



American Association of Tissue Banks®

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To Our Hospital Partners:

On January 6, 2024, FDA published two final guidance documents for industry:

**Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by HCT/Ps ([Sepsis guidance](#)) and Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* (Mtb) by HCT/Ps ([Mtb guidance](#))**

These documents, issued without public comment, impose a demanding four-week implementation timeline, effective February 3, 2025.

The American Association of Tissue Banks (AATB) submitted [a detailed letter to the FDA](#) on January 15, 2025, outlining concerns about the operational challenges, insufficient clarity, and potential patient access issues stemming from these guidance documents. In the letter, AATB also notes that the adoption of measures contained in the guidance documents is not feasible without additional clarification and revision, and that AATB is not able to adopt the new screening and eligibility criteria until further clarification is provided.

In addition, President Trump has issued a regulatory freeze by executive order. AATB believes that the two guidance documents are within the directive for department and agency heads to “consider” a pause for public comment for guidance documents that have been published but are not in effect. We do not know if FDA agrees with this interpretation, but the executive order provides additional support for AATB’s position that FDA should allow a public comment period before implementing the Mtb guidance and Sepsis guidance.

Therefore, AATB inspectors will not issue nonconformances and the Association will not take other accreditation-related actions until the criteria are included in AATB’s Standards for Tissue Banking (Standards). We do not intend to include the guidance documents in their current form in our Standards.

If you have questions or concerns about this, please do not hesitate to contact our Vice President of Accreditation, Regulatory, and Standards, Eduardo Nunes at [nunese@aatb.org](mailto:nunese@aatb.org).

A handwritten signature in black ink that reads 'Marc Pearce'.

Marc Pearce, MBA  
President and CEO  
American Association of Tissue Banks