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September 18, 2024

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Proposed Revisions to Part 52

Tissue Banks and Nontransplant Anatomic Banks

September 18, 2024

Part 52 From 1991 – 2024

1991 – Promulgated as emergency regulation, established basic licensure requirements and general standards (52-1 – 52-3).

1992 – Formally adopted, subsequently amended to include reproductive tissue (52-8, semen only).

1993 – Added tissue specific standards, sections 52-4 – 52-7, 52-9, 52-10 (incorporating human milk and HPCs).

2000 – Reproductive tissue expanded to include oocytes/embryos.

2005 – FDA regulates HCT/Ps based on NY's model.

2007 – Added standards for nontransplant anatomic banks, plus additional donor screening and testing requirements.

2024 – Minor corrections and updates to reproductive tissue banking.

Proposed Changes to Part 52 - Structural

Current	Proposed
52-1 Definitions	52-1 Definitions
52-2 Licensure (& General Requirements)	52-2 Licensure
52-3 General Tech. Standards	52-3 General Requirements
52-4 Cardiovascular	52-4 Technical Standards
52-5 Musculoskeletal	
52-6 Skin	
52-7 Eye	
52-8 Reproductive	52-5 Reproductive
52-9 Human Milk	52-6 Human Milk
52-10 HPCs	52-7 HPCs
52-11 Nontransplant Anatomic	52-8 Nontransplant Anatomic

Proposed Changes to Part 52 – Exemptions to Licensure

Current

Transplantation facilities if using only sterilized or virally inactivated tissue products.

Proposed

Transplantation of:

- Sterilized or virally inactivated tissue products.
- Amniotic membrane procured, processed and distributed by licensed tissue banks for ophthalmological use.
- Tissue products received “just in time”.
- Shelf-stable tissue products.
- Tissue by Article 28 facilities.

Proposed Changes to Part 52 – Licensure & Fees

Current

Licenses do not expire.

No fee for licenses.

Proposed

Licenses expire and must be renewed bi-annually.

Fees for licenses, amendments and renewals.

- Tissue banks: $1000 initial, $500 for amendments and renewals
- Transplantation facilities and nontransplant anatomic banks: $500 for initial, $250 for amendments and renewals.

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Proposed Changes to Part 52 – FDA compliance

Current	Proposed
Exemptions for out-of-state extensively processed tissue from screened and tested donors, (~FDA-licensed Biologics or INDs) with documentation and review.	FDA-licensed Biologics and products with INDs explicitly exempted from licensure.
“All antisera, reagents, devices, methods and procedures…shall be approved by FDA.”	Same, plus “all tissue and tissue-derived products shall be…in compliance with FDA…”

Proposed Changes to Part 52 – Donor Qualification

Current

Screening: extensive requirements, originally predates FDA, now mostly comparable, plus a few extras.

Testing: HIV, HepB/C, HTLV-I antibody tests.

Proposed

Screening: defer to FDA, plus a few other things carried over from the current reg (e.g., exposure to rabies, toxic metals).

Testing: defer to FDA, which adds NAT testing, expands the list, and sets a minimum of HIV, HepB/C, HTLV-I/II for leukocyte-rich tissues.

Proposed Changes to Part 52 - Standards

Current

Requirements for specific tissues in sections 52-4 through 52-7 (dating to 1993 and 2000). Otherwise, only 52-3 standards apply to other tissues.

Proposed

Common requirements incorporated universally into 52-4, plus a few tissue-specific requirements. Many overly-specific requirements removed, now reference “industry standards” or self-validation.

Proposed Changes to Part 52 - Structural

Current	Proposed
52-1 Definitions	52-1 Definitions
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52-4 Cardiovascular	52-4 Technical Standards
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52-10 HPCs	52-7 HPCs
52-11 Nontransplant Anatomic	52-8 Nontransplant Anatomic

Proposed Changes to Part 52 – Reproductive Tissue

Current	Proposed
Donor qualification includes regular tissue requirements, plus additional criteria. In some instances, a higher bar than FDA (i.e., ineligible donors based on + tests).	Mostly defer to FDA, but maintain some of the higher bars. Bring oocyte donor requirements mostly up to semen donor requirements.
Anonymous donation is not restricted.	Anonymous donation restricted to patients of the same IVF Center, otherwise ID reveal at 18.
Health history for donor qualification.	Health history for 25 years, provision to offspring on request.

Proposed Changes to Part 52 – Reproductive Tissue

Current

Quarantine of semen and retesting of donors.

Consent form has a statement that the reproductive tissue donor has the right to withdraw his/her consent to donation up until such time that a specific recipient has begun an assisted reproduction cycle in reliance on the availability of tissue from that donor.

Proposed

Quarantine of semen and, if frozen, eggs and embryos, and retesting of donors.

Consent form has an explanation of the circumstances, procedures and limitations regarding the donor's right to withdraw consent.

Proposed Changes to Part 52 – Human Milk Banks

Current

Preclusion on remuneration of donors.

Proposed

Remuneration allowed, but requires testing to detect adulteration.

Requires pasteurization (as HMBANA does now).

Requires assessment of caloric content.

Proposed Changes to Part 52 – Nontransplant Anatomic Banking

Current

Requirements split between 52-2 and 52-11.

Named director required for whole body acquisition services only.

Proposed

Requirements consolidated in 52-8.

Named director for all nontransplant anatomic banks.

Require “Universal Precautions”.

Questions?