



New York State Tissue Resources Program

Policy – Applicability of Public Health Law § 4364(4)(f-h) to tissue banks
Effective date – March 13, 2025

Valid until – Legislation, regulatory or policy change supersedes this policy

Effective March 13, 2025, Public Health Law § 4364(4) imposes several new requirements on tissue banks. This policy is intended to provide guidance to regulated entities on how the Department intends to ensure compliance with the new requirements. Specifically, paragraphs (f), (g) and (h) of section 4364(4) require the Department to consider the following when reviewing applications:

- (f) the applicant's ability to moderate and record temperature, including an adequate alarm notification system;
- (g) the applicant's ability to establish a chain of custody for specimens; and
- (h) the applicant's ability to establish administrative, technical, and physical safeguards to protect patient records;

The Department understands the intent of the legislature in enacting these changes, as indicated in the New York State Senate bill's sponsor memo, is to ensure reproductive tissue is appropriately tracked, monitored and safeguarded to prevent its loss, and to ensure that protected health information pertaining to reproductive health is protected from disclosure to unauthorized parties.

As such, effective March 13, 2025, the Department will consider the above factors when reviewing a reproductive tissue bank's application, including both new applications and applications to amend existing tissue bank licenses. These factors will also be considered during onsite surveys of reproductive tissue banks subsequent to submission of a new or amendment application for that bank. A reproductive tissue bank that has not submitted a new or amendment application will not be subject to the criteria during onsite surveys until such time as an application is submitted.

With regard to § 4364(4)(f), any reproductive tissue bank submitting an application for a new license, or to amend an existing license, must provide written documentation of the method(s) and/or system(s) used to control and monitor the temperature of reproductive tissues in storage, including the methods by which one or more employees of the tissue bank will be notified of deviations in temperature that may jeopardize the clinical utility of the reproductive tissue, and actions to be taken by personnel in response to such notifications.

With regard to § 4364(4)(g), establishing chain of custody, or traceability, of all tissues is already engrained in 10 NYCRR Part 52 in record keeping requirements. The Department already requires submission of standard operating procedures demonstrating that traceability of all tissues is documented and that such records are retained for the minimum lengths of time established in 10 NYCRR Part 52. As such, the Department will not implement any specific changes to the existing application review process or during onsite surveys.

With regard to § 4364(4)(h), any reproductive tissue bank submitting an application for a new license, or to amend an existing license, must provide written policies and descriptions of equipment, physical space, and procedures to ensure that patient records are protected. These must include a data management plan that describes physical safeguards, such as locks on doors behind which physical records or computers with access to electronic records are available, as well as policies and procedures regarding data security measures, including:

- Access controls with assigned personnel roles and responsibility to secure data from unauthorized access;
- Multifactor authentication for users; and
- Backup systems to prevent loss of data.