The following is the American Association of Bioanalysts' (AAB's) response to H.F. 203: 214.002 Evidence In Opposition of Regulation. AAB opposes H.F. 203 because it

- Exempts a large majority of clinical laboratory testing (moderate complexity and waived) that has the highest error rates as documented by surveys conducted by federal inspectors;
- Is overly restrictive by omitting alternate routes to a four-year college degree requirement for technologists (MTs/MLSs);
- Is unfair to military-trained laboratory professionals;
- It creates loopholes in Minnesota laboratory oversight by creating new state standards that would apply to some – but not all – Minnesota laboratories;
- Discourages Equal Pay for Equal Work by creating artificial levels of laboratory personnel that are differentiated not by the work performed, but by educational pedigree.

(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;

There is no harm to Minnesota patients by continuing with the existing regulation of laboratories by the federal government. Minnesota's laboratories are currently among the most accurate and safest in the nation according to surveys of laboratory performance by the federal government. The bill is a solution in search of a problem. –There is no data to support the allegation that two-year degreed MTs/MLSs are less capable than their four-year degreed counterparts.

In fact, data does not support that personnel licensure improves a laboratory's performance. In a 2004 study (*GAO-06-0879T, June 2006 Report)* results showed that ten (10) of the eleven (11) states with laboratory personnel licensure laws had **higher** percentages of laboratories with "condition-level" (serious) deficiencies than Minnesota. (New York did not have a personnel licensure law in 2004 when the study was conducted).

The percentage of laboratories with reported condition-level (serious) deficiencies in states with personnel licensure are as follows:

	State	**% (Serious) Deficiencies**
1.	Rhode Island	0.0
	Minnesota (no licensure)	**3.2**
2.	California	3.9
3.	Florida	4.1
4.	Nevada	4.1
5.	Georgia	4.3
6.	Hawaii	5.3
7.	West Virginia	7.1
8.	Montana	7.3
9.	North Dakota	10.1
10.	Tennessee	10.7
11.	Louisiana	12.1

In addition, the American Society for Clinical Pathology (ASCP) did **not** support the 2005 personnel licensure law in New York. In the ASCP newsletter *Pathology Today* (May 2007, Vol. 4,

Issue 3), in an article entitled "ASCP to NY: Fix the Law," the President of ASCP says *"ASCP did not and does not support the New York licensure law. Our members are very concerned about the adverse impact this law* (the New York licensure law) *has had on laboratory personnel, medical directors, clinical laboratories and, of course, patient care."*

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

Current laws and oversight are adequate. Forty-three states use CLIA for their clinical laboratory personnel standards.

CLIA is not "a minimum foundation" [Sec. 148G-01-4] and personnel requirements in CLIA are not limited to "entry level technical personnel." CLIA includes **very** detailed criteria for **all** levels of personnel in the clinical laboratory. For high complexity testing, these include the director, technical supervisor, clinical consultant, general supervisor, and testing personnel.

In addition, CLIA mandates extensive proficiency testing, quality control and quality improvement measures. In addition to these measures, CLIA mandates inspection of laboratories by either state inspectors or accrediting agencies. These inspections include verification of experience, training, and competency evaluations for all laboratory testing personnel.

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

~~[I like what we had here]~~ H.F. 203 allows both MLS (technologists) and MLT (technicians) to perform high complexity testing. So there is no distinction between the two licensing categories based on work performed. The only difference is the compensation that the two receive: A technician (MLT) typically makes $8,000 to $12,000 **less** than a technologist (MT/MLS) **for performing the same services**.

In the current economy, many individuals are finding the added cost of a four-year college degree prohibitively expensive, so Minnesota laboratories will be forced into a bidding war for more expensive four-year grads to replace the currently proficient two-year grads.

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

(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;

(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;

CLIA does not use the terminology of technologist (MT/MLS) or technician (MLT). The CLIA regulations list the testing personnel requirements for each level of testing [high complexity, moderate complexity, provider performed microscopy (PPM), and waived].

- **Medical Technologist (MT); Clinical Laboratory Scientist-Generalist (CLS); Medical Laboratory Scientist (MLS); Testing Personnel for High Complexity testing; and Technologist**

  These titles are essentially the same. These are individuals qualified to perform high complexity testing. This terminology is **not** related to any degree…it denotes the level of testing the individual is qualified to perform. Under CLIA regulations a person entering the field today must have, at a minimum, a two-year college degree (or equivalent) with a major in a laboratory science from an accredited institution in order to meet the requirements to perform high complexity testing. Individuals who have completed the military's advanced clinical laboratory training course meet this CLIA requirement.

- **Medical Laboratory Technician (MLT); Clinical Laboratory Scientist-Technician (CLS-T); Testing Personnel for Moderate Complexity testing; and Technician**

  This classification can be confusing because laboratory organizations define the procedures technicians are qualified to perform differently. AAB defines technicians as those individuals qualified to perform waived and moderate complexity tests, but not high complexity tests.

  Other laboratory organizations define MLTs as individuals who can also perform high complexity tests in addition to moderate complexity and waived tests.

  However, in most laboratory settings **both MTs and MLTs perform high complexity tests**. The only difference is the compensation that they receive. A technician (MLT) typically earns $8,000 to $12,000 **less** than a technologist (MT/MLT) **for performing the same laboratory procedures**

(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;

H.F. 203 changes the way practitioners acquire education, at least the type and amount of education. Currently, individuals who complete the military's advanced clinical laboratory training program and who perform clinical laboratory testing for our military personnel, often in adverse conditions, may return to Minnesota and find employment as a technologist (MT/MLS).

H.F. 203 would make it impossible for an individual who completes the military's advanced clinical laboratory training to receive an MT/MLS license unless he/she obtains at least two additional years of college credit, which could include classes in English literature, history, art appreciation or other non-science fields. If this were to happen, individuals who have served their country and performed quality medical testing for our military personnel and their families would not be able to come home after their service and practice as a MT.

The United States is now engaged in a significant reduction in military personnel. Many of Minnesota's sons and daughters have returned home, or will be returning home, and will be seeking civilian employment. Not only have these individuals earned the right for employment commensurate with their training, but they also can help lessen the expected personnel shortages in the clinical laboratory 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;

Some laboratory personnel currently working in Minnesota might not qualify to keep their positions under H.F. 203. Supporters of this bill have stated that the "grandfathering" clause in H.F. 203 will protect currently employed individuals in Minnesota. This is not correct. Lines 11.4-11.5 of H.F. 203 state that the commissioner shall determine the type of license the applicant shall be issued. This means that an individual currently paid as an MT/MLS could be downgraded to an MLT. See question #3, #6, and #7 for potential outcomes of the downgrade.

(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;

The bill sets a different entry requirement than currently exists under federal CLIA law and regulations.

(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

See question #8 above.

(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.

According to the US Department of Labor and a study conducted by the American Society for Clinical Pathology (ASCP), the population of MTs is aging, and younger individuals are not replacing them fast enough (See Reference #1 & #2).

Nationally, it is expected that 13% of the MT/MLS workforce will be lost due to retirement- in the next few years. . -This effect will be felt most by small and rural hospital and community clinical laboratories.

Any labor shortage in the field will drive up the cost of the remaining personnel. In today's economy, fewer individuals have the means to pursue an education, especially a four-year college degree. A "no-exception" four-year degree requirement will be especially hard on small and rural hospital and community clinical laboratories, many of which are already facing financial cutbacks that threaten their viability.

Supporters of H.F. 203 claim that H.F. 203 is needed to assure that laboratory practitioners are properly educated and competent**. But H.F 203 exempts waived and moderate complexity testing**, testing that has been shown to have CLIA's highest error rates. In addition, waived and moderate complexity tests comprise an overwhelming majority of tests on CLIA's List of Test Procedures. This clearly indicates that the primary motive of supporters of the bill is **not** to reduce error rates; rather, it is to create an artificial hierarchy of laboratory personnel that benefits individuals with a four-year college degree -at the expense of individuals with two-year degrees..

Supporters of H.F. 203 have also referenced nursing in many of their reportarguments. However, **the minimum educational requirement for a registered nurse (RN) in Minnesota is a two-year college degree, not a four-year college degree**. In addition, nursing has no federal oversight as do clinical laboratories in the form of CLIA. So if a two-year nursing degree is appropriate and recognized by the bill's supporters, for an RN license, then a two-year degree in a laboratory science should also be appropriate and recognized by the bill's sponsors for an individual -to obtain MLS license.

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

Laboratory personnel work in hospitals, clinics and private laboratories throughout Minnesota under the supervision of and at the direction of the laboratory director under authority granted by CLIA.

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

Currently, laboratory staff work under the supervision of the laboratory director as provided for in the federal CLIA regulations. The laboratory director is responsible under federal law to assess the proficiency of the staff and test validity.

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?

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

Supporters of H.F. 203 have stated that laboratory associations that are not part of their "coalition" have been consulted. This is not correct. AAB and NILA were **NOT** consulted in the drafting of H.F. 203. Over the past years, AAB has had multiple discussions with the bill's proponents and offered compromises that do not pick "winners and losers", but these have been rejected. In addition, supporters of H.F. 203 imply that all laboratory organizations are in support of this bill. This is also incorrect. AAB and NILA do **NOT** support H.F. 203 as written. The AAB can support H.F. 203, **IF** it is modified in the following ways:

1. CLIA's testing personnel qualifications are used for high complexity testing, which would allow individuals with an associate's degree or equivalent to obtain an MT/MLS license.
2. All clinical laboratories are covered~~, including physician office laboratories (POLs)~~.
3. Conflicts with CLIA's regulations are resolved.

References:

1. (United States Department of Labor: Bureau of Labor Statistics. Occupational Outlook Handbook, 2010-11 Edition, Clinical Laboratory Technologists, and Technicians. http://www.bls.gov/oco/ocos096.htm#outlook:
2. ASCP Wage and Vacancy Survey of U.S. Medical Laboratories, LABMEDICINE, Vol. 40: Number 3; March 2009. http://ccclw.org/Documents/ASCPWageand%20Vacancy2009.pdf).