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SECTION K
QUALITY ASSURANCE

K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a *QA program*.

K1.100 Basic Elements

The *QA program shall* include, at a minimum:

1) designating and managing *quality control* functions, including:

   a) environmental monitoring at designated intervals;

   b) performing periodic equipment and facility inspections and documenting in maintenance *records* or logs;

   c) reviewing equipment monitoring *records* for maintenance within specified *tolerance limits,* and reviewing *records* of other equipment or *processing* functions that have specified *tolerance limits*;

   d) inspecting and monitoring *in-process control* results, including collection and testing of representative samples;

   e) performing *qualification* of reagents, supplies, materials, instruments, or equipment when deemed *critical* or applicable; and

   f) monitoring laboratory performance, if applicable.

2) performing *process validation* studies when the results of a process cannot be fully *verified* by subsequent inspection and test. Each *tissue bank shall* establish and maintain *procedures* for monitoring and controlling process parameters for *validated* processes to ensure that the specified requirements continue to be met. Each *tissue bank shall* ensure that *validated* processes are performed by qualified individual(s). For *validated* processes, each *tissue bank shall* document the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process and the major equipment used. When changes or process deviations occur, the *tissue bank shall* review and evaluate the process and perform *revalidation* where appropriate, and *shall* document these activities.

3) performing equipment *qualification studies* as necessary;

4) establishing purchasing controls;

5) establishing procedures for implementing *corrective action* and *preventive action* and taking

action when appropriate. The *procedures shall* include requirements for:

a) analyzing processes, work operations, concessions, *quality audit reports, quality records, errors, accidents, complaints*, returns, and other sources of *quality* data to identify existing and potential causes of *nonconforming tissue*, or other *quality* problems. Appropriate statistical methodology *shall* be employed where necessary to detect recurring *quality* problems;

b) investigating the cause of *nonconformities* relating to *tissue*, processes, and the *quality system*;

c) identifying the action(s) needed to correct and prevent recurrence of *quality* problems;

d) *verifying* or *validating* the *corrective action* and *preventive action* to ensure that such action is effective and does not adversely affect the *finished tissue*;

e) implementing and *recording* changes in methods and *procedures* needed to correct and prevent identified *quality* problems;

f) ensuring that information related to *quality* problems is disseminated to those directly responsible for assuring the *quality* of *finished tissue* or the prevention of such problems; and

g) submitting relevant information on identified *quality* problems, as well as *corrective action* and *preventive actions*, for management review;

6) reviewing, as applicable at each *tissue bank* involved, *donor* screening, *informed consent* or *authorization*, *recovery, acquisition,* or *collection*, and *processing records*;

7) approving, as applicable, all *processing records* and *relevant medical records* prior to release of *tissue* for *transplantation*;

8) *auditing*;

9) documenting formal conclusions of all *accident*, *error*, *complaint*, *adverse outcome,* and *field correction, removal,* or *stock recovery* incidents;

10) maintaining documentation including, but not limited to:

a) master copy of current *SOPM*;

b) *records* of names, *signatures*, initials or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location);

c) reports and conclusions of process *validation* and *equipment qualification studies*;

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d) *records* of supply and reagent acceptance or rejection;

e) archived documents; and

f) master lists of preprinted *labels*.

11) evaluating training of personnel and, where required, the *competency* of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to the *SOPM*;

12) maintaining *labeling* controls, including all brochures, pamphlets, and promotional materials; and

13) establishing a process for sharing information with other *tissue banks* that are known to have *recovered* and/or received *tissue* from the same *donor*.

K1.200 Qualification, Verification, and Validation Requirements *(last amended July 9, 2018)*

Elements or items that *must* be *qualified*, *verified*, or *validated shall* be determined from a risk assessment that has been approved by the *tissue bank's quality* department and the frequency of these activities will be determined by the risk assessment and results of the initial and follow up *validations*.

Each *tissue bank shall*:

1) develop, document, and implement protocols for the *qualification*, *verification*, or *validation* of significant components of:

a) facilities;

b) processes;

c) equipment;

d) reagents;

e) *labels*;

f) *containers*;

g) packaging materials;

h) *electronic systems* including *quality* management systems; and

i) *donor* eligibility criteria.

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2) perform process *validations* for processes whose results cannot be fully *verified* by subsequent inspection and test;

3) assess process changes and perform *revalidation* as appropriate; and

4) evaluate parameters tested and determine the adequacy of the study to demonstrate necessary outcomes.

For information and guidance on validations, see Process Validation: General Principles and Practices (Jan. 2011) FDA Guidance for Industry, AATB Guidance Document No. 5 Microbiological Process Validation & Surveillance Program, and AATB Guidance Document No. 9 Qualification of Packaging and Validation of Shipping and Transport Procedures.

K1.210 Validation Methods

Where *validation* is required or desired, evidence supporting *validation must* be demonstrated. Acceptable methods to demonstrate *validation* are:

1) studies conducting challenges such as temperature, time, with indicator organisms, as appropriate, and/or other factors determined by the risk assessment that potentially affect *tissue quality*, as well as studies demonstrating consistency when the steps are repeated lot to lot; or

2) identification of an established procedure or process known to be effective, with implementation of the same *procedure* or process, without modification; such *procedure* or process *shall* be *verified*, as specified in K1.230. [For example, the implementation of a literature based *disinfection* process *shall* include conducting at least method suitability testing (Bacteriostasis/Fungistasis testing) per USP <71> prior to implementation (see AATB Guidance Document No. 5)]; If any steps are modified, all such modifications *shall* undergo documented evaluation (e.g., through a risk assessment) for potential impact, and a potential result may be that a *re-validation* is necessary per method 1 of this section.

Current (14th Edition)

K1.220 Packaging Qualification and Transport/Shipping Validation

Packages used to transport *recovered tissue,* to ship tissue in-*process*, or to *distribute finished tissue shall* be *qualified*. The method(s) used *shall* be *validated* to demonstrate that the *packages* can maintain the required conditions to meet the *finished tissue quality* at the end of its stated expiration date.

With amendments

K1.220 Packaging Qualification and Transport/Shipping Validation

Packages used to transport *recovered, acquired, collected, or ~~to ship tissue~~ in-process tissue,* or to *distribute finished tissue shall* be designed or *qualified* for their intended use.

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Transport/shipping container *validation* is required unless each transport/shipping event is adequately *verified* and documented. ~~The method(s) used *shall* be *validated* to demonstrate that the *packages* can~~ Adequacy of the *verification* method *shall* be established and justified. *Finished tissue* packaging shall be *validated* to maintain the required conditions to meet the *finished tissue quality* at the end of its stated expiration date.

As amended

K1.220 Packaging Qualification and Transport/Shipping Validation

Packages used to transport *recovered, acquired, collected, or in-process tissue,* or to *distribute finished tissue shall* be designed or *qualified* for their intended use. Transport/shipping container *validation* is required unless each transport/shipping event is adequately *verified* and documented. Adequacy of the *verification* method *shall* be established and justified. *Finished tissue* packaging shall be *validated* to maintain the required conditions to meet the *finished tissue quality* at the end of its stated expiration date.

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K1.230 Verification Methods

Where *verification* is required or desired, evidence supporting *verification must* be produced by one or more of the following methods:

1) review, examination, inspection, or testing of a defined number of samples (the justification of the number of samples *must* be documented) in order to establish and document that the *tissue*, service or system meets specified regulatory or technical standards;

2) *verification* of the implementation of an established, previously *validated*, *procedure* or process without modification; *such verification shall* be conducted using a defined number of samples/processing events (the justification of the number of samples/processing events *must* be documented); or

3) a documented review such as when a *tissue recovery* program *must verify* that a *processor's donor* eligibility criteria is compliant with federal regulations, state law, and AATB *Standards*.

K1.300 Purchasing Controls

Each *tissue bank shall* establish and maintain *procedures* to ensure that all purchased or otherwise received products and services, including testing services, conform to specified requirements. Each *tissue bank shall* establish and maintain the requirements, including *quality* requirements that *must* be met by suppliers, contractors, and consultants. Each *tissue bank shall*:

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1) evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation *shall* be documented;

2) define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results; and

3) establish and maintain *records* of acceptable suppliers, contractors, and consultants. Each *tissue bank shall* establish and maintain data that clearly describe or reference the specified requirements, including *quality* requirements, for purchased or otherwise received product and services. Purchasing documents *shall* include, where possible, an agreement in which the suppliers, contractors, and consultants agree to notify the *tissue bank* of changes in the product or service so the *tissue bank* can determine whether the changes *may* affect *quality.*

For contracted services involving *donor* screening, *donor* eligibility, *tissue recovery*, *acquisition*, *collection*, *processing*, *storage*, and/or *distribution*, refer to B1.500 for additional requirements. Also refer to specific information at B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

K1.310 Contracted Testing Services

Contracted testing services *may* be performed remotely at the contracted laboratory or on-site at the *tissue bank*, and evaluation of testing services is expected.

K1.311 Types of Testing Services

Examples of contracted testing services include, but are not limited to, the following:

1) donor infectious disease testing (also see B1.600);

2) microbiology testing (e.g., cultures on *tissue*, bioburden determination);

3) *environmental monitoring*;

4) *sterilization validation*;

5) irradiation dose auditing;

6) *lot* release testing (e.g., residual moisture, residual calcium, endotoxin levels);

7) calibration services (e.g., pipettes, temperature monitoring devices, equipment); and

8) cleanroom certification.

K1.312 Evaluation of Testing Services

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Each *tissue bank* utilizing outside testing services *shall* ensure the testing facility and test methods are adequate for the intended use of the test results. This evaluation *may* include, but is not limited to, the following:

1) FDA registration, if required;

2) applicable state licenses, certifications and accreditations;

3) maintenance of an adequate *quality assurance program* to ensure the validity of results (e.g., test sample integrity, *quality control* samples, personnel *competency,* equipment maintenance, materials management);

4) participation in a laboratory *proficiency testing* program, if available;

5) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);

6) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical, and/or environmental conditions);

7) appropriate test method selection and *validation/qualification*;

8) use of traceable reference materials and calibration standards, where applicable; and

9) results from a paper, virtual, or on-site *audit*.

K2.000 QUALITY CONTROL PROGRAM

The *QA program shall* establish and maintain *QC procedures* that include the following:

1) *environmental monitoring*;

2) equipment maintenance and monitoring;

3) *tolerance limits*;

4) *in-process controls* monitoring;

5) reagent and supply monitoring; and

6) laboratory performance monitoring.

K2.100 Laboratory Proficiency Testing

Laboratories *shall* participate in relevant *proficiency testing* programs for all analytes, if available. *Proficiency testing shall* be conducted in accordance with the laboratories' normal testing and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

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Procedures shall incorporate a plan for *corrective action* for poor performance on *proficiency testing*.

K2.200 Laboratory Quality Assurance Program

Laboratories *shall* establish and maintain a *quality assurance program* adequate to ensure the validity of test results. The laboratory *quality assurance program shall* include, but is not limited to, the following:

1) appropriate test method selection and *validation/qualification*;

2) monitoring/trending internal *quality control* samples;

3) test sample specifications and integrity (e.g., identification, transportation, type, quantity, rejection criteria, preparation, storage);

4) personnel qualification, training and *competency*;

5) equipment selection, *validation/qualification*, calibration and maintenance;

6) use of traceable reference materials and calibration standards, where applicable;

7) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical and/or environmental conditions);

8) materials management;

9) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);

10) result *verification*, review and release; and

11) *records*/data management.

K2.300 Microbiological Tissue Cultures

K2.310 Pre-Sterilization/Pre-Disinfection Cultures

Except for *reproductive tissue banks* and *skin* (S), each *tissue bank shall* establish appropriate *pre-sterilization/pre-disinfection culture* methods and sampling strategies to represent all *tissues* received from a particular *donor*. The *pre-sterilization/pre-disinfection culture* results *shall* be documented in the *donor's record*. See AATB Guidance Document No. 5 for expectations.

If tissue *sterilization* or *disinfection* will not occur a *pre-sterilization/pre-disinfection culture* is not required, however, refer to culture requirement at K2.320.

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The Medical Director or his/her physician designee [see exception that follows for (S)] *shall* review these *pre-sterilization/pre-disinfection culture* results prior to release of *tissue* for *transplantation*.

(MS, OA, SB)

Tissues with *pre-sterilization/pre-disinfection cultures* positive for *Clostridium, Streptococcus pyogenes (group A strep.),* or any other *microorganisms* determined by the *processor* to be virulent or difficult to eliminate, *shall* be discarded unless treated with a *disinfection* or *sterilization process validated* to eliminate the infectivity of such organisms. Other individual *tissues* from the same *donor* that were *recovered* under conditions that could result in *cross-contamination must* be discarded unless they will be treated with a *disinfection* or *sterilization process validated* to eliminate the infectivity of such organisms.

(BT, C, V, CT)

E2.800 applies.

(S) Cultures *shall* be obtained prior to *processing*. Culture methods *shall* be *validated* to ensure the suitability of the culture method selected. Inhibitory substances (e.g., *skin prep* solution(s), transport media, antibiotics, etc.) that *may* be added to unprocessed *skin* during *recovery* or for transport *must* not interfere with culture results. (i.e., produce false negative results).

Culture results *shall* be documented in the *donor's record*. Cultures positive for *microorganisms* considered pathogenic, highly virulent *must* be discarded unless the *tissue* can be *disinfected/sterilized* with a *validated* process (see E2.800). The Medical Director or designee *shall* review all available pre-processing *skin* culture results prior to releasing the *tissue* for *transplantation*. *Skin recovery shall* be performed as a separate zone from other *tissue* types so that culture results can be independently reviewed.

K2.320 Final/Pre-Packaging Cultures

Except for *autologous* and *reproductive tissues*, all *tissue* to be released for human *transplantation shall* have representative microbiological cultures obtained which includes testing to detect bacteria and fungi. The results *must* be documented in the *donor record*, unless *dosimetric release* has occurred by a *validated* process according to E2.820. Appropriate final packaging cultures (aerobic and anaerobic) *shall* be obtained and the results *shall* meet established parameters defining acceptable final packaging cultures before *tissue* is released for *transplantation*. All culture results *shall* be reviewed prior to release of *tissue* for *transplantation*. Any variance in the culture results from established parameters *shall* be reviewed and approved by the Medical Director or his/her designee prior to release. Except as described for *skin* (S) below, no *allografts* contained within the *processing batch may* be released for *transplantation* if post-*processing* final sterility test results show organism contamination. *Allograft*

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rework is permitted with an established program *validated* to eliminate the organism identified.

(A) Except for *skin*, if *autologous tissue* is being *processed*, microbiologic cultures, which includes testing to detect bacteria and fungi, *should* be obtained immediately prior to *processing*.

(C, V) Representative *cardiac tissue* and *vascular tissue* samples *shall* be cultured for fungal growth.

(MS, OA, SB, C, V, CT)
Microbiologic testing of *processed tissue*, which includes testing to detect bacteria and fungi, *shall* be performed on each donor *lot*.

(S) Representative fresh or *cryopreserved skin* samples *shall* be cultured for the presence of fast-growing fungal organisms. Fresh or *cryopreserved skin shall* not be used for *transplantation* if any one of the following is detected at final culture:

1) *Staphylococcus aureus;*

2) *Streptococcus pyogenes* (group A strep.);

3) *Enterococcus* sp.;

4) gram-negative bacilli;

5) *Clostridium*; and

6) fungi (yeasts, molds).

K2.400 Testing for Residues

(C, V) Initially, and as required at K1.200, each *tissue bank shall* thaw, rinse and prepare representative samples from *processed tissue* as if for use and test them to evaluate the concentration of residual *cryoprotectant(s)* (if applicable).

K2.500 Other Quality Control Procedures

K2.510 Lyophilized/Dehydrated/Desiccated Tissue

QC programs for monitoring performance of either a lyophilizer, a dehydrator or desiccator *shall* be established and *verified* for each *batch*. When a residual moisture limit has been established, a representative sample that demonstrates the worst-case scenario for that *batch shall* be tested and *shall* not exceed the limit. Refer to E2.710 and E2.720.

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K2.520 Calibrations of Storage Devices *(last amended July 9, 2018)*

Each tissue bank shall ensure calibrations of devices used for storage are performed according to manufacturer's requirements and recommendations, but no less frequently than once per year using a National Institute of Standards and Technology-traceable standard. The overall QA program shall include maintenance of calibration records.

K3.000 MICROBIOLOGIC TESTING

All microbiologic testing of *tissue* to be released for *transplantation shall* be performed by a qualified laboratory using appropriate test methods. If microbiologic testing is to be performed by the *tissue bank*, the requirements at K2.100 and K2.200 *shall* apply. If the services of an outside laboratory are used, the requirements at K1.300 and K1.310 *shall* apply.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding qualification of laboratories via accreditation, designation, authorization and/or licensure.

K3.100 Microbiologic Subcultures

The testing lab *shall* subculture a positive microbiologic culture to identify the organism(s) by genus, and species where appropriate. See Guidance Document No. 5.

K4.000 INVESTIGATIONS

The *QA program shall* ensure that there is an investigation and review for completeness of *accidents*, *errors*, *complaints*, *deviations*, and *adverse outcomes*. Investigation *shall* include a summary report, precipitating events, recommendations, and resolutions. The *QA program shall* retain for 10 years all reports generated.

K4.100 Errors and Accidents

The *QA program shall* ensure a documented investigation of any *errors* and or *accidents* in obtaining *informed consent* or *authorization*, in *donor* screening, *collection, acquisition,* or *tissue recovery*, *processing, quarantining*, releasing, *labeling, storing,* and *distribution* or dispensing. If the error or accident may affect the *safety* of *tissue* to be released or that has been released, the Medical Director or licensed physician designee *shall* also review and evaluate the incident. When *tissue may* have been contaminated, the *QA program shall* ensure the documented review and evaluation both of *processing procedures* and of any other *tissue processed* simultaneously or from the same donor.

K4.200 Complaints

The *QA program shall* ensure that a written and oral *complaints* regarding *tissue quality*, *safety*, packaging, or effectiveness are expeditiously investigated to determine whether the *complaint* is related to an *error*, *accident*, *adverse outcome*, or other factor, unless such investigation has already been performed for a similar complaint. If it is determined that no investigation is

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necessary, a *responsible person shall* document the reason that no investigation was made and the name of the individual responsible for the decision not to investigate. Each investigation *shall* determine whether associated *tissue may* be affected. If it is determined that they may be affected, *then* those associated *tissues shall* be located and *quarantined* until *resolution* of the incident (which *may* involve initiation of a *recall*). The Medical Director or licensed physician designee *shall* review *complaints* that are medical in nature.

When an investigation is made, a *record* of the investigation *shall* include:

1) the date the complaint was received;

2) the name of the *tissue*;

3) the unique *tissue identification number*;

4) the name, address, and phone number of the complainant;

5) the nature and details of the *complaint*;

6) the dates and results of the investigation;

7) any *corrective action* taken; and

8) any reply to the complainant.

K4.300 Adverse Outcomes

The *QA program shall* ensure that all reported *adverse outcomes* that are potentially related, directly or indirectly, to an *allograft* are investigated thoroughly and expeditiously. The Medical Director or licensed physician designee shall review all potential *adverse outcome* reports and participate in determination of the impact and *resolution* of any *adverse outcome.* If investigation indicates that the *adverse outcome* is related to an *error* or *accident*, then the *tissue bank shall* follow *procedures* for *errors* and *accidents* (see K4.100).

K4.310 Reporting

The *QA program shall* ensure that all cases of transmissible disease in a *recipient* attributed to the *allograft* are reported in writing as required by public health authorities, and in a timely fashion to organ procurement organizations and *tissue banks* involved in any manner with *tissue recovered* from the same *donor* and to the physician(s) involved in the *transplantation* of *tissue* from that *donor.* Reporting *shall* be documented in the *donor's record.*

See the Accreditation Policies for Transplant Tissue Banks for other required reporting.

K5.000 INTERNAL AUDITS

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All *tissue banks shall* establish policies and *procedures* regarding the scope and frequency of routine and focused *QA audits*. The *QA program* staff *shall* perform *audits*, at least annually, of the major *tissue banking* operational systems to identify trends or recurring problems in: *donor* evaluation and acceptance; *tissue recovery* or *collection*, *processing*, *preservation* and *packaging*; *donor* and *tissue* testing; *quarantining*; *labeling*; *storage*; *distribution*; *electronic systems*; and *records* management. The *QA program shall* perform focused *audits* of *critical areas* (unless the annual routine *audit* covers all *critical areas*), and of any area with a pattern of *quality* problems. All *audits shall* be performed by persons who do not have direct responsibility for the process being *audited*. The *tissue bank shall* take *corrective action(s)* when necessary, including a re-*audit* of deficiencies. The *QA program* staff *shall* document and report the dates and results of each quality *audit* (and re-*audit*) to management responsible for the *audited* systems, who *shall* review each report.

K6.000 EXTERNAL AUDITS

External *audits may* be indicated for certain services, suppliers, contractors, and consultants. See K1.300 and B1.521.

K7.000 ELECTRONIC SYSTEMS CONTROLS

K7.100 Authorized Access

Each *tissue bank shall* exercise appropriate controls over *electronic systems* to *limit* general access to authorized personnel and to permit only authorized personnel to alter master production and control *records* or other.

K7.200 Error Reduction

When automated data processing is used for decision-making in *processing*, adequate procedures *shall* be designed and implemented to prevent inaccurate input or output of data and programming *errors*.

K7.300 Backup Files

A backup file *shall* be maintained of all data that are entered into an *electronic system* and subsequently used for decision-making purposes, and of all data that are not otherwise *recorded* and accessible.

K7.400 Security

Electronic systems shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.

K7.500 Audit Trail

Records revised electronically *must* have an *audit trail* that includes the altered information, date of the revision, and the individual that made the revision.