



New York State Tissue Resources Program

Policy – Hematopoietic Progenitor Cell Bank Personnel Qualifications

Effective date – July 8, 2026

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

Hematopoietic progenitor cell (HPC) banks may establish internal qualifications for director and medical director.

10 NYCRR Section 58-5.2 establishes certain qualifications for personnel to serve as director or medical director of HPC banks that procure and/or process hematopoietic progenitor cells from bone marrow, peripheral blood and umbilical cord blood. These qualifications address education, training and experience, and include the performance or supervision of a specified number of HPC collections and/or processing procedures, respective of the services offered. New York State's criteria are significantly more prescriptive than those in the 49 other states, without obvious public health benefit. Further, the criteria pertain to a candidate's historical experience and do not consider recency or ongoing performance. As certain types of HPC collections have waned in usage, fewer personnel are able to meet the specified criteria, which are required for continued licensure, thereby jeopardizing access to a critical treatment.

In order to ensure that HPC transplants remain available, the Department will no longer enforce the requirements in 58-5.2(e) and 58-5.2(f) that specify a minimum number of collections and processing procedures. Instead, each HPC bank must either comply with the existing requirements in 58-5.2(e) and 58-5.2(f), or establish internal qualifications for personnel to serve as director and/or medical director. The Department will continue to enforce the requirements regarding education and training of the director and medical director.

When submitting an application for a new HPC bank license, an amendment reporting a change in HPC bank director or medical director, or an amendment to add sources of HPCs collected and/or processed, an applicant that has opted to establish internal qualifications rather than adhere to the requirements in 58-5.2(e) and/or 58-5.2(f) shall submit the respective policy to the Department along with the application. If the Department finds the policy inadequate, the Department may deny the application or return the policy for revisions, which shall be binding on the applicant.