214.002, Minnesota Statutes 2006

214.002 EVIDENCE IN SUPPORT OF REGULATION.

Introduction: This questionnaire will address issues related to the proposed licensure bill for medical laboratory personnel in the state of Minnesota. This bill (S.F.133 and HF0203) was introduced on January 28, 2013 The licensure coalition for laboratory professionals has developed the proposed legislation based on input from all segments of the medical laboratory community in the state (coalition organizations included)

- **American Society for Clinical Laboratory Science-MN**
- **American Society for Clinical Pathology**
- **American Medical Technologists-MN**
- **American Association for Clinical Laboratory Science-Midwest Section**
- **Clinical Laboratory Management Association-MN**
- **Minnesota Associate of Blood Banks**
- **Minnesota Interlaboratory Microbiology Association**
- **Association of Genetic Technologists**
- **Minnesota Society for Histotechnology**
- **Minnesota Society for Cytotechnology**

Like other licensed healthcare professions in the state, there are personnel shortages and with the aging workforce, this will not improve soon. However, we believe that consistent, elevated personnel requirements are needed. Our profession is in a situation to actually see an increase in the number of education providers for 4-year Clinical Laboratory Scientists with new programs at Mayo, Winona State University, and St. Cloud State University. In addition the University of Minnesota is committed to stabilizing and growing its program and has expanded its program to Rochester, MN. Finally, Argosy University is planning to open a 4-year program in 2009. In the two year associate degree programs for clinical laboratory technicians, there is enough capacity in the state, but here also we are seeing additional programs (3 Rasmussen programs in Eagan, Mankato and Moorhead, a new program at Dunwoody). In the area of histology technicians, there has only been one program in recent years, but in the fall of 2007 North Hennepin Community College opened a new program, and new programs at the University of North Dakota and Mayo Clinic have also begun. In addition, the number of distance, web-based learning programs is expanding in this country. We provide these examples as background to show that the ability to train qualified laboratory professionals does exist in this state and that the previous capacity needs for education are being addressed.

The basic belief of the licensure coalition is that licensure of this important profession, one that provides over 70% of the objective data used to make clinical decisions, is the foundation or framework that is needed to assure quality and patient safety. In addition the licensure of these key professions is necessary to assist the state in emergency preparedness planning.

Subd. 2. **Contents of report.**

(1) the harm to the public that is or could be posed by the unregulated practice of the occupation or by continued practice at its current degree of regulation;

Harm may occur when unlicensed individuals perform work that they may not be adequately educated/trained to perform. The proposed licensure legislation would require individuals to have specific education and experience and then obtain the proper certification. Currently, this certification is optional and up to the discretion of the employer and the practitioner (in some cases). Those who lack certification are usually trained on the job to perform specified tasks. Substandard and possibly misleading information could be produced by individuals who do not have adequate education or training to perform laboratory testing and make important judgments about the test results. This profession is not a "black box". Although many tests are performed with the assistance of highly automated pieces of equipment, a qualified laboratory professional is necessary to make technical judgments and to assure quality.

Laboratory information has a direct impact on patient diagnosis, treatment, health maintenance, safety, length of stay, as well as resource utilization and patient satisfaction.

(2) any reason why existing civil or criminal laws or procedures are inadequate to prevent or remedy any harm to the public;

The only current national regulations governing the laboratory environment are those under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). While those amendments and associated regulations have resulted in significant improvement in some segments of the laboratory environment, namely physician office laboratories and cytology, in general they only provide a basement level of regulation below which we would want no laboratory to perform. In reality the quality and regulatory standards most laboratories aim for are much higher and the personnel requirements under CLIA '88 would be considered minimal, at best, for most laboratory environments.

Most laboratory professionals are certified by a non-governmental agency or association which grants recognition to an individual who has met certain predetermined qualifications. Laboratory professionals are currently not be required to be certified and employers are not required to employ only certified professionals.

(3) why the proposed level of regulation is being proposed and why, if there is a lesser degree
of regulation, it was not selected;

<u>Registration</u> is a listing of individuals which generally has neither educational or competency requirements. Registration of laboratory personnel would be a lower regulation and although it would help us acquire necessary data for locating personnel and producing good workforce data, it does nothing in relation to maintaining or improving the quality of service nor does it address the scope of practice of the individuals.

<u>Licensure</u> is the process by which an agency of a state government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably protected. Licensure is required by law and defines that profession's scope of practice. Laboratory professionals practicing in a state with a licensing statute are required to be licensed to perform work within the defined scope of practice. Employers are required to employ only licensed individuals. State personnel licensure provides the only legal basis to bar incompetent practitioners from providing services to the public.

<u>Voluntary</u> certification does not require that employers employ only certified professionals.

<u>Title Protection</u> does not preclude anyone from performing tasks within the same scope of practice while using a different title.

(4) any associations, organizations, or other groups representing the occupation seeking regulation and the approximate number of members in each in Minnesota;

Minnesota Association of Blood Banks: 64 members
American Society for Clinical Laboratory Science - Minnesota: 490 members
American Society for Clinical Pathology - 3104 non-physician members in Minnesota
Clinical Laboratory Management Association - Minnesota Chapter: 104 members
American Association of Clinical Chemistry - Midwest Section: 406 members
Minnesota Interlaboratory Microbiology Association: 530 members
Association of Genetic Technologists: 77 members in Minnesota
Minnesota State Society of American Medical Technologists: 191 members
Minnesota Society for Histotechnology: 103 members
Minnesota Society for Cytotechnology: 120 members
In addition, many laboratory professionals are not a member of any professional organization. One must also be aware that some individuals are members of multiple organizations.

(5) the functions typically performed by members of this occupational group and whether
they are identical or similar to those performed by another occupational group or groups;

Medical laboratory science professionals provide essential services to professionals of the healing arts by furnishing vital information, usually in the form of medical laboratory test results, which may be used in the diagnosis, prevention and treatment of disease or impairment, and in the assessment of the health of humans. The medical laboratory tests performed include microbiological, serological, chemical, biological, hematological, immunological, immunohematological, radiobioassay, cytological, histological preparation, biophysical, or any other test or procedure performed on material derived from or existing in a human body. Medical laboratory tests include components of the pre-analytic (e.g., patient preparation, specimen collection and processing) and post-analytic (e.g., result reporting) phases of testing, as well as the analytic phase which occurs in the laboratory. Much more information is available on this topic from definitions (section 3) in the licensure bill and from practice or job analyses performed by the profession(s).

Some individuals in other health care professions perform specimen collection, blood sample analysis for blood gases (such as oxygen and carbon dioxide), and simple laboratory tests (referred to as "waived testing" - see item 19 of Section 3 Definitions/Scope of Practice). Other licensed professions which current perform procedures as mentioned in the previous statement are nurses, pharmacists, respiratory therapists and physicians.

(6) whether any specialized training, education, or experience is required to engage in the occupation and, if so, how current practitioners have acquired that training, education, or experience;

Currently, various levels of practitioners possess varying levels of training, education and/or experience - see Section 8 Standards for Licensure. There are numerous associate-degree and baccalaureate-degree programs from which current practitioners have acquired the required education and training and the ability to sit for national certification examinations. The examinations have several routes for eligibility, ranging from completion of an accredited program to some education with prescribed amounts of experience under a qualified person. Currently, there are some practitioners who were trained on the job and are not certified. The licensure regulation would require certification of all practitioners in the future except for individuals who have a Baccalaureate degree in a science field and are employed in a subspecialty for which no certification examination exists.

The professional categories defined in our legislation require either an associate degree (i.e. medical laboratory technician) or a Baccalaureate Degree (i.e. Medical Laboratory Scientist or one of the specialized categories). There are formal education routes for these categories with the requisite education and associated

certification. There are also alternate routes to achieve these through other Baccalaureate degrees, experience and ultimately certification. It is the certification, with the associated ongoing documentation of competency, that is the hallmark of our proposed legislation.

(7) whether the proposed regulation would change the way practitioners of the occupation acquire any necessary specialized training, education, or experience and, if so, why;

The proposed regulation would not change the way practitioners of the occupation acquire their training, education, or experience. Instead, it would require it of all practitioners entering the field.

(8) whether any current practitioners of the occupation in Minnesota lack whatever specialized training, education, or experience might be required to engage in the occupation and,
if so, how the proposed regulation would address that lack;

Current practitioners of the occupation who do not meet specialized training, education or experience are covered by Section 7, Subd. 3, Grandfathering. All others entering the field, from the effective date going forward, will be required to meet the education, experience and certification requirements of the legislation.

(3) Grandfathering

(a) Persons practicing in the field but not meeting the education, training and experience qualifications for any license described herein may apply for a license under grandfathering status within twenty four (24) months after the effective date of this Act.

(b) They shall be considered to have met the qualifications for a license providing they are practicing on the effective date of the act OR have 6 months of acceptable experience at least half time (1040 hours per year) in the three years immediately prior to the effective date of this Act, and submit to the Commissioner the job description of the position which the applicant has most recently performed, attested to by his or her employer. The Commissioner will determine which type of license the applicant is eligible for.

(9) whether new entrants into the occupation would be required to provide evidence of any
necessary training, education, or experience, or to pass an examination, or both;

New entrants into the occupation would be required to provide evidence of the appropriate degree from a regionally accredited college or university, Board-approved medical laboratory experience and/or training and a certification from a nationally recognized credentialing agency.

(10) whether current practitioners would be required to provide evidence of any necessary
training, education, or experience, or to pass an examination, and, if not, why not; and

Current practitioners would be required to provide evidence of the appropriate degree from a regionally accredited college or university, Board-approved medical laboratory experience and/or training and a certification from a nationally recognized credentialing agency. For a limited time, a grandfather provision will allow practitioners who do not have the required qualifications to obtain a license.

(11) the expected impact of the proposed regulation on the supply of practitioners of the
occupation and on the cost of services or goods provided by the occupation.

The key concept that must be emphasized is that the goal of this legislation is to assure that practitioners in the medical laboratory field are properly educated and certified and that once they enter the profession, they maintain their competency and document ongoing continuing education. As mentioned in the introduction, the educational programs needed to support the profession are in place and capacity is being expanded.

It is unacceptable that in the absence of the appropriately educated professional, that we would allow providers to "settle" for the least common denominator. That would never even be suggested if we were talking about Registered Nurses, Pharmacists, Physician Therapists, Occupational Therapists or other licensed health care professionals. In a hospital, if the appropriate nursing personnel are not available to provide a service, that service is shut down. The current environment of the laboratory allows for lesser trained individuals to make sure laboratories are staffed with "warm bodies".

Subd. 3. **Additional contents; health-related occupations.** In addition to the

contents listed
in subdivision 2, a report submitted by supporters of regulation of a health-related occupation
must address the following issues as specifically as possible:

(1) typical work settings and conditions for practitioners of the occupation; and

a. Hospitals
b. Clinics / Physician office laboratories
c. Private reference laboratories (i.e. MedTox, Viromed, Quest)
d. Public health

(2) whether practitioners of the occupation work without supervision or are supervised and
monitored by a regulated institution or by regulated health professionals.

Most of the laboratory professionals in this legislation have a direct reporting relationship to a laboratory supervisor, manager, or director (who are also, usually, laboratory professionals) In addition, in hospital and reference laboratories, licensed pathologists are medical directors for the laboratories and in the physician office environment, a licensed physician might be the person providing oversight to the laboratory professional. The provider organizations are regulated in one or both of two mechanisms. All laboratories are regulated under the CLIA '88 regulations and therefore CMS (Commission for Medicare and Medicaid Services through state departments of health). Most hospital institutions are voluntarily accredited by a accrediting agency such as the Joint Commission. Many laboratories are accredited by an organization that has deemed status to act on behalf of CLIA such as COLA (Commission on Office Laboratory Accreditation) or CAP (College of American Pathologists).

The report must succinctly address the questions set forth in Minn. Stat. 214.002 subd. 2 and subd. 3 (attached) and the following:

1. What other professions are likely to be impacted by the proposed regulatory changes?

   Other professions that may perform laboratory testing at the point of care include physicians, nurses, respiratory therapists, and pharmacists. There is language in the bill that addresses these other healthcare professions whose scope of practice overlaps slightly with that of laboratory professionals:
   This chapter does not apply to:
   6.5 (2) other licensed or registered professionals performing functions within the
   6.6 professional's scope of practice;

   The laboratory licensure coalition has also met with numerous professional groups and other stakeholders, such as hospitals and clinics (see last paragraph of response to question #2.)

2. What position, if any, have professional associations of the impacted professions taken with respect to your proposal?

   The Minnesota Nursing Board was represented on the Council of Health Boards subcommittee that reviewed the bill in detail 2009. While officially neutral, they have expressed verbal support. The Board of Medical Practice (which also manages Respiratory Therapy licensure), and the Board of Pharmacy are part of the full Council of Health Boards that approved the review of this bill, and no reservations were expressed.

   The following laboratory professional associations are members of the coalition working toward licensure of laboratory personnel and participated in the development of the bill:

   a. American Society for Clinical Laboratory Science-MN
   b. American Association of Clinical Chemistry-Midwest Section
   c. American Society for Clinical Pathology
   d. American Medical Technologists – Minnesota Chapter
   e. Clinical Laboratory Management Association-MN
   f. Minnesota Society for Cytology
   g. Minnesota Society for Histology
   h. Minnesota Interlaboratory Microbiology Association
   i. Minnesota Association of Blood Banks
   j. Representatives for the phlebotomy profession
   k. Representative for Molecular Diagnostics
   l. Representative from the Minnesota Department of Health

   Laboratory associations that have not been part of the coalition have been consulted. These include the Minnesota Society of Pathologists and the College

of American Pathologists. The Minnesota Society supports the bill and has provided testimony to that effect.

In addition, discussions have been held with organizations not directly impacted by scope of practice concerns. These include the Minnesota Medical Association, the Minnesota Hospital Association, and several groups representing military veterans in Minnesota. In each case, bill language was carefully reviewed and modifications in wording were made to address concerns of these groups. Several meetings have been held with the administrations of individual hospitals. Discussions with Mayo Medical Laboratories resulted in the addition of language in Section 8, Subdivision 7 addressing unique needs of their specialized esoteric laboratories.

3. Please describe what efforts you have undertaken to minimize or resolve any conflict or disagreement described above.

   To our knowledge, no conflict exists with current scope of practice for other health professions.