SITE INSPECTION QUESTIONNAIRE

Section 1. Pre-Inspection Materials

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

			Yes	No	N/A	Tier PT/SO
D1.200	1-A	Applicable information for all INFECTIOUS DISEASE TESTING providers utilized since last inspection? (***Worksheet 1-A***)				
C3.300, C3.510, C3.700	1-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? (***Worksheet 1-B***)				
C1.300, C2.000	1-C	Acceptable information for NON-EMPLOYEES providing recovery, preservation and/or processing services utilized since last inspection? (***Worksheet 1-C***)				
C1.100-C1.300	2-A	Completed information provided for authorized staff? (***Worksheet 2-A***)				
C1.300	2-B	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**
C2.000	2-C	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**
C1.200	2-D	Observation of Staff Trainer annually by the Medical Director?				**SO**
C1.200	3-A	Name of Medical Director?				
C1.200	3-B	Qualifications of Medical Director?				
C1.200	3-C	Name and qualifications of back-up Medical Director?				
C1.300	3-D	Documentation of Medical Director CEBT?				
C3.500	3-E	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**
C1.200	4-A	Valid EBAA provided documentation of Medical Director attendance, within the past three years, at a Medical Director Symposium and a Medical Advisory Board Meeting?				**SO**
C1.300	4-B	Valid CEBT certificate covering each year since last inspection?				
B1.000	4-C	Valid copy of FDA registration for each year since last inspection?				
C3.200	4-D	Valid annual certificate for Processing Environment(s) per MS E1.200 for each year since last inspection?				
C3.200	4-E	Valid documentation that the continuous temperature recorder has been calibrated at least annually against a NIST thermometer for each year since last inspection?				
F1.200	4-F	Valid documentation of annual calibration of endothelial cell counting equipment for each year since last inspection?				
J1.000	4-G	Sample labels submitted for all tissue distributed?				
B1.000	4-H	Documentation of ICCBBA registration for FIN.				
J1.000	5	Does the numbering system provide for a unique ISBT 128 Tissue Identifier for each surgical tissue or fraction thereof?				
D1.200	6	Was the plasma dilution worksheet / algorithm problem solved correctly?				**SO**
M1.300-M1.500	7-A	Attached sample forms used to record donor and recipient information?				
L1.100	7-B	Does the Tissue Report Form include all of the following? (Check missing items)				**SO**
		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 <u>each</u> 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				

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Section 1 - Pre-Inspection Materials (continued)

			Yes	No	N/A	Tier PT/SO
L1.200	7-C	Does the Package Insert form include all of the following? (Check missing items)				**SO**
		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.				
B1.200	8	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**
	9	Was the eye bank's manual, tabbing and/or crosswalk, and "Declaration of Compliance with Governmental Regulations" received at least 20 working days prior to the scheduled inspection?				**SO**
	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**.				

Comments:

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Section 2 - 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**
B1.200	1	Reporting requirements following inspections by official agencies?				
C2.000	2	An orientation program for new employees performing eye bank functions?				
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?				
C2.000	4	Documentation of annual competency reviews of skills and job related knowledge for all employees and non-employees performing eye bank functions?				
C3.200	5	Monitoring, inspection and cleaning procedures and schedules for each piece of equipment?				
C3.200	6	Requiring testing of the refrigerator alarm system on a regular basis?				
C3.600	7	Utilizing Standard Precautions according to applicable regulatory requirements?				
C3.600	8	An exposure control plan that meets OSHA or other applicable regulatory requirements (i.e. reporting needlestick injuries)?				
C3.700	9	Disposing of biohazardous waste?				
D1.000	10	Physical inspection of the donor with special attention to physical signs of HIV disease, infectious hepatitis and injecting drug use?				**SO**
D1.000	11	Routine examination and documentation of prospective donors' medical records and death investigation?				
D1.000	12	Obtaining a medical and social history of each donor?				
D1.000	13	Adequate documentation of donor information/completion of donor files, including medical examiner reports and gross autopsy results?				
D1.100	14	Screening for and listing of exclusion criteria listed in EBAA Medical Standards Section D1.100?				**SO**
D1.200	15	Obtaining donor sample for infectious disease testing?				
D1.200	16	Infectious disease (and microbiological, if applicable) testing performed by CLIA certified and FDA registered laboratories?				
D1.200-D1.220	17	Screening by infectious disease testing in accordance with EBAA Medical Standards and all applicable federal and state laws?				**SO**
D1.200	18	Calculating the plasma dilution status of a donor?				**SO**
D1.200	19	Not releasing tissue designated for surgical use without documentation of required negative infectious disease testing				**SO**
D1.230	20	Handling laboratory reports of non-required tests, whether received before or after tissue distribution?				
D1.300	21	Obtaining a unique identifying number for each donor?				
D1.400	22	Obtaining legal authorization for eye tissue donation consistent with EBAA Medical Standards, federal law, and state law?				
D1.500	23	Donor age exclusion criteria?				
D1.600	24	Recording date and time of death, enucleation,preservation, additional processing and cooling of ocular tissues for each donor?				
D1.700	25	Eye maintenance prior to ocular tissue removal procedures?				
E1.000	26	Detailing aseptic technique for recovery, processing and preservation?				**SO**
E1.100	27	Special handling of tissue that is hazardous to eye bank personnel (active viral hepatitis, AIDS, HIV seropositivity, etc.)?				
E1.100	28	Examining tissue with a penlight or a portable slit lamp prior to enucleation or in situ removal?				
E1.100	29	Concentration, volume of solution, and duration of ocular surface exposure to povidone iodine?				
E1.100	30	Eye enucleation?				**SO**
E1.100	31	In situ corneoscleral disc removal?				**SO**
E1.210	32	Preserving whole eyes?				**SO**
E1.230	33	Preserving sclera?				**SO**
E1.221	34	Laboratory preservation of tissue?				**SO**
E1.222, E1.223	35	Other tissue preparation (i.e. pre-cutting for EK, preparation for LAK, etc.)?				**SO**
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?				
E1.400	37	Long term tissue preservation?				**SO**

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Section 2 - 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?				
F1.100	39	A slit lamp examination of the corneoscleral disc after excision?				
F1.100	40	Slit lamp examination following additional tissue preparation (i.e. for EK, LAK, etc.)?				
F1.200	41	Specular microscopic exam of corneas?				
F1.200	42	Specular microscopic exam of corneas following additional tissue preparation (i.e. for EK, LAK, etc.)?				
F1.200	43	Medical Director waiver of specular exam?				
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)?				
G1.000	45	Soliciting reports of adverse reactions from surgeons?				
G1.000	46	Adverse reaction reporting, investigating and implementing corrective actions as needed?				**SO**
G1.000	47	A quality assurance program which monitors and evaluates activities, identifies problems and develops plans for corrective action?				**SO**
G1.200	48	Reporting positive rim culture results to the transplanting surgeon or receiving eye bank?				
G1.300	49	Tissue recall or withdrawal?				
H1.000	50	Biohazardous labeling of nonsurgical tissue that is not screened with infectious disease testing?				
I1.000	51	Storage conditions for surgical tissue?				**SO**
J1.000	52	Labeling tissue?				
K1.300	53	A distribution policy that is just, equitable and fair for all patients served by the bank?				
K1.400	54	Documenting and sharing tissue transportation and storage information to distributing eye banks and transplanting surgeons for corneas returned and redistributed?				
K1.500	55	Investigating and reporting fraudulent activity in the distribution, shipping or labeling of tissue?				
L2.000	56	Packaging tissue individually and sealing it using a tamper-evident seal?				
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**
M1.100	58	Keeping all donor records for a minimum of ten years from the date of transplantation/ implantation, distribution or whichever is longer?				
M1.200	59	Maintaining records and communications between the eye bank and its donors and recipients as confidential and privileged?				
M1.500	60	Seeking recipient information?				
M1.500	61	When the distributing bank, seeking 3-6 month post-operative outcome information?				
	62	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**.				
	63	Were at least 90% of applicable policies and procedures listed above in compliance with EBAA Medical Standards?				**PT**

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Section 3 - The Director

These questions should be answered by the eye bank director:			Yes	No	N/A	Tier PT/SO
B1.200	64	Can the Director explain the eye bank's policy and procedure for reporting findings of inspections by official agencies?				
K1.300	65	Can the Director accurately describe the tissue distribution system that is being used by the bank?				
C1.000 C2.000	66	Can the Director describe the training program?				**SO**
C1.200	67	Can the Director describe who is responsible for training at this bank?				
C3.400	68	Can the Director name the processing procedures performed at this bank?				
C3.400	69	Can the Director describe how the SOP's are reviewed and approved?				
D1.400	70	Can the Director describe the bank's process for obtaining legal authorization for donation such as NOK consent, donor designation, ME Law?				
G1.000	71	Can the Director describe the quality assurance program at this bank and explain his/her duties and/or functions in the program?				**PT**
D1.230	72	Can the Director describe the method for handling positive / reactive results on a non-required test?				
G1.000	73	Can the Director describe how complaints are handled at this bank?				
G1.000	74	Can the Director explain the method for dealing with reports of adverse reactions at this bank?				
G1.300	75	Can the Director explain the method for dealing with regulatory recalls and withdrawals at this bank?				
D1.210-D1.220	76	Does the Director know what infectious disease testing is required to be performed on donor blood samples at this eye bank?				
F1.200	77	Does the Director know the endothelial cell count lower limit that has been established for specular microscopy at this bank?				
C1.300	78	Can the Director name the individuals who may determine suitability and release tissue for transplant?				**SO**
D1.110	79	Does the Director know the suitability of a cornea that had prior laser corneal refractive surgery?				
D1.500	80	Does the Director know the age limits that have been established for tissue distribution at this bank?				
M1.100	81	Can the Director explain the policy and procedure for donor file retention?				
M1.500	82	Does the Director know the procedure for seeking post-operative outcome information on all donor tissue?				
	83	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**.				

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Section 4 - Medical Director

These questions should be answered by the Medical Director:			Yes	No	N/A	Tier PT/SO
D1.210-D1.220	84	Does the Medical Director know what infectious disease testing is required to be performed on donor blood samples at this eye bank?				SO
D1.230	85	Can the Medical Director describe the method for handling positive / reactive results on a non-required test?				
G1.000	86	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
C1.200 G1.000	87	Can the Medical Director describe the CAPA (Corrective and Preventative Actions) program performed at this bank?				
C3.400	88	Can the Medical Director name the processing procedures performed at this bank?				SO
E1.300	89	Does the Medical Director know what medium is used for cornea storage?				
E1.230	90	Does the Medical Director know the storage solution used to preserve sclera?				
K1.300	91	Can the Medical Director accurately describe the tissue distribution system that is being used by the Eye Bank?				
G1.000	92	Can the Medical Director explain this eye bank's procedure for investigating, documenting and reporting an adverse reaction?				PT
G1.000	93	Can the Medical Director give examples of what constitutes an adverse reaction? (e.g. endophthalmitis, primary donor failure, keratitis, systemic disease.)				SO
C1.200 C2.000	94	Can the Medical Director describe the training program?				
C1.200	95	Can the Medical Director describe who is responsible for training at this bank?				
K1.100	96	Can the Medical Director name the individuals whom he/she has designated may review donor information to determine suitability of tissue for transplant?				SO
D1.500	97	Does the Medical Director know the age limits that have been established for tissue distribution at this bank?				
E1.220	98	Can the Medical Director explain the procedure for corneoscleral disc removal as described in the P&P manual?				SO
E1.220-E1.223	99	Can the Medical Director explain the procedure for other tissue preparation (for EK, LAK) as described in the P&P manual?				SO
C3.200	100	Does the Medical Director know the temperature range required for corneal tissue storage at this bank?				
C3.400	101	Can the Medical Director describe how the SOP's are reviewed and approved?				
F1.200	102	Does the Medical Director know the endothelial cell count lower limit that has been established for specular microscopy at this bank?				SO
D1.110	103	Does the Medical Director know the parameters for distributing a cornea from a donor with previous cataract surgery established at this bank?				SO
D1.200	104	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
	105	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**.				

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Section 5 - 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	106	Can the QA Director describe the quality assurance program at this bank and explain his/her duties and/or functions in the program?				**PT**
C3.510 G1.000	107	Can the QA Director list and describe the types of audits (both internal and external) performed at this bank and their frequency?				
D1.000	108	Can the QA Director explain the process of donor eligibility determination at this bank?				**SO**
D1.000 K1.100	109	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?				
G1.000	110	Can the QA Director list the individuals at this bank that perform quality assurance activities / audits / functions?				
C1.200 G1.000	111	Can the QA Director describe the Medical Director's responsibilities and involvement in the operations and review of the quality assurance program?				**SO**
G1.000	112	Can the QA Director describe the CAPA (Corrective and Preventative Actions) program performed at this bank?				
G1.000	113	Can the QA Director explain their eye bank's procedure for the investigation, documentation and reporting of an adverse reaction?				**SO**
G1.000	114	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?				
G1.000	115	Can the QA Director describe how complaints are handled by this bank?				
G1.300	116	Can the QA Director describe how withdrawals / recalls are handled by this bank?				**SO**
	117	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**.				

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Section 6 - Technical Personnel & Procedures

These questions shall be answered by direct observation and interview of appropriate eye bank technical staff:			Yes	No	N/A	Tier PT/SO
C1.300	118	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**
C1.300	119	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**
C3.700	120	Did eye bank personnel describe appropriate disposal of ocular tissue?				
D1.000	121	Did the technician(s) describe accurately the bank's procedure for physical inspection of the donor's body?				**PT**
D1.110	122	Did the technician correctly describe the bank's policy for suitability of a cornea for transplantation if the donor had previous cataract surgery?				**SO**
D1.110	123	Did the technician correctly describe the bank's policy for use of tissue from a donor whose death was listed solely as cardiopulmonary arrest?				
E1.100	124	Did the technician describe the procedure for the pen light examination prior to recovery?				
E1.100	125	Did the technician(s) describe the enucleation procedure accurately as written in the eye bank's procedure manual?				**SO**
E1.100	126	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**
E1.221	127	Did the technician(s) describe and/or perform the laboratory corneal excision procedure accurately as written in the eye bank's procedure manual?				**SO**
E1.222-E1.223	128	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**
E1.220	129	Did the certified technician demonstrate corneal removal / lamellar tissue preparation according to the eye bank's written protocol?				**SO**
E1.220	130	Did the certified technician adequately demonstrate the aseptic and surgical techniques of the practical exam?				**PT**
E1.220	131	Did the non-certified technician demonstrate corneal removal / lamellar tissue preparation according to the eye bank's written protocol?				**SO**
E1.220	132	Did the non-certified technician adequately demonstrate the aseptic and surgical techniques of the practical exam?				**PT**
E1.230	133	Did a technician describe scleral preservation according to the eye bank's written procedure?				**SO**
E1.300	134	Did the technician describe the eye bank's procedure for inspection of all corneal storage solution and methods for storage?				
F1.100	135	Did the technician describe the eye bank's tissue evaluation rating system by slit lamp biomicroscopy?				**SO**
F1.100	136	Did the eye bank technician satisfactorily demonstrate the use of the slit lamp?				**SO**
F1.200	137	Did the technician satisfactorily demonstrate the use of the specular microscope?				**SO**
K1.400	138	Did the technician explain the eye bank's protocol for tissue that is returned and redistributed?				
L2.000	139	Did the technician demonstrate packaging, sealing, and packing of tissue for transport as described in the eye bank's procedure manual?				**SO**
L2.000	140	Was the tissue individually packaged and sealed with a tamper-evident seal?				**SO**
L2.000	141	Was the corneal tissue packed in a waterproof container to maintain cool conditions without freezing, i.e. with wet ice?				**SO**
L2.000	142	Was the tissue packed so that the documentation accompanying tissue and tissue label do not become wet?				**SO**
L1.000	143	Were the package insert and donor information forms included with the tissue?				**SO**
	144	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**.				

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Section 7 - 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	145	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**
C3.100	146	Was there satisfactory evidence that access to the eye bank laboratory is limited to authorized personnel?				**SO**
C3.100	147	Does the laboratory have a sink with a drain and running water?				
C3.100	148	Are the walls, counter tops, and sink clean?				**SO**
C3.600	149	Are hazardous chemicals properly stored and labeled according to OSHA or other applicable regulations?				
C3.200	150	Does the laboratory contain a refrigerator solely for storage of tissue, preservation media and items related to tissue banking functions?				**SO**
C3.200	151	Does the refrigerator have a device, visible without opening the refrigerator, for recording temperature variations?				**SO**
C3.200	152	Does the temperature recording device reflect the temperature of the stored tissue under normal storage conditions?				**SO**
C3.200	153	Are areas of the refrigerator clearly labeled according to use (i.e., quarantined tissue, surgical tissue awaiting distribution, research tissue)?				**SO**
C3.200	154	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**
E1.200	155	Does the bank perform tissue processing in an acceptable environment (ISO Class 5 LFH, operating room, etc.) per Medical Standards?				**PT**
C3.300	156	Is there adequate instrumentation for sterile ocular tissue recovery and processing?				
C3.300	157	Are instruments functional and well maintained, i.e., absence of rust?				
C3.300	158	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**
C3.300	159	Are all supplies and reagents within the expiration dates on the label, if applicable?				**SO**
C3.600	160	Are there Safety Data Sheets available per OSHA or other applicable regulations?				
C3.600	161	Are personal protective equipment (e.g., gloves and eye wear) and a puncture resistant sharps box available in the laboratory?				**SO**
C3.600	162	Is there evidence that the puncture resistant sharp instrument disposal container is changed before reaching the fill line?				
C3.700	163	Are there biohazard disposal bags available for use?				
C3.700	164	Is the trash can in the laboratory free of biohazardous materials and sharps?				
E1.300	165	Is there evidence that storage solution was inspected for damage upon arrival?				**SO**
E1.300	166	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**
F1.100	167	Is there a functional slit lamp for tissue evaluation in the laboratory or nearby?				**SO**
F1.200	168	Is there a functional specular microscope for tissue evaluation in the laboratory or nearby?				**SO**
H1.000	169	Does untested research tissue have an appropriate biohazard label?				**SO**
	170	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**.				

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Section 8 - 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	171	Is there documentation that the Director consulted with the Medical Director to address routine medical operations?				
C1.200	172	Is there documentation that the Medical Director participated in the oversight and training of technical staff?				**SO**
C2.000	173	Can the Director produce documentation that employees performing eye bank functions attended an orientation/training program when first hired?				
C2.000	174	Is there documentation of annual competency reviews of skills and job-related knowledge for all employees and non-employees performing eye bank functions?				**SO**
C1.200	175	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**
C3.200	176	Is there documentation that the refrigerator is cleaned according to the eye bank's policy and procedure manual?				
C3.200	177	Is there written documentation that the refrigerator alarm system is tested on a regular basis?				
C3.200	178	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**
C3.200	179	If there was evidence of refrigerator malfunction, was there documentation of corrective action (i.e., service or purchase of a new refrigerator)?				**SO**
C3.200 E1.100	180	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**
C3.300	181	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**
C3.400	182	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?				
C3.510	183	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**
C3.600	184	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?				
G1.000	185	Do QA Records demonstrate review by an individual not regularly involved in procedures being monitored?				**SO**
G1.000	186	Do QA Records demonstrate routine audits of donor charts?				**SO**
G1.000	187	Do QA Records demonstrate routine review of environmental control and equipment maintenance?				
G1.000	188	Do QA Records demonstrate documentation of corrective actions taken?				

PT = Potential Threat
SO = Significant Observation

Section 8 - Records (continued)

			Yes	No	N/A	Tier PT/SO
C1.200	189	Do QA Records demonstrate participation by the Medical Director in establishment of operations and review of the QA program?				PT
G1.000	190	Have all potential adverse reactions reported since the last inspection been documented, investigated and reported to EBAA, if applicable?				PT
G1.000	191	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
K1.000	192	Is there documentation that the distribution system described in the Procedures Manual is being followed?				

Comments:

Section 8 - 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	193	Is there evidence that donor file retention is being appropriately followed ?				
M1.400		Did 90% or more of the donor records reviewed contain the following? (Check items that fall below 90% compliance)				
	194	Eye bank identification including name, telephone number, and location				
	195	Unique Donor Identifying # (SSN, Med Rec, etc)				
	196	Name of source eye bank and source eye bank's unique tissue number for imported tissue				
	197	Age or Date of Birth of donor				
	198	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**
	199	Date and time of death, enucleation, preservation, additional processing and cooling of ocular tissues and/or refrigeration to the body				**SO**
	200	Copy of legal authorization for donation (D1.400)				
	201	Documentation of review of negative results for all applicable required infectious disease tests from a non plasma diluted blood sample recorded on tissue information form or other form which accompanies the tissue				**PT**
	202	Printed results of any additional non-EBAA required infectious disease screening tests				
	203	Indication of review and sign-off by medical director or designee (D1.000)				**SO**
	204	Unique ISBT 128 Tissue Identifier for each tissue graft				
	205	Slit lamp evaluation results				**PT**
	206	Specular microscopy results				**SO**
	207	Results of donor cultures (if performed)				
	208	Type of storage solution used and lot #				
	209	Transportation and storage information for tissue that has been returned and redistributed (K1.400)				
	210	Date, time, method of transportation				
	211	Name of person(s) performing tissue recovery/preservation procedures and tissue evaluation				
	212	Utilization of tissue: i.e. surgical, research, training				
	213	Name of surgeon or consignee receiving tissue				**SO**
	214	Evidence of traceability from donor to consignee for each unique graft number				**SO**
	215	Adverse reactions if reported				**SO**
M1.500	216	Documentation that recipient information was sought?				
	217	Documentation of follow up request for post-operative outcome information.				
M1.600	218	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)*				
	219	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**.				

Comments:

PT = Potential Threat
SO = Significant Observation