

IMPORTANT NOTICE REGARDING STORAGE OF ALLOGRAFT TISSUE

The Tissue Bank Program of Laboratory Field Services is in the process of formulating regulations to interpret and clarify tissue bank statutes. In the interim we have revised some of the responses to frequently asked questions (FAQ) posted on the Laboratory Field Services website. One major change is the response regarding tissue storage. Under California law, the holder of a California tissue bank license is responsible for the storage of allograft tissue. Current allograft shipping practices ensure validation of the unopened shipping container and we have modified the FAQ response.

FAQ and response currently on the website:

When does a dentist, ambulatory surgical center, or any other non-exempt facility require a tissue bank license?

Response: Whenever the facility stores any allograft material without utilization (implantation) or return of the tissue on the same calendar day of receipt.

Revised FAQ and response:

When does a facility in California require a tissue bank license to store allograft tissue?

Response: Whenever a facility stores allograft tissue as part of its inventory, unless the storage is specifically exempted by law, the facility requires a tissue bank license. If the facility orders a frozen or cryopreserved allograft for a specific patient and holds it in the unopened, validated, temperature-controlled shipping container no longer than the validation expiration date and time specified by the shipper before implanting, returning, or discarding the tissue, the facility does not require a tissue bank license. The temporary storage of the allograft tissue in the unopened, validated, temperature-controlled shipping container is covered by the California tissue bank license of the facility that ships the tissue. The temporary storage of room temperature or refrigerated allografts ordered for a specific patient is covered by the shipping facility's California tissue bank license until implanted into that patient or returned to the shipping facility. If the receiving facility stores the tissue as part of available allograft inventory, the facility requires a California tissue bank license.

Sincerely,

California Department of Public Health
Laboratory Field Services / Tissue Bank Program