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# Application for Preliminary Sunrise Review Assessment

## 1. Profession/Occupation seeking regulation

**Name**

**Medical Laboratory Science Professionals**

**A coalition of: Medical Laboratory Scientists (Generalists and Specialists), Medical Laboratory Technicians, Cytotechnologists, Histotechnologists, Histotechnicians and Pathologists' Assistants**

## 2. Person/Organization submitting application:

**Name**

**David McLane MT(ASCP) for ASCLS-VT  
Carol Roberts CLS(NCA) for ASCLS-VT  
Sandra Giroux SCT(ASCP) for ASCP  
Carol Colasacco SCT (ASCP) for VTNHCA  
Jude Carpenter HTL(ASCP) for VTNHSH  
Jeannette Mitchell, HTL, QIHC(ASCP) for VTNHSH  
Michelle Schwartz, PA(ASCP) for AAPA**

**Organization**

**American Society for Clinical Laboratory Science-Vermont Chapter  
Vermont/New Hampshire Cytotechnology Association  
Vermont/New Hampshire Society of Histotechnology  
American Association of Pathologists' Assistants**

**Address: (Street) (City) (State) (Zip Code)**

**For Licensure Coalition: David McLane 247 Collins Pond Rd., Hyde Park, VT 05655**

Phone # FAX # E-mail	phone	fax	e-mail
David McLane MT(ASCP) for ASCLS-VT	802-888-8341	802-888-8225	dmclane@chsi.org
Carol Roberts CLS(NCA) for ASCLS-VT	802-847-7639	802-847-4103	carolofvt@aol.com
Sandra Giroux SCT(ASCP)			sandra.giroux@vtmednet.org
Carol Colasacco SCT(ASCP)			carol.colasacco@vtmednet.org
Jude Carpenter HTL(ASCP)			jude.carpenter@vtmednet.org
Jeannette Mitchell, HTL,QIHC(ASCP)			jeannette.mitchell@vtmednet.org
Michelle Schwartz, PA(ASCP) for AAPA			michelle.schwartz@vtmednet.org

3. Vermont Society/Association - (Attach copies of Standards of Practice and Code of Ethics)

See Tab A

<b>Name</b> American Society for Clinical Laboratory Science-Vermont Chapter Vermont/New Hampshire Cytotechnology Association Vermont/New Hampshire Society of Histotechnology
<b>Contact Person</b> as above
<b>Address: (Street) (City) (State) (Zip Code)</b> as above
<b>Phone # FAX # E-mail</b> as above

4. National Society/Association - (Attach copies of Standards of Practice and Code of Ethics)

See Tab B

<b>Name</b> American Society for Clinical Laboratory Science American Society for Cytotechnology National Society of Histotechnology American Association of Pathologists' Assistants
<b>Contact Person</b> as above
<b>Address: (Street) (City) (State) (Zip Code)</b> as above
<b>Phone # FAX # E-mail</b> as above

5. Does the National Organization have a license or certification process? YES NO  
Yes for Certification No for License

If yes, attach supporting documentation.

See Tab C

6. List other states currently regulating this profession/occupation. For each state attach copies of the laws and rules.

Alaska - Tab D	California - Tab E (not yet included)	Florida - Tab F	Georgia - Tab G (not yet included)
Hawaii - Tab H	Louisiana - Tab I	Montana - Tab J	Nevada - Tab K
New York - Tab L	North Dakota - Tab M	Puerto Rico - Tab N (not yet included)	Rhode Island - Tab O
Tennessee - Tab P	West Virginia - Tab Q		

The following states have submitted or are preparing legislation for licensure: Illinois, Indiana, Massachusetts, Minnesota, Missouri, Pennsylvania, Iowa, Maine and Vermont

7. Define the services provided by this profession/occupation. What is the Scope of Practice?

#### **Medical Laboratory Scientists**

(g) "Medical laboratory scientist" or "generalist" or "specialist" means an individual eligible for licensure under this chapter who:

- (1) performs medical laboratory tests, including tests that require exercise of independent judgement;
- (2) establishes and implements protocols, quality assessment, method development and selection, equipment selection and maintenance, and activities related to the preanalytic, analytic, and postanalytic phases of laboratory testing; and
- (3) directs, supervises, consults, educates, and performs research functions.

#### **Medical Laboratory Technicians**

(k) "Medical laboratory technician" means an individual eligible for licensure under this chapter who performs medical laboratory tests pursuant to established and approved protocols that are performed with oversight from a medical laboratory scientist, laboratory supervisor, or laboratory director. The technician may supervise and educate.

#### **Cytotechnologists**

(a) "Cytotechnologist" means an individual eligible for licensure under this chapter who specializes in the cellular analysis of patient samples from all body sites, for the purpose of evaluating, detecting, and

providing information regarding disease processes, including analyses that require the exercise of independent judgment, and who:

- (1) assists health care providers with the collection, detection, and interpretation of normal and abnormal cells, infectious agents, and other noncellular material from submitted specimens;
- (2) performs a variety of ancillary tests to ascertain information to help in classification, prognosis, or disease detection, including, but not limited to, immunohistochemical and molecular techniques;
- (3) establishes and implements protocols, quality assessment, method development and selection, equipment selection and maintenance, and activities related to the preanalytic, analytic, and postanalytic phases of testing; and
- (4) directs, supervises, consults, educates and performs research functions.

### **Histotechnologists**

(b) "Histotechnologist" means an individual eligible for licensure under this chapter who:

- (1) prepares tissue specimens for microscopic examination:
- (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy and validity of laboratory testing and procedures including, but not limited to, techniques in fixation, processing embedding, microtomy, cryotomy, ultramicrotomy, and staining;
- (3) prepares gross specimens under the direction of a board-certified pathologist;
- (4) establishes and implements protocols, quality assurance, and quality control related to a variety of ancillary procedures including but not limited to immunohistochemical and molecular techniques;
- (5) participates in method selection, development, equipment selection and maintenance, and activities related to the preanalytical and analytical phases of tissue preparation;
- (6) establishes and implements new protocols and procedures dealing directly in quality assessment, method development, and equipment selection and maintenance; and
- (7) directs, supervises, consults, educates and performs research functions.

### **Histotechnicians**

(c) "Histotechnician" means an individual eligible for licensure under this chapter who:

- (2) prepares tissue specimens for microscopic examination:
- (3) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy and validity of laboratory testing and procedures including, but not limited to, techniques in fixation,

processing embedding, microtomy, cryotomy, ultramicrotomy, and staining;

- (4) prepares gross specimens under the direction of a board-certified pathologist;
- (5) establishes and implements protocols, quality assurance, and quality control related to a variety of ancillary procedures including but not limited to immunohistochemistry and molecular techniques;
- (6) participates in method selection, development, equipment selection and maintenance, and activities related to the preanalytical and analytical phases of tissue preparation; and
- (7) directs, supervises, consults, educates and performs research functions.

#### **Pathologists' Assistants**

(l) "Pathologist's assistant" means an individual eligible for licensure under this chapter specializing in prediagnostic surgical pathology and autopsy pathology who assists pathologists by:

- (1) processing surgical samples, including dissection and description of pertinent features, submission of tissue samples for microscopic examination, assistance in frozen section preparation to include cryotomy, and other ancillary duties to be performed under the supervision of a pathologist; and
- (2) performing functions in autopsy pathology, including prosection, selection of tissues for microscopic examination, and other ancillary duties to be performed under the supervision of a pathologist.
- (3) Pathologists' assistants may direct, supervise, consult, educate and perform research functions.

#### **Pathology Technicians**

(m) "Pathology Technician" means an individual eligible for licensure under this chapter specializing in prediagnostic surgical pathology and autopsy pathology who assists pathologists and/or Pathologists' Assistants by:

- (1) processing surgical samples, including dissection and description of pertinent features, submission of tissue samples for microscopic examination, assistance in frozen section preparation to include cryotomy, and other ancillary duties to be performed under the supervision of a pathologist and/or Pathologists' Assistants; and by
- (2) performing functions in autopsy pathology, including prosection, selection of tissues for microscopic examination, and other ancillary duties to be performed under the supervision of a pathologist and/or Pathologists' Assistant.
- (3) Pathology Technicians may direct, supervise, consult, educate and perform research functions.

*When space provided is insufficient, attach additional sheets as needed*

**8. What harm or danger to the health, safety, or welfare of the public can be demonstrated if the practice of this profession/occupation were to remain unregulated? (Note: The potential for harm must be recognizable and not remote of speculative.)**

- Medical Laboratory Scientists and Technicians are responsible for ensuring accurate diagnoses of patient tissues and the routine and high complexity testing performed on these irreplaceable patient samples.
- Medical Laboratory Scientists and Technicians working in the Blood Bank section are responsible for all phases of preparing red blood cells and other blood products for transfusion. A single mistake during any part of that testing can result in irreversible kidney damage and death.
- More than 70% of all medical decisions are based on laboratory data. Individuals who have not successfully passed certification examinations are more likely to make errors as determined by JCAHO studies.
- Medical Laboratory Scientists and Technicians make decisions independently regarding the accuracy and quality of laboratory data throughout the day, evening and night. The minimal level of expertise required to make these decisions is best obtained through formal education.
- Medical Laboratory Scientists working in the Microbiology section of the laboratory assess growth patterns and morphology of bacterial and viral cultures for suspected pathogenic organisms. Failure to recognize pathogens can result in failure to initiate appropriate antimicrobial treatment.
- Individuals who commit serious errors, whether due to inability or intent, may be terminated at one facility only to be hired by another facility.
- An inappropriate decision or action can delay appropriate treatment and cause harm to the patient.
- Medical Laboratory Scientists working in the Hematology section of the laboratory assist physicians during bone marrow aspiration, a very painful process. The laboratory scientist transfers a portion of the marrow to special media for culture, chromosome studies and various other specialized laboratory procedures. The laboratory scientist also prepares direct smears on glass slides at the time of collection for later staining and review. Failure to handle these tasks in a timely and accurate manner can render the bone marrow unsuitable for testing. This may not be recognized immediately. The result can be a missed diagnosis or the need for repeat collection which delays treatment.
- Current laboratory regulations allow untrained or uneducated individuals to perform medical lab tests. Many of these tests are highly complex and appropriate levels of education and experience are required to ensure accuracy of testing.
- Inappropriate testing results in prolonged illness, missed diagnoses, failure to treat, and increased health care costs.
- Through microscopic evaluation, Cytotechnologists determine which Pap Tests need to be

referred on to a Cytopathologist and which ones do not require further review. These "Negative" Paps are signed out by one individual cytotechnologist. Under calling an abnormal Pap as Negative results in a delay in treatment as the patient will not be scheduled for another Pap for another 1 - 3 years depending on her age. During this time frame a pre-malignant lesion can progress into a more advanced lesion, even cancer.

- Cytotechnologists evaluate non-gynecologic specimens from a wide variety of body sites such as lung, liver, pancreas, bladder, breast, thyroid and salivary gland. During the review process the cytotechnologist selects the cells that are the most representative of the disease process if present. All non-gynecologic specimens are referred to a Cytopathologist who will focus their attention to the areas selected by the Cytotechnologist. Therefore the quality of the final review by the Cytopathologist is directly impacted by the quality of the initial evaluation and selection process by the Cytotechnologist. In cases with more than one disease process present, if the Cytotechnologist mistakenly only selects one, then the Cytopathologist will most likely make the same mistake.
- Cytotechnologists must interpret the cellular specimens in the context of each patient's clinical history and situation. They must understand the nuances of changes caused in the specimens by non-disease states. Not all changes are linked to a disease process. Factors like previous radiation therapy, surgery, chemotherapy and infection all can impact the morphology present in any specimen. Cytotechnologists must weed through these changes and thus not overcall cases that do not have disease present. Overcalling results in unnecessary treatment, and incorrect changes in prognosis.
- Cytotechnologists assist during Fine Needle Aspiration (FNA) procedures. The procedures are usually performed by a radiologist, surgeon or pathologist. These procedures involve the removal of cells from a mass using a needle and syringe apparatus. After the specimen has been collected the needle is handed off to a Cytotechnologist on site who is responsible for the appropriate retrieval of the cellular specimen and placement on glass slides. If the slides are not handled properly, the cellular specimen can be damaged thus reducing its morphologic value. This damage would not be apparent until the slides were stained and evaluated in the lab. The patient would then have to have an unnecessary second FNA procedure, if they could tolerate another one.
- The profession of Clinical Laboratory Science is facing a dramatic workforce shortage nationwide. The current vacancy rate nationwide is 13%. Quest Diagnostics, which employs about 8,500 lab professionals, making it one of the nation's largest lab companies, currently has about 1,200 openings nationwide.

Vermont has been somewhat insulated from the true statistics of the shortage as we have a 4 year Medical Laboratory Science program at the University of Vermont. This will not hold true as the average age of a Clinical Laboratory Scientist is 48 years old and the ensuing retirement of this group is going to have a dramatic impact on laboratories throughout the state. This combined with the closure of many educational programs for Clinical Laboratory Science will create a dramatic shortage within 5 years. Currently only two new clinical laboratory professionals enter the field for every seven who retire. It is estimated 13% of the work force is expected to retire in the next five years, with 25% retiring within the next 10 years.

Licensure of Clinical Laboratory Professionals is an essential step moving forward. If

laboratories are not able to find educated and certified personnel they may have to resort to training an under competent staff. This in turn will put additional pressure on the certified staff in these laboratories as they will have greater supervisory duties to train and monitor these individuals. Licensure for the state of Vermont will provide 3 fundamental pieces to continue high quality laboratory results for patients and the clinicians evaluating these results:

1. It will define the minimum educational standards required to work in that scope of practice. It will also require a certification exam that passage of indicates the individuals have achieved adequate education. This part alone is the most integral part of licensure.

2. It defines the scope of practice of the profession so that if we are not able to meet the demands of the testing needed to be done other interested individuals cannot try to fill the gap with unqualified personnel.

3. It raises the professional status of the profession. Individuals may want to pursue an educational experience in Clinical Laboratory Science if the pride and status are elevated.

- If under-qualified individuals are allowed to perform laboratory testing in the state of Vermont, quality of the results generated are at much greater risk of error, thus putting the public at risk of great harm.
- Lowering the standards so that more under-qualified individuals are able to perform patient testing will only worsen the national shortage of qualified individuals and this is not in the best interest of the residents of Vermont.
- If a person without proper training was grossing a specimen there could be:
  - inadequate or improper sampling of specimens.
  - inaccurate assessment of tumor size and distance to margins.
  - misinformation leading to inappropriate stage and grade being assigned to a case leading to a change in the patient's further treatment.
  - delay in diagnosis resulting from having to go back to the specimen if something is missed.

*When space provided is insufficient, attach additional sheets as needed*

**9. What benefit can the public reasonably expect if this profession/occupation is regulated and how would it be measured?**

- Individuals who commit serious errors, whether due to inability or intent, can be appropriately and consistently retrained and or disciplined.
- Individuals who have had their licenses terminated for cause in another state can be identified prior to hiring.
- Knowledge of the theory behind the tests and the clinical relevance of the test greatly improves the likelihood of a quality result as compared to only having sufficient knowledge to perform the

steps needed to run the test.

- Continuing education leads to more understanding of the testing process and a higher quality product.
- Licensure will restrict medical laboratory personnel to practice in the areas of their education and experience.
- Licensure will ensure that all citizens of Vermont receive safe, accurate, and cost-effective medical laboratory tests.
- Establish a framework at the state level for improving laboratory personnel standards based on a multi tiered approach which recognizes that different levels of skill are required for different kinds of medical laboratory tests.
- Assure that medical laboratory testing personnel are required to meet professional standards of quality.
- The shortage of qualified medical laboratory personnel will begin to reverse as the profession regains respect and visibility.
- Decreased litigation from injured parties due to poor laboratory testing which in turn would decrease legal costs of hospitals. This ultimately reduces healthcare costs to consumers.
- Licensure would require certification through examination which serves as a quantifiable factor that the medical laboratory professional acquired the necessary knowledge and skill required for entry-level professional. (See the various certification examination content outlines in Tab C for question #5)
- If the Laboratory Science Professionals are licensed, thus setting the minimum standards of education and certification, the public will gain from the quality of the individuals performing their laboratory tests. The benefit can be measured by the error rates of laboratory tests at individual facilities and correlated with the number of qualified people employed there.
- Licensure would raise the professional status and recognition of Medical Laboratory Science Professionals, putting them on the same playing field as other health professionals who are already licensed. This recognition and validation of the profession should benefit career recruitment and ultimately help alleviate the personnel shortage.
- The public could expect to receive more accurate diagnoses which may have a higher rate of correlation with clinical and radiologic diagnoses than if their specimens were handled by inadequately trained Pathologists' Assistants. The length of time before results become available would be less because consults would be kept to a minimum and there would not be as much need to go back to review the specimen.

*When space provided is insufficient, attach additional sheets as needed*

**10. Why isn't the public protected from unprofessional practitioners through means other than regulation? (For example, criminal penalties, consumer fraud laws, small claims court, civil litigation, etc.)?**

- Federal law CLIA88 includes personnel qualification guidelines for a variety of medical laboratory positions. CLIA88 is not considered adequate by JCAHO. See Tab R
- Currently all Medical Laboratory Professionals work within a structured laboratory which assumes the liability for essentially all errors.

*When space provided is insufficient, attach additional sheets as needed*

11. Are you seeking Licensure, Certification or Registration? Licensure  
See 26 V.S.A. 3101a. Definitions.

12. a. What other regulated professions/occupations perform similar services to those of this profession/occupation?

none

b. How will the program distinguish between or among respective scopes of practice?

- The various Medical Laboratory Professions perform testing on distinct types of specimens from patients.

*When space provided is insufficient, attach additional sheets as needed*

13. How many practitioners of this profession/occupation do you estimate are practicing in Vermont? 400

14. Estimate the percentage of the practitioners practicing in the following settings.

Independent: \_\_\_\_\_ Clinics: \_\_\_\_\_ Hospitals: 90% \_\_\_\_\_

Other: 10% private laboratories

15. Is formal education required? YES NO If yes, complete below. **Yes**

<p><b>Educational Requirements</b></p> <p><b>Associates degree</b>  <b>Medical Laboratory Technician</b>  <b>Histotechnician</b>  <b>Pathology Technician</b></p> <p><b>Baccalaureate degree</b>  <b>Medical Laboratory Scientist (Generalist or Specialist)</b>  <b>Cytotechnologist</b>  <b>Histotechnologist</b>  <b>Pathologists' Assistant</b></p> <p><b>Masters degree</b>  <b>Pathologists' Assistant (alternate)</b></p>
<p><b>Where may this education be obtained?</b></p> <p><b>Only at accredited colleges and universities</b></p>

16. Is supervised experience required in addition to, or instead of, formal education? YES NO If yes, complete below. Yes

<p><b>Experience Requirements</b></p> <p><b>All Medical Laboratory Science curricula include appropriate clinical internships. Additional supervised experience is typically required as part of any laboratory initial orientation program.</b></p>
<p><b>Where may this experience be obtained?</b></p> <p><b>Internships are only available at medical facilities who have formal agreements with accredited college or university programs</b></p>

17. Is there a National examination? YES NO If yes, complete below. Yes

<p><b>Name and Address of Examination Agency</b></p> <p><b>American Society of Clinical Pathology</b>  <b>Medical Laboratory Scientists (Generalist and Specialist)</b>  <b>Medical Laboratory Technician</b>  <b>Cytotechnologist</b>  <b>Histotechnologist</b>  <b>Histotechnician</b>  <b>Pathologists' Assistant</b></p> <p><b>National Certifying Agency</b>  <b>Medical Laboratory Scientists (Generalist and Specialist)</b>  <b>Medical Laboratory Technician</b></p>
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**18. Does this profession/occupation need continuing education? YES NO If yes, explain below.**

**Yes**

- All disciplines of Medical Laboratory Science are rapidly changing.
- The complexity of the testing requires continual specialized training.
- Every laboratory result must be assessed as it relates to a variety of disease processes.

*When space provided is insufficient, attach additional sheets as needed*

**19. Based on the criteria you propose as a requirement to become licensed/certified/registered estimate how many of the current practitioners will qualify? \_\_Essentially all\_\_ with grandfather provisions. \_\_\_\_**

**20. What transitional provisions/"grandfather provisions" do you propose for current practitioners to obtain licensure/certification/registration?**

§ \_\_\_\_\_ **Employment reentry for medical laboratory science professionals**

- (a) An individual who does not meet the current education requirements described in this chapter may apply for a license under this section.
- (b) The director shall issue a license under this subdivision if the applicant:
  - (1) has passed a nationally recognized certification examination approved by the director; and
  - (2) has completed the education requirements in place at that time.
- (c) The director shall determine which type of license the applicant is eligible for and issue the license if the requirements of this subdivision are met.
- (d) This subdivision expires \_\_\_\_\_ (5 years after effective date of bill).

§ \_\_\_\_\_ **Employed medical laboratory science professional transition**

- (a) An individual who does not meet the education qualifications for any license described in this chapter may apply for a license under this section.
- (b) The director shall issue a license under this subdivision if the applicant:
  - (1) has two years of acceptable experience of at least half time (1040 hours per year) in the three years immediately prior to \_\_\_\_\_ (effective date of bill); and
  - (2) submits to the director the job description of the position, which the applicant has most recently performed, attested to by the applicant's employer.
  - (3) The director shall determine which type of license the applicant is eligible for and issue the license if the requirements of this subdivision are met.
  - (4) This subdivision expires \_\_\_\_\_ (effective date of bill)

*When space provided is insufficient, attach additional sheets as needed*

**21. Attach copies of any proposed legislative bill(s) related to this request.**

**See Tab S**

**22. Attach a list of all interested persons or groups in favor of, or opposed to, this request. Have they been consulted?**

**See Tab T for copies of letters where available.**

ASCP Supports  
CAP Supports  
VAHHS not yet discussed  
ASCLS Supports  
VT/NHSH Supports (Jeannette Mitchell, current President supports)  
NSH Supports (Kerry Crabb, current President supports)  
AAPA Supports  
Miscellaneous interested individuals  
Additional endorsement letters will be forthcoming

23. Include any statistical data on disciplinary actions for this profession/occupation in other states.

See Tab U

**Go to Administrative Rules for Procedures for Preliminary Sunrise Review Assessments**

**Return to Professions Home Page**

**Return to Professional Regulation Home Page**  
E-mail questions and comments about these pages to  
Christopher D. Winters, Director, Office of Professional Regulation  
([opr@sec.state.vt.us](mailto:opr@sec.state.vt.us))