functions?					ALL
C2.000	3	Does the eye bank have a comprehensive and well-defined training program outlining specific job-related tasks that each employee and non-employee is being trained to perform?					ALL
C2.000	4	Documentation of annual competency reviews of skills and job related knowledge for all employees and non-employees performing eye bank functions?					ALL
C3.200	5	Monitoring, inspection and cleaning procedures and schedules for each piece of equipment?					R, P, S, TE, FD
C3.200	6	Requiring testing of the refrigerator alarm system on a regular basis?					R, P, S, TE, FD
C3.600	7	Utilizing Standard Precautions according to applicable regulatory requirements?					R, P, S, TE, FD
C3.600	8	An exposure control plan that meets OSHA or other applicable regulatory requirements (i.e. reporting needlestick injuries)?					R, P, S, TE, FD
C3.700	9	Disposing of biohazardous waste?					R, P, S, TE, FD
D1.000	10	Physical inspection of the donor with special attention to physical signs of HIV disease, infectious hepatitis and injecting drug use?				SO	R, DE
D1.000	11	Routine examination and documentation of prospective donors' medical records and death investigation?					R, DE
D1.000	12	Obtaining a medical and social history of each donor?					R, DE
D1.000	13	Adequate documentation of donor information/completion of donor files, including medical examiner reports and gross autopsy results?					ALL
D1.100	14	Screening for and listing of exclusion criteria listed in EBAA Medical Standards Section D1.100?				SO	R, DE
D1.200	15	Obtaining donor sample for infectious disease testing?					R, DE
D1.200	16	Infectious disease (and microbiological, if applicable) testing performed by CLIA certified and FDA registered laboratories?					R, DE
D1.200-D1.220	17	Screening by infectious disease testing in accordance with EBAA Medical Standards and all applicable federal and state laws?				SO	DE
D1.200	18	Calculating the plasma dilution status of a donor?				SO	R, DE
D1.200	19	Not releasing tissue designated for surgical use without documentation of required negative infectious disease testing				SO	DE, FD
D1.230	20	Handling laboratory reports of non-required tests, whether received before or after tissue distribution?					DE, FD
D1.300	21	Obtaining a unique identifying number for each donor?					R, DE
D1.400	22	Obtaining legal authorization for eye tissue donation consistent with EBAA Medical Standards, federal law, and state law?					R, DE
D1.500	23	Donor age exclusion criteria?					R, DE
D1.600	24	Recording date and time of death, enucleation,preservation, additional processing and cooling of ocular tissues for each donor?					R, P, S, DE
D1.700	25	Eye maintenance prior to ocular tissue removal procedures?					R
E1.000	26	Detailing aseptic technique for recovery, processing and preservation?				SO	R, P, TE
E1.100	27	Special handling of tissue that is hazardous to eye bank personnel (active viral hepatitis, AIDS, HIV seropositivity, etc.)?					ALL
E1.100	28	Examining tissue with a penlight or a portable slit lamp prior to enucleation or in situ removal?					R
E1.100	29	Concentration, volume of solution, and duration of ocular surface exposure to povidone iodine?					R, P
E1.100	30	Eye enucleation?				SO	R
E1.100	31	In situ corneoscleral disc removal?				SO	R
E1.210	32	Preserving whole eyes?				SO	R, P, S
E1.230	33	Preserving sclera?				SO	P, S
E1.221	34	Laboratory preservation of tissue?				SO	P, TE
E1.222, E1.223	35	Other tissue preparation (i.e. pre-cutting for EK, preparation for LAK, etc.)?				SO	P
E1.300	36	Storage solution that is manufactured in accordance with U.S. FDA Good Manufacturing Practices and stored in accordance with the manufacturer's recommendations?					R, P, S
E1.400	37	Long term tissue preservation?				SO	P, S, TE

A. Policies and Procedures Manual (continued)

			Yes	No	N/A	Tier PT/SO	
F1.100	38	A slit lamp examination of the whole eye prior to distribution for surgical use as a whole eye?					TE, DE, FD
F1.100	39	A slit lamp examination of the corneoscleral disc after excision?					P, TE, DE, FD
F1.100	40	Slit lamp examination following additional tissue preparation (i.e. for EK, LAK, etc.)?					P, TE, DE, FD
F1.200	41	Specular microscopic exam of corneas?					TE, DE, FD
F1.200	42	Specular microscopic exam of corneas following additional tissue preparation (i.e. for EK, LAK, etc.)?					P, TE, DE, FD
F1.200	43	Medical Director waiver of specular exam?					TE, DE
F1.300	44	Appropriate evaluation criteria to determine suitability of all tissues prepared by the bank (penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, keratolimbal allograft, and/or tectonic use)?					P, TE, DE
G1.000	45	Soliciting reports of adverse reactions from surgeons?					FD
G1.000	46	Adverse reaction reporting, investigating and implementing corrective actions as needed?				SO	DE, FD
G1.000	47	A quality assurance program which monitors and evaluates activities, identifies problems and develops plans for corrective action?				SO	ALL
G1.200	48	Reporting positive rim culture results to the transplanting surgeon or receiving eye bank?					FD
G1.300	49	Tissue recall or withdrawal?					DE, FD
H1.000	50	Biohazardous labeling of nonsurgical tissue that is not screened with infectious disease testing?					R, P, S, FD
I1.000	51	Storage conditions for surgical tissue?				SO	S, FD
J1.000	52	Labeling tissue?					R, P, S, FD
K1.300	53	A distribution policy that is just, equitable and fair for all patients served by the bank?					FD
K1.400	54	Documenting and sharing tissue transportation and storage information to distributing eye banks and transplanting surgeons for corneas returned and redistributed?					R, P, S, FD
K1.500	55	Investigating and reporting fraudulent activity in the distribution, shipping or labeling of tissue?					FD
L2.000	56	Packaging tissue individually and sealing it using a tamper-evident seal?					R, P, S, TE, FD
L2.000	57	Packaging transplantable corneal tissue to maintain cool conditions without freezing, and other tissues (e.g. sclera) with a method appropriate to the method of preservation used?				SO	R, P, S, TE, FD
M1.100	58	Keeping all donor records for a minimum of ten years from the date of transplantation/ implantation, distribution or whichever is longer?					ALL
M1.200	59	Maintaining records and communications between the eye bank and its donors and recipients as confidential and privileged?					ALL
M1.500	60	When the distributing bank, seeking 3-6 month post-operative outcome information?					FD
	61	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL
	62	Were at least 90% of applicable policies and procedures listed above in compliance with EBAA Medical Standards?				PT	ALL

Comments:

B. The Director

These questions should be answered by the eye bank director:			Yes	No	N/A	Tier PT/SO	
B1.200	63	Can the Director explain the eye bank's policy and procedure for reporting findings of inspections by official agencies?					ALL
K1.300	64	Can the Director accurately describe the tissue distribution system that is being used by the bank?					FD
C1.000 C2.000	65	Can the Director describe the training program?				SO	ALL
C1.200	66	Can the Director describe who is responsible for training at this bank?					ALL
C3.400	67	Can the Director name the processing procedures performed at this bank?					P
C3.400	68	Can the Director describe how the SOP's are reviewed and approved?					ALL
D1.400	69	Can the Director describe the bank's process for obtaining legal authorization for donation such as NOK consent, donor designation, ME Law?					R, DE
G1.000	70	Can the Director describe the quality assurance program at this bank and explain his/her duties and/or functions in the program?				PT	ALL
D1.230	71	Can the Director describe the method for handling positive / reactive results on a non-required test?					DE, FD
G1.000	72	Can the Director describe how complaints are handled at this bank?					ALL
G1.000	73	Can the Director explain the method for dealing with reports of adverse reactions at this bank?					ALL
G1.300	74	Can the Director explain the method for dealing with regulatory recalls and withdrawals at this bank?					ALL
D1.210-D1.220	75	Does the Director know what infectious disease testing is required to be performed on donor blood samples at this eye bank?					R, DE, FD
E1.300	76	Does the Director know what medium is used for cornea storage at this bank?					ALL
F1.200	77	Does the Director know the endothelial cell count lower limit that has been established for specular microscopy at this bank?					TE, DE
C1.300	78	Can the Director name the individuals who may determine suitability and release tissue for transplant?				SO	TE, DE
D1.110	79	Does the Director know that a donor cornea that had laser corneal refractive surgery is a contraindication for elective PKP surgery?					TE, DE, FD
D1.500	80	Does the Director know the age limits that have been established for tissue distribution at this bank?					DE, FD
C3.200	81	Does the Director know the temperature range required for tissue storage at this bank?					S, DE
M1.100	82	Can the Director explain the policy and procedure for donor file retention?					ALL
M1.500	83	Does the Director know the procedure for seeking post-operative outcome information on all donor tissue?					FD
	84	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

C. Medical Director

These questions should be answered by the Medical Director:			Yes	No	N/A	Tier PT/SO	
D1.210-D1.220	85	Does the Medical Director know what infectious disease testing is required to be performed on donor blood samples at this eye bank?				SO	DE
D1.230	86	Can the Medical Director describe the method for handling positive / reactive results on a non-required test?					DE
G1.000	87	Can the Medical Director describe the quality assurance program as described in the eye bank's P&P manual and explain his/her role in the program?				PT	ALL
C1.200 G1.000	88	Can the Medical Director describe the CAPA (Corrective and Preventative Actions) program performed at this bank?					ALL
C3.400	89	Can the Medical Director name the processing procedures performed at this bank?				SO	P
E1.300	90	Does the Medical Director know what medium is used for cornea storage?					ALL
E1.230	91	Does the Medical Director know the storage solution used to preserve sclera?					P
K1.300	92	Can the Medical Director accurately describe the tissue distribution system that is being used by the Eye Bank?					FD
G1.000	93	Can the Medical Director explain this eye bank's procedure for investigating, documenting and reporting an adverse reaction?				PT	ALL
G1.000	94	Can the Medical Director give examples of what constitutes an adverse reaction? (e.g. endophthalmitis, primary donor failure, keratitis, systemic disease.)				SO	ALL
C1.200 C2.000	95	Can the Medical Director describe the training program?					ALL
C1.200	96	Can the Medical Director describe who is responsible for training at this bank?					ALL
K1.100	97	Can the Medical Director name the individuals whom he/she has designated may review donor information to determine suitability of tissue for transplant?				SO	DE
D1.500	98	Does the Medical Director know the age limits that have been established for tissue distribution at this bank?					R, P, DE
E1.220	99	Can the Medical Director explain the procedure for corneoscleral disc removal as described in the P&P manual?				SO	R, P
E1.220-E1.223	100	Can the Medical Director explain the procedure for other tissue preparation (for EK, LAK) as described in the P&P manual?				SO	P
C3.200	101	Does the Medical Director know the temperature range required for corneal tissue storage at this bank?					ALL
C3.400	102	Can the Medical Director describe how the SOP's are reviewed and approved?					ALL
F1.200	103	Does the Medical Director know the endothelial cell count lower limit that has been established for specular microscopy at this bank?				SO	TE, DE
D1.110	104	Does the Medical Director know the parameters for distributing a cornea from a donor with previous cataract surgery established at this bank?				SO	TE, DE, FD
D1.200	105	Can the Medical Director describe the eye bank's policy for release of tissue for transplant to another eye bank without documentation of negative results of required infectious disease testing?				PT	DE, FD
	106	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

D. Quality Assurance Director

These questions shall be answered by the QA Director or the person(s) responsible for these functions:			Yes	No	N/A	Tier PT/SO	
G1.000	107	Can the QA Director describe the quality assurance program at this bank and explain his/her duties and/or functions in the program?				PT	ALL
C3.510 G1.000	108	Can the QA Director list and describe the types of audits (both internal and external) performed at this bank and their frequency?					ALL
D1.000	109	Can the QA Director explain the process of donor eligibility determination at this bank?				SO	DE
D1.000 K1.100	110	Can the QA Director list the individuals in their bank who have been designated by the Medical Director to review donor information to determine suitability of tissue for transplant?					DE
G1.000	111	Can the QA Director list the individuals at this bank that perform quality assurance activities / audits / functions?					ALL
C1.200 G1.000	112	Can the QA Director describe the Medical Director's responsibilities and involvement in the operations and review of the quality assurance program?				SO	ALL
G1.000	113	Can the QA Director describe the CAPA (Corrective and Preventative Actions) program performed at this bank?					ALL
G1.000	114	Can the QA Director explain their eye bank's procedure for the investigation, documentation and reporting of an adverse reaction?				SO	ALL
G1.000	115	Can the QA Director explain the difference between a reportable adverse reaction and a reportable biologic product deviation (error/accident) and give examples of each?					ALL
G1.000	116	Can the QA Director describe how complaints are handled by this bank?					ALL
G1.300	117	Can the QA Director describe how withdrawals / recalls are handled by this bank?				SO	ALL
	118	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

E. Technical Personnel & Procedures

These questions shall be answered by direct observation and interview of eye bank technical staff:			Yes	No	N/A	Tier PT/SO	
C1.300	119	If the facility performs any of the following functions: processing, evaluation, donor eligibility determination, and final distribution, do they employ at least one CEBT in a supervisory and training role?				SO	P, E, DE, FD
C1.300	120	If the facility performs recovery-only and/or storage only do they have a documented consultative relationship with a CEBT and with the accredited organization in which that CEBT is employed?				SO	R, S
C3.700	121	Did eye bank personnel describe appropriate disposal of ocular tissue?					R, P, S, DE, FD
D1.000	122	Did the technician(s) describe accurately the bank's procedure for physical inspection of the donor's body?				PT	R, DE
D1.110	123	Did the technician correctly describe the bank's policy for suitability of a cornea for transplantation if the donor had previous cataract surgery?				SO	TE, DE
D1.110	124	Did the technician correctly describe the bank's policy for use of tissue from a donor whose death was listed solely as cardiopulmonary arrest?					DE
E1.100	125	Did the technician describe the procedure for the pen light examination prior to recovery?					R
E1.100	126	Did the technician(s) describe the enucleation procedure accurately as written in the eye bank's procedure manual?				SO	R
E1.100	127	Did the technician(s) describe and/or perform the in situ corneal excision procedure accurately as written in the eye bank's procedure manual?				SO	R
E1.221	128	Did the technician(s) describe and/or perform the laboratory corneal excision procedure accurately as written in the eye bank's procedure manual?				SO	P
E1.222-E1.223	129	Did the technician(s) describe and/or perform the other tissue preparation procedure(s) accurately as written in the eye bank's procedure manual? (for EK, LAK, etc.)				SO	P
E1.220	130	Did the certified technician demonstrate corneal removal / lamellar tissue preparation according to the eye bank's written protocol?				SO	R, P
E1.220	131	Did the certified technician adequately demonstrate the aseptic and surgical techniques of the practical exam?				PT	R, P
E1.220	132	Did the non-certified technician demonstrate corneal removal / lamellar tissue preparation according to the eye bank's written protocol?				SO	R, P
E1.220	133	Did the non-certified technician adequately demonstrate the aseptic and surgical techniques of the practical exam?				PT	R, P
E1.230	134	Did a technician describe scleral preservation according to the eye bank's written procedure?				SO	P
E1.300	135	Did the technician describe the eye bank's procedure for inspection of all corneal storage solution and methods for storage?					R, P, S
F1.100	136	Did the technician describe the eye bank's tissue evaluation rating system by slit lamp biomicroscopy?				SO	TE
F1.100	137	Did the eye bank technician satisfactorily demonstrate the use of the slit lamp?				SO	TE
F1.200	138	Did the technician satisfactorily demonstrate the use of the specular microscope?				SO	TE
K1.400	139	Did the technician explain the eye bank's protocol for tissue that is returned and redistributed?					DE, FD
L2.000	140	Did the technician demonstrate packaging, sealing, and packing of tissue for transport as described in the eye bank's procedure manual?				SO	R, P, FD
L2.000	141	Was the tissue individually packaged and sealed with a tamper-evident seal?				SO	R, P, S, TE, FD
L2.000	142	Was the corneal tissue packed in a waterproof container to maintain cool conditions without freezing, i.e. with wet ice?				SO	R, FD
L2.000	143	Was the tissue packed so that the documentation accompanying tissue and tissue label do not become wet?				SO	R, FD
L1.000	144	Were the package insert and donor information forms included with the tissue?				SO	FD
	145	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

II. Laboratory and Equipment

These questions shall be answered following inspection of the laboratory, ***and satellite laboratories, if applicable:***

			Yes	No	N/A	Tier PT/SO	
C3.100	146	Is the laboratory located in a separate area or room dedicated only to eye bank laboratory procedures (i.e., upon inspection did the laboratory contain instruments or equipment used only for eyebanking activity)?				SO	R, P, S, TE, FD
C3.100	147	Was there satisfactory evidence that access to the eye bank laboratory is limited to authorized personnel?				SO	R, P, S, TE, FD
C3.100	148	Does the laboratory have a sink with a drain and running water?					R, P, S, TE, FD
C3.100	149	Are the walls, counter tops, and sink clean?				SO	R, P, S, TE, FD
C3.600	150	Are hazardous chemicals properly stored and labeled according to OSHA or other applicable regulations?					R, P, S, TE, FD
C3.200	151	Does the laboratory contain a refrigerator solely for storage of tissue, preservation media and items related to tissue banking functions?				SO	R, P, S, TE, FD
C3.200	152	Does the refrigerator have a device, visible without opening the refrigerator, for recording temperature variations?				SO	R, P, S, TE, FD
C3.200	153	Does the temperature recording device reflect the temperature of the stored tissue under normal storage conditions?				SO	R, P, S, TE, FD
C3.200	154	Are areas of the refrigerator clearly labeled according to use (i.e., quarantined tissue, surgical tissue awaiting distribution, research tissue)?				SO	R, P, S, TE, FD
C3.200	155	Is the refrigerator served by an operational alarm system that will notify someone in the event of a temperature deviation outside the acceptable range?				PT	R, P, S, TE, FD
E1.200	156	Does the bank perform tissue processing in an acceptable environment (ISO Class 5 LFH, operating room, etc.) per Medical Standards?				PT	P
C3.300	157	Is there adequate instrumentation for sterile ocular tissue recovery and processing?					R, P
C3.300	158	Are instruments functional and well maintained, i.e., absence of rust?					R, P
C3.300	159	Are all sterile instruments and assembled kits labeled with an expiration date that has not yet passed or packaged consistent with an event related sterilization policy?				SO	R, P
C3.300	160	Are all supplies and reagents within the expiration dates on the label, if applicable?				SO	R, P
C3.600	161	Are there Safety Data Sheets available per OSHA or other applicable regulations?					R, P, S, TE, FD
C3.600	162	Are personal protective equipment (e.g., gloves and eye wear) and a puncture resistant sharps box available in the laboratory?				SO	R, P, S, TE, FD
C3.600	163	Is there evidence that the puncture resistant sharp instrument disposal container is changed before reaching the fill line?					R, P, S, TE, FD
C3.700	164	Are there biohazard disposal bags available for use?					R, P, S, TE, FD
C3.700	165	Is the trash can in the laboratory free of biohazardous materials and sharps?					R, P, S, TE, FD
E1.300	166	Is there evidence that storage solution was inspected for damage upon arrival?				SO	R, P, S
E1.300	167	Is all storage solution stored according to manufacturer's guidelines and unexpired at the time of inspection? If not, is it labeled as such and stored separately?				SO	R, P, S
F1.100	168	Is there a functional slit lamp for tissue evaluation in the laboratory or nearby?				SO	P, TE
F1.200	169	Is there a functional specular microscope for tissue evaluation in the laboratory or nearby?				SO	P, TE
H1.000	170	Does untested research tissue have an appropriate biohazard label?				SO	R, P, S, TE, FD
	171	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

PT = Potential Threat
SO = Significant Observation

Inspectors Initials: _____

III. Records

These questions are answered following the record review. ***Include records from all satellites, if applicable.***

			Yes	No	N/A	Tier PT/SO	
C1.100	172	Is there documentation that the Director consulted with the Medical Director to address routine medical operations?					ALL
C1.200	173	Is there documentation that the Medical Director participated in the oversight and training of technical staff?				SO	ALL
C1.300	174	Is there a written statement from the Medical Director or Medical Director designee specifying which procedures each individual staff member is qualified to perform independently, including determination of suitability and release of tissue for transplant?				SO	ALL
C2.000	175	Can the Director produce documentation that employees performing eye bank functions attended an orientation/training program when first hired?					ALL
C2.000	176	Is there documentation of annual competency reviews of skills and job-related knowledge for all employees and non-employees performing eye bank functions?				SO	ALL
C1.200	177	Do the annual competency reviews include the Medical Director's or Staff Trainer's observation of all staff who perform in-situ or C/S rim removal, posterior lamellar preparation, laser assisted processing or other manual dissections?				SO	R, P
C1.200	178	If a Staff Trainer observes all staff performing skills outlined in the previous question, has the Trainer been observed annually by the Medical Director?				SO	R, P
C2.000	179	Is the person conducting the annual competency reviews for all remaining skills a CEBT or an individual who has been qualified by a CEBT who is part of the organization's comprehensive quality program?				SO	ALL
C3.200	180	Is there documentation that the refrigerator is cleaned according to the eye bank's policy and procedure manual?					R, P, S, TE, FD
C3.200	181	Is there written documentation that the continuous temperature recorder is calibrated at least annually against a NIST thermometer?					R, P, S, TE, FD
C3.200	182	Is there written documentation that the refrigerator alarm system is tested on a regular basis?					R, P, S, TE, FD
C3.200	183	Does a review of temperature readings from the previous year(s) include documentation that the quality of the storage solution and/or tissue was maintained even if the temperature deviated outside of 2-8 C?				SO	R, P, S, TE, FD
C3.200	184	If there was evidence of refrigerator malfunction, was there documentation of corrective action (i.e., service or purchase of a new refrigerator)?				SO	R, P, S, TE, FD
C3.200 E1.100	185	Is there documentation that the tissue processing environment (LFH, OR, processing room) is cleaned according to the eye bank's policy and procedure manual?				SO	P
F1.200	186	Is there documentation of annual calibration of endothelial cell couting equipment?					R, P, S, TE
C3.300	187	Was there documentation that the autoclave(s) was tested per the most current version of ANSI/AAMI Standard 79? If an outside laboratory was used, was there documentation that quality control is maintained at that facility?				SO	ALL
C3.400	188	Is each procedure in the P&P dated according to the time frames the procedures were in use? For example, are revision dates noted or is the manual dated in a way that identifies the date the procedures therein were put into practice?					ALL
C3.500	189	If the facility performs specialized or specific eye banking functions, does it have a Medical Director or access to a Medical Director through a documented consultative relationship with an accredited organization?				PT	ALL
C3.510	190	If the eye bank uses eye banking services from another establishment, does it have 1. documentation of the establishment's EBAA accreditation certificate and status; OR 2. documentation that the establishment is in compliance with EBAA Medical Standards, state and federal regulations appropriate to their function(s), including a written agreement, a documented compliance audit plan, and documentation of audits performed?				PT	ALL
C3.600	191	Can the Director produce written evidence that technicians attended an annual inservice or received self-study materials annually on Infection Control/Safety and OSHA or other applicable regulations?					ALL
G1.000	192	Does the QA program include a review by an individual not regularly involved in procedures being monitored?				SO	ALL
G1.000	193	Does the QA program include routine audits of donor charts?				SO	DE
D1.220	194	Does the QA program include documentation of continuous CLIA certification and FDA Registration for testing labs utilized since last audit?					DE
G1.000	195	Does the QA program include routine review of environmental control and equipment maintenance?					R, P, S, TE
G1.000	196	Does the QA program include documentation of corrective actions taken?					ALL

III. Records (continued)

			Yes	No	N/A	Tier PT/SO	
C1.200	197	Does the QA program include participation by the Medical Director in establishment of operations and review of the QA program?				PT	ALL
G1.000	198	Have all potential adverse reactions reported since the last inspection been documented, investigated and reported to EBAA, if applicable?				PT	ALL
G1.000	199	Is there written documentation that the Medical Director has reviewed all adverse reactions that were reported since the last site inspection, evaluated the potential causes of those adverse reactions, and taken corrective actions (if indicated) to prevent future occurrences of similar events?				PT	ALL
K1.000	200	Is there documentation that the distribution system described in the Procedures Manual is being followed?					FD
K1.300	201	Is there documentation of tissue that is offered?					FD
L1.100	202	Does the tissue report form include all of the following? (Check missing items)				SO	FD
		Unique ISBT 128 Tissue Identifier					
		Name of source eye bank					
		Location of eye bank					
		Telephone number					
		Type of storage solution					
		All dates and times written as YYYY-MM-DD HH:MM					
		Pre-cut method performed or the indicated use (e.g. EK, PLK, ALK, etc.) (if applicable)					
		Tissue evaluation reporting requirements according to Matrix II					
		Age of donor					
		Cause of Death					
		Death date and time					
		Preservation date and time					
		Additional tissue processing date and time					
		Date and time of cooling of ocular tissues					
		Slit lamp report					
		Specular microscopy report					
		Identification of enucleator, evaluator, and technicians					
		Name and EBAA accreditation status (including accredited functions) of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, tissue storage, evaluation, donor eligibility determination, and final distribution					
		Summary of records reviewed in determining suitability					
L1.200	203	Does the package insert form include all of the following? (Check missing items)				SO	FD
		Recommended storage temperature with emphasis on DO NOT FREEZE					
		Note to check integrity of seal and report possible tampering					
		Note to check for color change in storage solution					
		Advisement regarding performance of cultures and microbiologic results, if applicable					
		Statement that the tissue is delivered with no warranty and that surgeon is ultimately responsible for its use					
		Advisement that consignee is responsible for tracking of recipient name, unique ID#, age and/or DOB, date/type/location of sx, name of transplanting surgeon and ISBT 128 Tissue Identifier					
		Statement that infectious disease testing is performed by CLIA certified and FDA Registered lab					
		Statement that approved infectious disease tests for cadaveric blood are used when applicable.					
		A list of infectious disease test results for that specific donor.					

Comments:

III. Records (continued)

Note: The Donor / Recipient Record Review Summary must be completed prior to answering the following questions.

			Yes	No	N/A	Tier PT/SO	
M1.100	204	Is there evidence that donor file retention is being appropriately followed ?					DE
M1.400		Did 90% or more of the donor records reviewed contain the following? (Check items that fall below 90% compliance)					
	205	Eye bank identification including name, telephone number, and location					DE
	206	Unique ISBT 128 Tissue Identifier(s)					DE
	207	Name of source eye bank and source eye bank's unique tissue number for imported tissue					DE, FD
	208	Age of donor					DE
	209	Cause of death, physical inspection of body, results of medical record review and social history interview, and indication of whether an autopsy was performed and gross results, and medical examiner/coroner investigation records (if applicable).				PT	DE
	210	Date and time of death, enucleation, preservation, additional processing and cooling of ocular tissues and/or refrigeration to the body				SO	DE
	211	Copy of legal authorization for donation (D1.400)					DE
	212	Documentation of review of negative results for all required infectious disease tests from a non plasma diluted blood sample recorded on tissue information form or other form which accompanies the tissue				PT	DE
	213	Printed results of any additional non-EBAA required infectious disease screening tests					DE
	214	Indication of review and sign-off by medical director or designee (D1.000)				SO	DE
	215	Unique ISBT 128 Tissue Identifier for each tissue graft					DE
	216	Slit lamp evaluation results				PT	DE
	217	Specular microscopy results				SO	DE
	218	Results of donor cultures (if performed)					DE
	219	Type of storage solution used and lot #					ALL
	220	Transportation and storage information for tissue that has been returned and redistributed (K1.400)					DE, FD
	221	Date, time, method of transportation					FD
	222	Name of person(s) performing tissue recovery/preservation procedures and tissue evaluation					FD
	223	Utilization of tissue: i.e. surgical, research, training					FD
	224	Name of surgeon or consignee receiving tissue				SO	FD
	225	Evidence of traceability from donor to consignee for each unique graft number				SO	FD
	226	Adverse reactions if reported				SO	DE, FD
M1.500		Did 90% or more of the recipient records reviewed contain documentation that the following information was present or sought? (Check items that fall below 90% compliance)					FD
	227	Name of transplanting surgeon					FD
	228	Name of recipient					FD
	229	Unique recipient I.D. number					FD
	230	Age and/or date of birth of recipient					FD
	231	Recipient's diagnosis					FD
	232	Date of surgery					FD
	233	Location of surgery					FD
	234	Type of surgery performed					FD
	235	Documentation of follow up request for post-operative outcome information.					FD
M1.600	236	Did the eye bank submit statistics to the EBAA in accordance with the policy established by the EBAA Board of Directors? *(Evidence of submission will be provided to inspectors by the EBAA office)*					DE
	237	For all of the above questions which were answered 'NO' on this site inspection, ***was the eye bank in compliance at the time of the last inspection***? (Mark N/A if no questions answered "NO".) Please indicate any items were repeatedly non-compliant in the 'Comments' section below **and mark with an "X" on the Summation Report**.					ALL

Comments:

PT = Potential Threat
SO = Significant Observation

Inspectors Initials: _____