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Dear Ms. Ceroalo,

The Association for Advancing Tissue and Biologics (AATB) appreciates the opportunity to comment on the proposed revisions to Standards for Tissue Banks and Nontransplant Anatomic Banks, and Conforming Changes, I.D. No. HLT-09-26-00001-P (proposed revisions).

AATB is a non-profit organization dedicated to advancing the safety, quality, availability, and benefits of donated human tissue for transplantation worldwide. AATB achieves this through standards development, accreditation, education, and collaboration with regulatory partners to ensure donated tissue has the greatest impact on patient care.

AATB commends the Department's effort to provide regulatory clarity by modernizing 10 NYCRR Part 52. AATB supports the alignment of New York State regulations with appropriate recognized standards, including *Standards for Tissue Banking.* We appreciate the effort to reorganize the regulation into generalized requirements with additional technical standards across applicable tissue types, and we believe this systematic structure improves the readability of the regulations and will ease implementation by our members.

A consortium of experts representing our membership has assessed the impact of the proposed regulations, resulting in the comments contained in this letter. Many of our comments are similar in desired outcome, generally seeking that the proposed revisions be:

- Modified to further align with federal regulations or industry standards, such as *Standards for Tissue Banking;*
- Further simplified, clarified, or made more flexible to ease adoption by tissue establishments of varying sizes and organizational structures; and
- Refined to ensure the intended requirement is established and enforced in a manner that is understandable and actionable by the tissue banking industry.

Specific areas we encourage you to thoroughly review, which are described in more detail in the table appended to this letter, include:

- Requirements and roles of the Tissue Bank Director;
- Responsibilities for records and reporting across establishments;
- Frequency and rationale for required document and record reviews;
- Timing of test result review; and
- Use of electronic media for records and communications.

During our review, the following provisions were raised as potentially having very significant impact to accredited tissue establishments. We greatly appreciate your consideration of these key comments.

1) 52-4.4 Donor qualification and 52-5.5 Qualification of reproductive tissue donors.

52-4.4 Donor qualification.	No tissue shall be released for transplantation without a documented determination by the tissue bank director or designee that the donor is qualified according to the requirements of this section and the written policies and procedures of the facility. (b)(3) The medical director shall be responsible for acceptability of the donor based on donor screening, comprising the physical examination or evaluation, and medical and health history, including social history as recorded in the medical chart of the donor or as provided by a friend or family member, according to established criteria: (i) for all cadaveric donors and for living donors of perinatal tissue, prior to tissue release and within two weeks of tissue retrieval; or (ii) for all other living donors, prior to tissue retrieval.
52-5.5 Qualification of reproductive tissue donors.	(b) Prior to collection of tissue, the donor shall be found acceptable as described in section 52-5.7 of this Subpart, and reassessed:… (c) Prior to release of tissue for artificial insemination or assisted reproductive procedures, and following a quarantine as described in section 52-5.8(e) of this Subpart, the tissue bank director shall determine if the donor is qualified based on subdivisions (a) and (b) of this section, the requirements in section 52-5.8 of this Subpart, and the policies and procedures of the reproductive tissue bank.

This section introduces the concept of donor "acceptability," although the term is not defined. We find the introduction of this concept to be problematic in that it includes prescriptive requirements for a preliminary review of the donor's potential eligibility, without appropriate recognition of the many operational considerations involved. Critically, the proposed language does not reflect current practice, and in fact represents a significant and burdensome departure from current practice.

Retrieval and processing of tissue may be performed by two or more different tissue banks, each with their own medical director. The proposed requirements are silent on which of the medical directors is responsible for donor "acceptability," and they conflict with current practice, which typically involves the retrieval bank's application of preliminary criteria developed by each processing bank's medical director.

AATB's interpretation of these proposed requirements is that the determination of "acceptability" on the part of the medical director is a preliminary review in that it is more closely associated with the donor's acceptance for recovery and/or processing, and that it must occur within two weeks of tissue retrieval. We further understand that acceptability as used here is not equivalent to donor eligibility determination given that the full information required for such a determination may not be available at that time (e.g., autopsy, toxicology results, certain cultures) and that the donor "qualification" necessary for tissue release is proposed to be the purview of the processing tissue bank director.

Based on this interpretation, AATB has several significant concerns with these proposals:

- Tissue establishments conduct preliminary checks to assess whether a donor is appropriate for significant activities such as retrieval and processing, using criteria developed by the processing tissue bank medical director, but they are not performed by a medical director. While medical directors are available for consultation, they are generally only directly responsible for the final donor eligibility determination. Requiring medical directors to conduct a review such as that proposed here would essentially double their workload, resulting in a major operational change with significantly increased financial costs to the establishment.
- Preliminary reviews as currently conducted are based only on the information available at the time the review is conducted. Gaps in available information, such as clarification required of donor screening interviews, may still exist within two weeks of retrieval. Such comprehensive donor acceptability reviews as those required by this proposal may not be feasible.
- This additional "acceptability" review represents a new and burdensome requirement without providing a clear benefit. Currently, retrieval and processing procedures are conducted based on the best available information about the donor, providing an up-to-date level of safety, and all tissues (with narrow exceptions, such as autologous tissue) remain in quarantine until donor eligibility is complete. The creation of an interim review that is significantly burdensome – without being as comprehensive or useful as the donor eligibility determination required by federal regulations – risks disrupting established pathways for the qualification of tissue donors.
- We further note that the term "acceptability" is undefined and not aligned with any existing qualification paradigm, especially to the extent that it might require direct involvement of the medical director at a much earlier stage of the retrieval process. This outcome would lead to confusion and might create new operational risks.

AATB strongly recommends alignment with industry best practice and FDA's and AATB's established approaches to determination that a donor is appropriate for retrieval, processing, and ultimately, release. We propose:

- Utilization of donor eligibility determination as the terminology for the final decision that a donor satisfies all screening and testing requirements;
- That the donor eligibility determination be made based upon a totality of information

when that information is available; and

- That the medical director of the processing tissue bank be solely responsible for that decision.

We understand that the Department may wish to codify an upstream review to determine whether a donor or their tissue may proceed to a pursuant procedure, although we believe this represents an unnecessary departure from internationally recognized standards and regulations. If this additional review is incorporated into New York State regulations, we urge the Department to take great care to avoid requiring the review of information which is often not available within the specified timeframe and to permit the review to be performed by qualified staff based on established processes and policies (e.g., a designee). Lastly, if the Department must move forward with these proposals as currently conceived, we encourage clear definitions of terminology and roles to minimize the potential for confusion, with special attention paid to the need to clarify the responsibilities of individual tissue banks when retrieval and processing are not performed by the same bank.

2) 52-1.1(y)(1)(v) Definitions: Tissue Bank- Perinatal Tissue

52-1.1 Definitions.	(y)(1) Tissue bank means any person or facility that conducts tissue banking services, including autologous procedures, unless exempted from licensure by this Part. Categories of tissue as used in this Part include, but are not limited to: (v) perinatal tissue, including the placenta, amnion, chorion, umbilical cord, and components thereof, except for hematopoietic progenitor cells, for transplantation. With regard to perinatal tissue, the birth mother shall be considered the donor for purposes of donor qualification;

AATB commends the Department's formal recognition of birth tissue donation through the definition of "perinatal tissue" as a tissue category. During the review of the proposed definition, our members raised concerns about the designation of the birth mother as the "donor" for the purposes of donor qualification. AATB Standards appropriately reflect the fact that the birth mother provides informed consent for donation, completes the donor risk assessment interview describing the medical and social history used for eligibility determination, and provides a blood sample representative of the donation for the purposes of completing infectious disease testing. Because the U.S. Food and Drug Administration (FDA) requires the screening of the donor's blood relatives for a family history of Creutzfeldt-Jakob disease (CJD), the FDA designates the newborn as the perinatal tissue donor, in order to ensure that the male partner's familial history of risks for CJD is included. If the mother is considered the donor, the male partner would not be included in the CJD risk evaluation. Such familial history may not be raised when the birth mother is considered the donor of perinatal tissue. Also, the draft FDA guidance Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) affirms that, under FDA's current thinking, the "infant is considered the donor" of perinatal tissue. While we understand the Department's perspective that there are medical, scientific, and practical reasons for asserting that the mother is the donor of gestational tissue, we fear that conflicting definitions may create conflicting requirements for donor screening, now and/or potentially in the future. As such, AATB encourages the Department to either align with FDA's position that the infant is the donor of birth tissue, or to participate in productive dialog with FDA and AATB to identify a common and

well-reasoned path forward.

3) 52-2.2(a) Application for Licensure, Including Renewal

52-2.2 Application for licensure, including renewal	(a) An application for licensure, including an application to renew or amend a license, as a tissue bank, other than a tissue transplantation facility, may require information including but not limited to: (17) documentation of a determination, designation, or other information from the FDA that the applicant's tissue product(s) is regulated solely as a human cell, tissue, and cellular tissue-based product (HCT/P) and does not require FDA premarket approval;

AATB recognizes the Department's role in protecting the public health of the people of New York and its desire to do so through requiring FDA-sourced information that a tissue product is regulated solely under PHS Act Section 361 and 21 CFR 1271, i.e., a "361 HCT/P", and does not require FDA premarket approval. However, we note that federal regulation does not require FDA-sourced documentation to introduce a tissue product to market. 21 CFR 1271.10 describes the criteria and requirements that must be met for tissue products to be regulated as 361 HCT/Ps and allows self-designation and justification in lieu of premarket approval. 21 CFR 1271.10(a) describes criteria that must be met in order to be regulated solely under Section 361 of the Public Health Service Act and 21 CFR 1271; subparagraph (b) states that firms which meet the requirements of subparagraph (a) need only to register, list, and comply with the regulations of part 1271 to bring a 361 HCT/P to the market. There is no requirement for documentation from FDA for premarket approval. Given the traditional avenues by which such documentation is provided by FDA (i.e., Tissue Reference Group and Request for Designation), this requirement may be burdensome to tissue establishments due to potentially lengthy response times and may limit the selection of tissue products available to New Yorkers. We recommend removal of this potential requirement for licensure in New York; if some kind of regulatory documentation must be required in some cases, AATB recommends the Department clearly define when such a requirement would apply, what documentation would be satisfactory, and what options for documentation may be allowable that are reasonably attainable (preferably documentation which can be generated by the applicant justifying the self-designation).

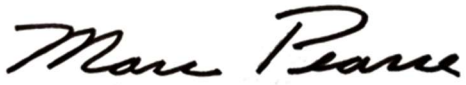
AATB appreciates the significant reorganization of regulations and applauds the Department for taking steps to improve the readability and modernity of the regulations. Regarding their implementation, AATB encourages the Department to:

- Establish a reasonable timeline for the transition to the reorganized regulations;
- Exercise enforcement discretion for a reasonable period to allow adoption of the final rule;
- Provide stakeholder education materials (e.g., guidance documents, webinars, FAQs);
- Clearly communicate its plans related to the collection of establishment fees;
- Utilize a phased implementation of license expiration and renewal for currently licensed banks; and
- Provide clarity on renewal timing relative to inspection cycles and guidance on the handling of submitted amendments in proximity to renewal deadlines.

We look forward to our continued collaboration with the New York State Department of Health's Wadsworth Center and would be pleased to make available our staff and member experts to discuss any of the comments above or the additional concerns described in the below table.

Thank you for considering our comments. AATB stands ready to work with you to achieve our shared goals.

Regards,



Marc Pearce, MBA
President and CEO
Association for Advancing Tissue and Biologics

Additional comments for consideration:

Reference	Text	Comment
52-4.10 Additional requirements for tissue release.	(d) Except as specifically approved by the medical director of the tissue bank and in conformance with generally accepted standards of practice, allogeneic donor tissue for clinical use shall not be released if the donor was determined to be at risk of transmitting a communicable disease agent, or from donors with: (7) history of abuse of non-prescription recreational drugs; or	AATB encourages the Department to align with current or anticipated FDA requirements for donor screening and exclusionary criteria regarding persons who have injected drugs for a non-medical reason (see Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (2007 FDA Guidance), IV.E.2).
52-4.10 Additional requirements for tissue release.	(b) Except for corneal tissue and human milk, all tissue from living donors intended for allogeneic use shall be quarantined for at least six months. After such time and prior to release of the tissue, the donor shall be retested for the presence of communicable disease agents indicated in section 52-4.4(c) of this Subpart.	AATB recommends that perinatal tissue be exempt from this requirement. Perinatal tissue is generally subject to the same donor eligibility requirements as tissue from deceased donors, often is terminally sterilized, and may have shelf lives as short as six months. In addition, obtaining samples needed for such testing at six months may be difficult, as birth mothers may not make themselves available that much later for the collection of a sample for repeat testing or may be difficult to locate. Regarding oocytes, AATB recommends aligning with both FDA (see 1271.80(b)(1)) and Health Canada for testing of oocyte donors (30 days prior or 7 days after retrieval with no quarantine period).

Reference	Text	Comment
52-2.5 License issuance, renewal, denial, suspension, and revocation.	(f) Grounds for denial and revocation. (7) failure of the director to be on the premises for an adequate amount of time and adequately supervise technical personnel to ensure the proper performance of all tissue banking services provided;	AATB recommends that the amount of time the tissue bank director is expected to be on the premises not be a subject of regulation and instead be allowed to be determined by the tissue establishment based on their unique operational and management structures. Regarding technical staff, AATB believes that it is similarly appropriate for a tissue establishment to determine and document to whom the term "technical staff" applies within their organization, and we recommend a similar principle be applied in eventual enforcement of related requirements. We also request the ability of the tissue bank director to delegate supervisory activities to other appropriately trained and qualified personnel.
52-2.2 Application for licensure, including renewal	(a) An application for licensure, including an application to renew or amend a license, as a tissue bank, other than a tissue transplantation facility, may require information including but not limited to: (7) whether the director, medical director, or any person with a direct or indirect controlling interest in the applicant is licensed in good standing and has:	AATB recommends that "*tissue bank* director" be specified for clarity.
52-3.2 Administration and direction of tissue banks other than transplantation facilities.	(a) Every tissue bank shall have a director who meets the requirements of section 52-2.5(a)(2) of this Part. The tissue bank director shall develop and implement policies and procedures for the operation of the bank, consistent with this Part. The tissue bank director shall be responsible for: (1) the technical and scientific operation of the bank, including recruitment of sufficient numbers, training, and supervision of all personnel participating in tissue banking services;	AATB recommends that supervisory responsibilities that must be performed by the tissue bank director be distinguished from those that may be delegated. Responsibilities that may be delegated should include the supervision of personnel performing retrieval.
52-4.7 Tissue retrieval.	(b) Except for human milk and semen, retrieval shall be performed only by qualified personnel under the supervision of the tissue bank director. The tissue bank director shall be responsible for developing policies, procedures and standards for the educational background, training, certification, and continuing education of retrieval technicians.	AATB also suggests that trained, "qualified personnel" may not require direct supervision of task performance (e.g., retrieval) by the tissue bank director.

Reference	Text	Comment
	Documentation of compliance with this requirement and the standards developed shall be maintained.	
52-3.4 Required records.	(f) The following records shall be kept by each tissue transplantation facility or insemination/implantation site: (9) outcome of the transplantation, including but not limited to, any adverse outcome or communicable disease in the recipient, the latter of which shall be reported to the tissue bank from which the tissue was obtained; and	AATB recommends that any communicable disease potentially transmitted to a tissue recipient should be required to be reported to the tissue processor, as typically directed by the package insert, if the processor is not the tissue bank from which the tissue was obtained.
52-5.8 Donor testing and quarantine requirements.	(e) All non-identified donor semen shall be frozen and quarantined for a period of at least six months from the date of collection. All directed donor semen shall be frozen and quarantined for a period of at least 35 days from the date of collection. If frozen, donor oocytes shall be quarantined for a period of at least 35 days from the date of oocyte retrieval. If donor oocytes are used in assisted reproductive procedures prior to freezing, any resulting embryos that are frozen shall be quarantined for the same 35-day period. After the quarantine period and prior to release of tissue for clinical use, the donor shall be retested and found negative or non-reactive for communicable diseases identified in subdivision (a) of this section.	AATB recommends removal of the 35-day quarantine period for oocytes, in alignment with FDA (see 1271.80(b)(1)) and Health Canada, which require initial testing 30 days prior or 7 days after retrieval; otherwise, there is no requirement for a specific quarantine period followed by retesting.
52-3.4 Required records	(d) The following records shall be kept by each facility processing tissue: (1) a log or other similar record indicating: (e) The following records shall be kept by each tissue bank storing or distributing tissue: (1) a log or other similar record indicating: (i) donor's identification code or unique tissue product number; (ii) date of receipt of tissue; (iii) name and address of the tissue bank providing the tissue; and (iv) location of the tissue in the storage chamber; and (2) a record of the disposition of the tissue, including but not limited to, distribution records, destruction logs, and autoclave or incineration records. A signed form shall be kept on file at the tissue bank documenting the identification of tissue distributed, including the names of both the person(s) releasing the tissue and the person(s) receiving the tissue.	AATB recommends that electronic media be specifically authorized for use in record retention provisions.

Reference	Text	Comment
52-5.10 Importation of client-depositor reproductive tissue.	Client-depositor reproductive tissue may be distributed to licensed insemination/implantation sites in New York State by an unlicensed reproductive tissue bank located out-of-state, without a written exception from the department, provided: (d) the tissue bank maintains a log of all tissue imported under this section.	
52-4.5 Quality assurance and safety requirements.	(a) Quality assurance. (1) Records shall document that the following quality control procedures are in place, as applicable: (i) preventive maintenance, periodic inspections and testing for proper operation of equipment, including biannual calibration of thermometers; (vi) documented approval of procedures and procedural modifications by the tissue bank director or designee, and documented biannual review by the tissue bank director or designee;	AATB recognizes that the term "biennial" will be utilized instead of "biannual."
52-4.5 Quality assurance and safety requirements.	(a) (5) Current standard operating procedure manuals or other procedural guides specific to the facility shall be available at all times in the immediate work area of personnel engaged in tissue banking. There shall be a clearly written procedure for each tissue banking service performed at the facility. To the extent possible, each procedure shall be validated and currently accepted by leading authorities in tissue banking. Manuals shall contain a protocol for writing, maintaining and annual review of standard operating procedures by user personnel and management staff. Procedure manuals shall have the following features:	AATB recommends that the frequency of SOP review be determined by the tissue establishment based on risk.
52-4.4 Donor qualification. 52-5.8 Donor testing and quarantine requirements.	(c) Donor testing. (2) The medical director or designee shall be responsible for review and acceptance of the donor's testing results, based on established criteria, prior to release of tissue and within two weeks of receipt of the results. (c) All donor test results shall be reviewed and approved by the medical director or designee within two weeks of receipt of results and prior to release of tissue for clinical use.	AATB recommends removing the requirements for review of test results within two weeks of receipt of the results and for review prior to labeling. Review by the medical director as part of the donor eligibility assessment (prior to tissue release) is standard industry practice.

Reference	Text	Comment
52-4.5 Quality assurance and safety requirements.	(a) Quality assurance. (1) Records shall document that the following quality control procedures are in place, as applicable: (v) supervisory review of test results prior to labeling of the tissue.	AATB recommends clarification of "supervisory review" to enable review by trained and qualified personnel.
52-2.1 Licensure	(a) Except as provided in sections 52-2.3 and 52-5.10 of this Part, any person, facility or entity that conducts tissue banking activity in, or directly or indirectly distributes tissue to, New York State shall be licensed by the department as a tissue bank prior to conducting such activity. No facility in New York State shall receive tissue distributed by an unlicensed person or entity, unless the person or entity is exempted from licensure by this Part or has been issued a written exception to the requirement for licensure by the department. Licensure as a tissue bank shall be for one or more of the following tissue banking services: (1) qualification of donors; (2) tissue retrieval; (3) tissue processing; (4) tissue storage and distribution; and (5) tissue transplantation.	AATB recommends specificity be added to clearly indicate the types of organizations and/or activities that will require licensure, and additional clarity indicating what contributions to a final tissue product that is distributed to NY constitute distribution "directly or indirectly."
52-2.1 Licensure	(b) A tissue bank that is responsible for retrieval of tissue at an offsite location shall ensure the personnel performing the retrieval have documentation of their authority, and department approval for their activities, on the premises of the offsite location during any such retrieval. The tissue bank director shall ensure the offsite location is suitable for tissue retrieval, and the retrieval is conducted, in compliance with standards in this Part.	AATB understands that semen collection of client depositors will be exempted from any requirements associated with "offsite locations." Additionally, we request allowance for the suitability of the offsite location to be determined by trained and qualified personnel instead of the tissue bank director.
52-4.7 Tissue retrieval.	(h) Tissue specimen containers, packaging materials, and storage solutions shall be sterile and nontoxic. (i) Each tissue and blood specimen container shall be labeled legibly at the time of retrieval with the tissue bank identification, and donor identification code or unique tissue identification number. The date, time and anatomic site of retrieval shall be recorded on accompanying documents.	AATB recommends specification that oocytes and semen be exempt from the requirement to include the anatomic site of retrieval on the container label.
52-5.8 Donor testing and quarantine requirements.	(d) Tissue, including embryos, from any donor who is disqualified based on subdivision (a) of this section shall not be used for artificial insemination or assisted reproductive procedures. Such tissue shall be destroyed unless it is to be used for research studies approved by the appropriate institutional	AATB encourages reasonable latitude for use of disqualified samples for internal establishment quality control and training purposes, with appropriate authorization or consent.

Reference	Text	Comment
	review board, in which case all samples from the donor shall be labeled "For research use only" and immediately sequestered from other samples.	
52-5.9 Collection, processing, storage, disposition, and distribution of reproductive tissue.	(e) All processing steps that involve manipulation of tissue shall be witnessed by a second party, unless an electronic witnessing system is used, to ensure identification is maintained throughout.	AATB recommends clarity regarding what is considered “manipulation of tissue.”
52-2.1 Licensure	(c) The valid tissue bank license shall be conspicuously posted on the premises of the facility.	AATB recommends including the option to satisfy this requirement through electronic posting (e.g., a website).
52-4.4 Donor qualification.	(c) Donor testing. All allogeneic donors shall be tested for communicable diseases including HIV-1, HIV-2, hepatitis B and C viruses, and any other communicable diseases the department may require. Donors of leukocyte-rich tissues shall also be tested for HTLV-I and HTLV-II. For tissue banks located in New York State and for tissue retrieved in New York State, all clinical laboratory testing shall meet New York State requirements. Otherwise, all clinical laboratory testing must meet applicable requirements. No donor shall be qualified unless they are found negative in testing for the abovenamed communicable diseases.	AATB recommends verification that tissues classified as leukocyte rich align with those specified by FDA (semen and hematopoietic stem/progenitor cells).
52-4.6 Reporting requirements.	(a) The tissue bank shall have a written procedure for documenting errors, accidents, or non-conformance events in qualification of donors and in retrieval, testing, processing, storage, or distribution of tissue that may affect the safety of any product or recipient. If the error, accident, or non-conformance event is not detected prior to issuance of the tissue, specimens, or test results to a hospital or other tissue bank, the error, accident, or non-conformance event shall be reported immediately to the receiving facility. All such errors, accidents and non-conformance events shall also be reported to the department's Wadsworth Center within 30 calendar days of discovery.	AATB supports the extension in due date but recommends alignment with 21 CFR 1271.350(b)(3), which requires reporting within 45 days of discovery of the event.
52-4.7 Tissue retrieval.	(e) All tissue shall be transported to the tissue processing facility at temperatures and within time limits specified in written policies approved by the medical director.	AATB does not consider transportation temperatures and time limits to be medical requirements and thus should not require medical director approval.

Reference	Text	Comment
52-5.5 Qualification of reproductive tissue donors.	(d) Reproductive tissue collected from donors prior to <DATE of effectiveness> may be released for artificial insemination or assisted reproductive procedures if the donor was qualified in compliance with regulations active at the time of collection. Subsequent repeat testing of donors… shall be compliant with current requirements. Intended recipients of donor tissue collected prior to <DATE of effectiveness> shall be informed in writing of any current qualification requirements the donor does not meet by the director, the director's designee, or the practitioner performing the procedure, prior to the procedure.	AATB membership would welcome the development of a document summarizing the new/revised requirements to help establishments educate patients undergoing reproductive treatment.
52-4.4 Donor qualification.	(c) Donor testing. All allogeneic donors shall be tested for communicable diseases including HIV-1, HIV-2, hepatitis B and C viruses, and any other communicable diseases the department may require. Donors of leukocyte-rich tissues shall also be tested for HTLV-I and HTLV-II. For tissue banks located in New York State and for tissue retrieved in New York State, all clinical laboratory testing shall meet New York State requirements. Otherwise, all clinical laboratory testing must meet applicable requirements. No donor shall be qualified unless they are found negative in testing for the above-named communicable diseases. (1) Except for donors of reproductive tissues and human milk, all specimens for testing shall be collected within seven days before or after tissue retrieval.	AATB recommends alignment with FDA regarding timeframes for collection of blood specimens for reproductive tissue for clarification, since the timeframe is not otherwise indicated (7 days before or after for initial collection of semen, and 30 days prior or 7 days after for oocytes, per 2007 FDA Guidance, V.E).
5-3.4 Required records	(d) The following records shall be kept by each facility processing tissue: (4) air quality measurements for work areas as required by the FDA	AATB recommends aligning with FDA's view that reproductive tissue is exempt from FDA Good Tissue Practice, and thus air quality measurements should not be required.
52-3.4 Required records.	(a) Complete and accurate records of tissue and nontransplant anatomic parts retrieved, processed, stored, distributed and/or transplanted shall be kept by all tissue banks. Such records shall be open to inspection, including the reproduction of records, by the department. Unless specified elsewhere in this Part, such records shall be kept for at least 10 years after distribution, disposition, or expiration of unused tissue, whichever is later.	AATB supports the change in record retention time frame to 10 years.