6.14.2024 - - FOR DISCUSSION PURPOSES ONLY

Stem Cell Process Restricted License
Scope of Practice

In 2008, the Education Law established a "Stem Cell Process" Restricted License. (NYSED cannot update the name of this license.) Initially, licensees worked in clinical laboratories/tissue banks that processed hematopoietic stem cells for homologous therapeutic use (i.e., bone marrow transplants). Recent scientific advances have led to the development of new stem cell therapies using additional types of cells and new clinical laboratory processes. The CLT Board Office seeks guidance from CLT Board Members to describe the scope of services authorized by a Stem Cell Process Restricted License, which reflects current clinical laboratory standards and practices. Key questions/issues are summarized below.

Identification of Clinical Laboratory Services authorized by a Stem Cell Process Restricted License

1. Identification of stem cell therapy products or stem cells that may processed under a Stem Cell Process Restricted License

The following types of stem cells or stem cell therapy products may be processed under a Stem Cell Process Restricted License:

- Hematopoietic progenitor cells (HPCs) obtained from bone marrow, umbilical cord tissue, and/or whole blood for homologous and processed therapeutic use (i.e., bone marrow transplant)
- Mesenchymal stem cells (MSCs) obtained from bone marrow, umbilical cord tissue, and other tissues and processed for therapeutic use (i.e., to treat graft versus host disease (GVHD))

Are there other types of stem cells or stem cell therapy products that may be processed under a Stem Cell Process Restricted License, such as those listed below?

- Mononuclear cells or nucleated cells from a hematopoietic tissue source (bone marrow, umbilical cord, whole blood) and processed for non-homologous therapeutic uses (i.e., CART-T cell or other immune effector cell therapies)
- Induced pluripotent stem cells (iPSC) - adult stem cells that have been engineered in a laboratory to be pluripotent for therapeutic use. (Are IPSCs administered to patients in investigational new drug trials)

2. Services that may be performed on stem cells or stem cell therapy products under a Stem Cell Process Restricted License.

Which types of processing services are performed on stem cells or stem cell therapy products under a Stem Cell Process Restricted License?

- Accessioning harvested stem cell tissue. *Note: Although "unlicensed staff" and clinical laboratory practitioners may perform accessioning services, accessioning is none the less within the scope of practice of the clinical laboratory practitioner.*
- Selective removal of cell populations or isolation of specific cell populations
- Cell culturing and/or cell population activation and/or expansion of cell populations
- Cell cryopreservation, thawing and storage under appropriate environmental conditions
- Procedures that functionally alter cell populations (i.e., genetic modifications using viral vectors or CISPR)
- Any other specific types of services?

Note: Processing means any activity necessary to prepare, preserve for storage, remove from storage and/or conduct laboratory testing to assure the potency, quality and/or sterility of.... tissue for transplantation, transfer, ... or implantation. (see, 10 NYCRR sec. 52-1.1)

Which types of assays are performed on stem cells or stem cell therapy products under a Stem Cell Process Restricted License?

- ABO blood group and Rh type
  - *DOH Permit Category(ies): Immunohematology*
- Cell Sterility assays – (i.e., testing for microbes, antigens, antibodies, contaminants)
  - *DOH Permit Category(ies):* Bacteriology, Diagnostic Immunology, Virology, *Mycology*
- Cell phenotyping analysis
  - *DOH Permit Category(ies) Cellular Immunology*
- Targeted cell counts, viability tests and/or cell product potency testing during processing.
- HLA Testing (i.e., cross matching, antibody testing)
  - *DOH Permit Category(ies) Histocompatibility Testing)*
- Tests that demonstrate that final cell therapy product includes adequate viable targeted cell yields, microbial sterility, etc.)
- Endotoxin Tests/ CFU
- Any other clinical laboratory testing methods/procedures?

3. Identification of laboratory tests that may be performed on specimens from sources OTHER THAN stem cells or stem cell therapy products

- Donors: (i.e., obtaining a blood sample from the donor to test for ABO group and RH type, HLA typing infectious diseases, etc.).
- For cord blood donations, testing of a sample of the donor's birth mother's blood for infectious diseases.
- Stem Cell Transplant Recipients (i.e., obtaining a blood sample from the stem cell transplant recipient to perform transplant monitoring tests)

Updating Requirements for Training Programs in Stem Cell Processes

After updating and clarifying scope of services authorized by a Stem Cell Process Restricted License, the CLT Board Office start work on updating requirements for Stem Cell Process Training Programs and may seek guidance from CLT Board Members on Training Programs at a later date.

State Education Department regulations describe content requirements for Stem Cell Process Training Programs, as follows:

> For a certificate in the area of stem cell process, the training program shall include knowledge of stem cell biology. It shall also include, but need not be limited to, general laboratory principles and skills; infection control and aseptic technique methods; instrumentation and equipment; quality control and quality assurance; laboratory mathematics; the process of handling stem cell specimens in the laboratory; enumeration and characterization of stem cells; ABO/Rh confirmatory typing; and reagent preparation. 8 NYCRR sec. 70-13.5 (c)(2)(v)(c)

Current Training Program requirements, described below, are also being provided for your information.

- A NY clinical laboratory with a DOH issued permit in immunohematology must operate the Training Program.
- A laboratory director or sole assistant laboratory director holding a DOH issued CQ in immunohematology must oversee the Training Program. Qualified staff must provide onsite supervision and hands-on training.
- The Training Program must have a planned sequence of supervised employment or engagement in activities appropriate for a Restricted License in Stem Cell Processes.
- The Training Program must be at least 1750 clock hours (I year).
- The Training Program must cover stem cell biology; general laboratory principles and skills; infection control and aseptic techniques; instrumentation and equipment; quality control and quality assurance; laboratory math; handling stem cell specimens in the laboratory; enumeration and characterization of stem cells; ABO/Rh confirmatory typing; and reagent preparation.

Please Note: If a Restricted License in Stem Cell Processes scope of practice includes new/additional clinical laboratory services, then requirements for Stem Cell Processes TRAINING PROGRAMS will increase to cover the additional services.