



## **New York State Tissue Resources Program**

### **Guidance for Tissue Transplantation Facilities Regarding the Need for Licensure**

New York State tissue bank regulations are found in [10 NYCRR Part 52](#). Part 52-2.1 requires that any person who plans to operate a tissue bank or distribute tissue in New York State obtain a license prior to operation or conduct of such activity. For purposes of tissue bank licensure, “person” includes an individual, corporation, government, partnership, or any other legal entity such as a physician’s practice. A person that temporarily stores and transplants human tissue is considered a tissue transplantation facility and, except for certain limited circumstances, must hold a tissue bank license.

Section 52-2.1(e) exempts from licensure as a tissue bank physicians and dentists whose use of human tissue is limited to tissue products that have been virally inactivated, which is defined in 52-1.1(af) to include sterilization.

Under Department policy, a facility that receives tissue “just-in-time” and, within 24 hours of receipt, either transplants the tissue or returns it to the distributor, without otherwise removing it from the transport packaging, is not considered to be storing tissue and does not need a license.

Additionally, Section 52-2.1(f) identifies several pathways to exemption from licensure for processors and distributors of tissue. The pathways identified in 52-2.1(f)(2) and (3) require Department review and approval.

### **What this means to the end-user**

You do not need a license if you only receive tissue products “just in time,” as described above, and are not storing them, regardless of whether the products have been sterilized or not.

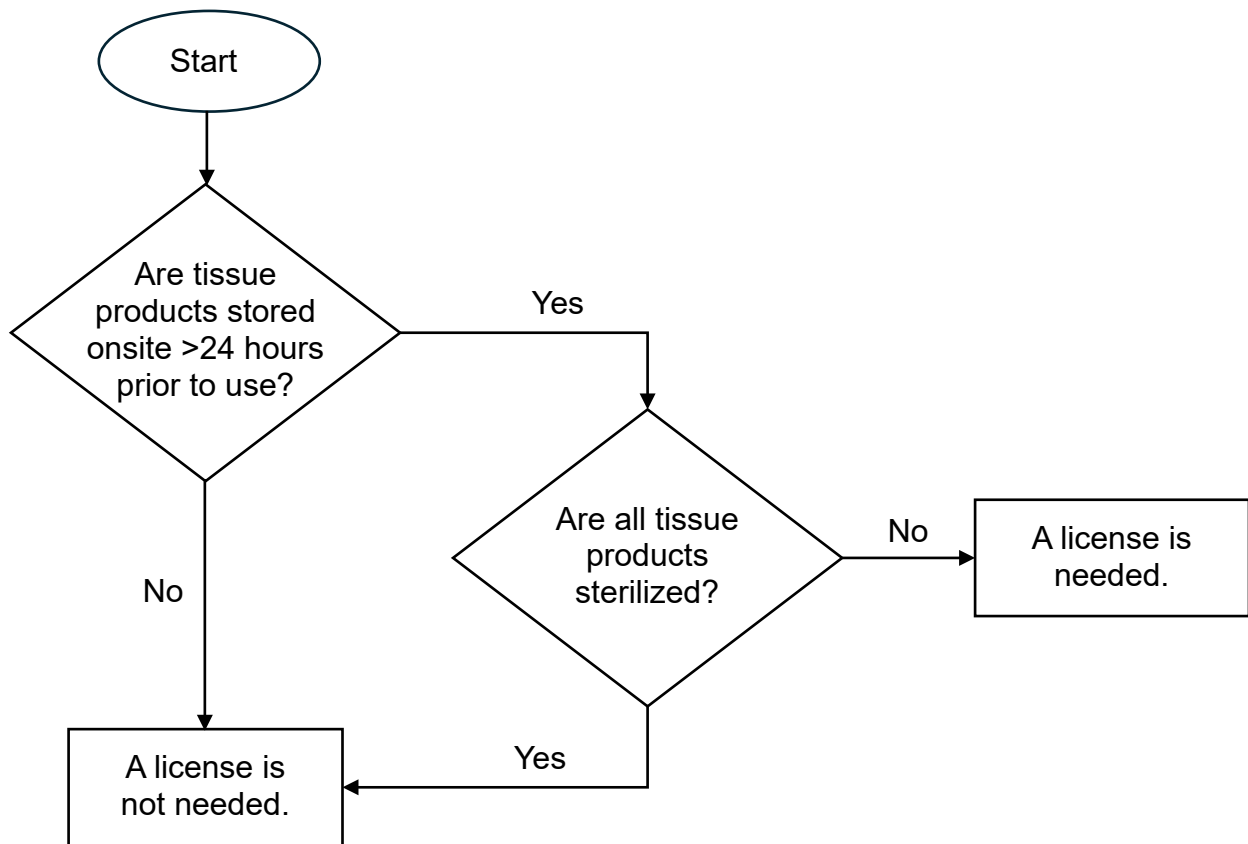
You do not need a tissue bank license if your clinical use of human tissue is limited to sterilized products. You should review the “Instructions for Use” (or IFU) that accompanies a tissue product to determine if the specific product has been sterilized.

If you need a license, the requirements in Part 52 apply to all human tissue products you receive, even those that are sterilized, and even those that are used or returned within 24 hours.

If the Department has exempted a specific tissue product from licensure under 52-2.1(f)(2) or (3), neither the distributor nor the end-user needs a license. Otherwise, all tissue distributed in New York State, including “off-the-shelf” tissue products, must be distributed by a licensed tissue bank.

No tissue may legally be distributed in New York State unless the distributor holds a New York State tissue bank license that includes the category of tissue, or the product has been exempted from licensure. Licensed tissue banks are listed on the Open NY website. To determine if a specific tissue product has been exempted from licensure, you may request documentation of

the Department's determination from the supplier or directly from the Department's [Tissue Resources Program](#).



### Examples

Tissue Bank A distributes a sterilized human tissue product to a physician in New York State. The physician uses only this product in their practice. Tissue Bank A needs a tissue bank license. The physician's practice does not need a tissue bank license.

Tissue Bank B distributes multiple human tissue products to a physician in New York State. Some of the products are sterilized, some are not. The physician orders tissues only for the day of surgery and does not remove them from the transport container until they are transplanted. The physician returns any unused tissue to the distributor within 24 hours of receipt, without removing it from the transport box. Tissue Bank B needs a tissue bank license. The physician's practice does not need a tissue bank license.

Tissue Bank B distributes the same multiple human tissue products to a different physician in New York State, who stores them for several weeks prior to using them. This physician's practice needs a tissue bank license, and the requirements in Part 52 apply to all tissue products.

Tissue Bank C has demonstrated to the Department that a product is virally inactivated and the Department has exempted the product from licensure. A physician's practice does not need a tissue bank license to use this product.