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Training:**

S. A. Hill, PhD., FCACB,  
Hamilton Regional  
Laboratory Medicine  
Program,

August 5, 2008

Ms. Barbara Sullivan

Chair

Health Professions Regulatory Advisory Council

Suite 806

55 St. Clair Avenue West

Toronto, ON

M4V 2Y7

Dear Ms. Sullivan

Re: CLMTO, OSMT, CSMLS Joint Submission to the HPRAC

The Ontario Society of Clinical Chemists (OSCC) and the Clinical Doctoral Laboratory Scientists of Ontario (CDLSO) represent approximately 200 self regulated clinical doctoral laboratory scientists who practice in both the acute care hospital and community laboratories in Ontario. Our members provide a significant proportion of the laboratory medical/scientific services in the licensed clinical pathology laboratories of Biochemistry, Biochemical Genetics, Cytogenetics, Molecular Genetics, Microbiology, Immunohistocompatibility and Virology. Our responsibilities include administration, clinical interpretation of laboratory tests, supervision of laboratory operations and analytical processes and development, validation and implementation of new tests and methodologies. In addition, the majority of our members hold university academic appointments and are active in teaching and research.

While the majority of our member's principle practice is based out of the large academic health science center (AHSC) hospital laboratories, we also provide consulting and laboratory directorship services to many rural and community hospitals through the regional laboratory networks across Ontario.

Clinical Doctoral Laboratory Scientists have earned doctoral degrees in basic or life sciences and have completed extensive post-graduate training in selected sub-specialty disciplines of laboratory medicine. The majority of our members have completed comprehensive oral and written examination processes to achieve fellowship with one of the national professional bodies (e.g. FCACB- Fellow Canadian Academy of Clinical Biochemistry, FCCMG- Fellow Canadian College of Medical Genetics).

We have read with interest the joint submission of the CLMTO, OSMT and CSMLS requesting changes to the Medical Laboratory Technologists' Scope of Practice and the Regulation of Medical Laboratory Assistants/Technicians. On a daily basis clinical doctoral laboratory scientists work closely with MLTs providing direction and supervision on most aspects of their current scope of practice in all working environments (e.g. rural and community hospitals, AHSC's and private (community) laboratories). As such, for the clinical pathology laboratories in particular, we have an intimate understanding of the knowledge and skills MLTs currently possess and the challenges many MLTs face in meeting and maintaining the stringent competency requirements for their current scope of practice.

We would like to share our comments and some significant concerns including patient safety implications regarding the requested changes detailed in the CLMTO submission.

## OSCC and CDLSO Comments on CLMTO/OSMT/CSMLS Submission to Request Change in MLT Practice

- a) Pg 11. Expand scope of practice to include *“Administering a substance by injection”* to allow injections for various therapeutic procedures, for example allergy testing.

**Comment:** none

- b) Pg 11. Expand scope of practice to include *“Putting an instrument, hand or finger, beyond the opening of the urethra and beyond the labia majora”* for the purposes of various therapeutic procedures such as PAP tests.

**Comment:** it is difficult to imagine scenarios where an MLT would be the only individual available to perform this procedure (eg no nurse or physician available). Procurement of a PAP specimen should be part of a clinical examination that includes obtaining an appropriate clinical history. The submission provides insufficient explanation or description of situations which would warrant including this activity in the MLT general scope of practice.

While we don't have any specific concerns about patient risk or impact on quality of laboratory services by including this in the scope of MLTs, we do question the benefit as a general addition to the scope of practice of all MLTs. Training of current and future MLTs to perform PAP specimen procurement would present significant challenges as would on-going assessment of competence as required under the Ontario Laboratory Accreditation (OLA) standards.

In rare and unusual circumstances where an MLT may provide this service, it would be better addressed through a specific medical directive or a delegated act from a physician who has properly trained and assessed the competency of the individual MLT to perform the task.

### WE DO NOT SUPPORT THIS REQUEST

- c) Pg 11. Propose rewording the statutory scope of practice along the lines of the scope of practice statement for the profession devised by the American Society for Clinical Laboratory Science (ASCLS): *“...the design, performance, evaluation, reporting, interpreting and clinical correlation of clinical laboratory testing in the management of all aspects of these activities”*

**Comment:**

This is an extremely wide and non-specific scope of practice statement. We are particularly concerned about *“...interpreting and clinical correlation of laboratory testing”*. On page 14 of the submission it is stated that *“MLTs that perform these analyses are not only skilled in the technical aspects of the testing, but also in the pathology of the disease. They have the knowledge, skill and judgment to interpret the test results and advise not only the primary care provider, but also the patient in point of care and other venues on follow up required”*

We note that interpretation of laboratory tests is rarely simple and straightforward. The pathophysiology of disease is complex. Interpreting a laboratory test result is not done in isolation and requires review of the clinical history and other laboratory tests which may not be available to an MLT. As an example, an increase in serum glucose might be interpreted as due to diabetes but may in fact be due to any number of other complex pathological processes or therapeutic interventions. Laboratory medicine is one of the most dynamic subspecialties of medicine. New laboratory tests are constantly emerging and our understanding of the relationship of “traditional” laboratory tests with specific disease processes is rapidly changing. Laboratory physicians and clinical doctoral laboratory scientists undergo 3 to 5 years of postgraduate training and are constantly attending clinical CME activities to attain the knowledge and competency required to interpret laboratory test results. It is our opinion that the majority of MLTs do not have sufficient knowledge required to safely interpret and provide clinical correlation of laboratory tests.

We would note that based on the information provided in the submission (pg 29 to 38), in no other jurisdictions does the scope of practice for MLTs include the interpretation and clinical correlation of laboratory results.

We believe this change in scope of practice would lead to a significant risk to patients and the general population through misinterpretation (including "under" and "over" interpretation) of test results.

**WE DO NOT SUPPORT THIS REQUEST.**

d) Pg 11. Proposed change to allow MLTs to draw blood from arteries.

**Comment: none**

e) Pg 12. Change Laboratory and Specimen Collection Centre Licensing Act R.R.O. 1990 Regulation 682 to Allow MLT's to initiate laboratory tests.

**Comment:**

Currently in many laboratories, tests are added on based on algorithms which have been approved by the laboratory medical/scientific director usually in consultation with the appropriate physicians. MLTs currently add on tests under these approved algorithms.

The request to change the scope of practice of MLTs to allow them to initiate any laboratory test raises a number of significant concerns:

- Unnecessary duplication of tests: the MLT may not be aware of tests which have already been performed in other laboratories
- Selecting which tests to perform on a patient should be driven by the clinical history and differential diagnosis not solely by other laboratory tests.
- Performance of unnecessary tests. Some abnormal test results will be expected based on the clinical history of the patient (eg an increased glucose on a patient receiving glucocorticoids). In these situations, the MLT made add on tests that are of no value.
- Patient may have expressed indicated to their physician that they do not wanted to have specific tests performed.

**WE DO NOT SUPPORT THIS REQUEST**

f) Pg 12-13. Change Medical Laboratory Technology Act to allow MLTs to inject substances into veins arteries for testing or therapeutic purposes .

**Comment**

Injection of a substance into veins or arteries for therapeutic purposes requires comprehensive knowledge and training to understand and monitor the effectiveness and safety of these procedures. This appears to be well outside the current scope of practice of MLTs. An extensive program of clinical education would need to be added to the current two year training program. The submission provides no details on how this change in scope would be safely implemented and/or how the cost of retraining and monitoring the competency of hundreds of current MLTs would be addressed

**WE DO NOT SUPPORT THIS REQUEST.**

g) In several places the document refers to the limitations of medical directives and the "work arounds" used to implement these directives.

**Comment**

These "work arounds" do not significantly limit the scope of practice of MLTs. Rather, they represent the practical implementation of medical directives. The ordering of follow-up tests is currently well covered by medical directives and reflex testing algorithms which have developed by laboratory physicians and clinical doctoral laboratory scientists, through review of the literature and extensive consultation with appropriate subspecialty physicians and professional organizations. (see section c and e for additional comments).

- h) Pg 14 "Medical Directives are prescriptive. All patients fitting the criteria outlined by the medical directive are expected to have all procedures and tests that have been ordered. This does not, however, allow for independent judgment on the part of the delegatee to initiate necessary follow-up procedures and tests, or not to perform procedures and test that are unnecessary or might even be harmful."

**Comment**

Well designed medical directives can and do cover all eventualities of follow-up testing. Moreover, nothing in the current scope of practice obliges MLTs to perform procedures they judge to be harmful. MLTs can, and should, seek clarification and guidance from the ordering physician and/or the laboratory medical/scientific director or delegate medical/scientific staff.

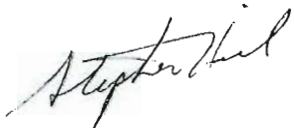
- i) Pg 16 The CMLTO sponsored a "Crystal Clear" summit on April 3, 2008. They report general agreement from invited attendees. The Ontario Society is listed in Appendix B as an invited attendee.

**Comment**

The President and Council of the OSCC have no record of an invitation, nor did anyone in a position to speak for the OSCC attend this meeting.

We would be pleased to further discuss or elaborate on our comments and concerns.

Your truly,



Stephen Hill, PhD, FCACB  
President - Ontario Society of Clinical Chemists  
c/o Hamilton General Hospital  
Laboratory Medicine



Sherry L. Perkins, PhD, FCACB, FACB  
President - Clinical Doctoral Laboratory Scientists of Ontario  
c/o The Ottawa Hospital  
Division of Biochemistry

Cc: Ontario Medical Association-Laboratory Medicine Section Executive:  
Dr. B. Mullen  
Dr. V. Walley  
Dr. D. Macdon  
Dr. C.M. McLachlin