New York State Clinical Laboratory Technology Board Guidance for Stem Cell Process Training Programs

Background

In 2008, New York law established a Clinical Laboratory Technologist Restricted License in Stem Cell Processes. At that time, people with a Restricted License in Stem Cell Processes worked in clinical laboratories/tissue banks that processed hematopoietic stem cells for homologous therapeutic use. Since that time, scientific advances have led to the development of new stem cell technologies and cell processing services provided by clinical laboratories. The CLT Board Office requests assistance from CLT Board Members to describe minimum requirements for Training Programs in Stem Cell Processes that reflect current clinical laboratory standards and practices. Below is an early draft of guidance for such Training Programs.

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New York State law established a Clinical Laboratory Technologist Restricted License in Stem Cell Process. To qualify for this license, an applicant must complete: (1) an acceptable bachelor's or higher degree with a major in biology, chemistry, physical sciences, or mathematics, and (2) a New York State Education Department (NYSED) approved Stem Cell Processes Training Program.

This Guidance describes *minimum* requirements relating to Stem Cell Process Training Programs. Training Programs may offer Stem Cell Process education in addition to the learning experiences described in this guidance. Each Training Program must have a written Stem Cell Process Training Program Plan that demonstrates how the Training Program meets all criteria described in this guidance (or equivalent criteria).

Approval Process for Participation in a Stem Cell Process Training Program

To obtain NYSED approval to participate in a Stem Cell Process Training Program, an applicant for a Restricted License in Stem Cell Process must submit to NYSED: *Form 1-Application for a Restricted License*, *Form 4-Attestation of Training Program Content in Stem Cell Process*, and a written Stem Cell Process Training Program Plan. The applicant must arrange to have *Form 2 -Certification of Professional Education* and a college transcript(s) submitted to NYSED for review. NYSED may require the applicant to submit additional documentation relating to Training Program requirements.

If acceptable, NYSED will issue to the applicant a Stem Cell Process Training Program Certificate, which authorizes the applicant to participate in the Stem Cell Process Training Program.

To verify to NYSED that the applicant has successfully completed the NYSED approved Stem Cell Process Training Program, the applicant must submit to NYSED *Form 4A-Certification of Completion of Training Program in Stem Cell Process*.

General Requirements for Stem Cell Process Training Programs

A Clinical Laboratory located in New York must operate the Stem Cell Process Training Program. The Clinical Laboratory must have a New York State Department of Health (DOH) issued clinical laboratory permit in blood banking and a permit in hematopoietic progenitor cell processing and/or storage. These permits must authorize the Clinical Laboratory to provide on premises services necessary to prepare, preserve, store, and/or remove from storage stem cell products, and conduct clinical laboratory testing to assure the potency, quality, or sterility of stem cell products for transfer to another facility or for transplantation into patients.

The Training Program must have a planned sequence of supervised employment or engagement in activities appropriate for a Restricted License in Stem Cell Process. The Training Program must be at least 1750 clock hours (I year).

The Clinical Laboratory must employ a Laboratory Director or Sole Assistant Laboratory Director holding a DOH issued Certificate of Qualification (CQ) in immunohematology to oversee the Training Program. This person (hereinafter the Training Program Director) must sign NYSED's forms *4 and 4A*.

The Clinical Laboratory and Training Program Director must ensure that at least one of the following qualified staff provide continuous onsite training and supervision of the Stem Cell Process Training Program trainee while they perform clinical laboratory services:

- A laboratory director or sole assistant laboratory director with a DOH issued Laboratory Director CQ in immunohematology; or
- A clinical laboratory technologist or physician who qualifies as a "laboratory supervisor" under DOH regulations (10 NYCRR section 58-1.4) and authorized by the Clinical Laboratory to perform stem cell process services and authorized by the Training Program Director to train or supervise Training Program trainees or,
- A laboratory director or sole assistant laboratory director may supervise or train a trainee who performs stem cell processing tests in the same testing area in which the director holds a DOH issued CQ. For example, a laboratory director with a CQ in cellular immunology may train a trainee to perform flow cytometry on stem cell products.

Important Note: The Stem Cell Process Training Program Plan must identify by name and credentials the Training Program Director and all staff who provide onsite training and supervision of the Training Program trainee.

<u>Stem Cell Process Training Program Content Requirements</u>

The Stem Cell Process Training Program must provide didactic education (i.e., lectures, reading) in clinical laboratory services necessary to prepare, preserve for storage, and remove from storage stem cells and/or conduct clinical laboratory testing to assure the potency, quality, or sterility of stem cells for transplantation, transfer, or implantation into patients. The following topics, at a minimum, must be covered:

1. Human cell biology (including hematopoietic, cord blood and immune cells biology as well) and cellular therapies.
2. Laboratory operations relevant to stem cell processes, including, but not limited to, laboratory principles and procedures, quality control, quality assurance, safety, aseptic techniques, and instrument operation and maintenance, infection control.
3. Stem cell processing procedures, including but not limited to, reagent preparation; cell product accessioning and labeling; cell isolation; cell cryopreservation; storage and thawing; and procedures that expand, functionally, or alter or manipulate cell populations.
4. Clinical laboratory tests to assure the potency, quality, or sterility of stem cells transfer to other facilities or for transplantation into patients.

The Training Program may cover additional subjects relating to stem cell therapies (such as donor eligibility, cellular product procurement). The Training Program Plan must identify reading materials (i.e., textbooks, articles, online training modules) that cover relevant science-related content.

Hands-on Training/Practicum Requirements

Each trainee must engage in hands-on training in stem cell process, including, but not limited to stem cell product identification, cryopreservation, maintenance, and thawing; techniques to prevent specimen contamination; reagent preparation; and, clinical laboratory tests to assure the potency, quality, and/or sterility of stem cells for transfer to another facility, or for transplantation into patients. The Training Program **may offer additional** hands-on training in the field of stem cell processes if the Clinical Laboratory is authorized to provide services in the additional fields. For example, if the Clinical Laboratory is authorized by its permit to perform flow cytometry, the training program may offer hands-on training in the use of flow cytometry on stem cell products. The Training Program Director must verify that the trainee has successfully completed a summative competency assessment in stem cell processes. The Training Program Plan must describe in detail how hands-on training will be provided and include evaluation criteria used to assess the trainee's learning.