ANALYSIS

California Association of Bioanalysts **The Voice of the Bioanalyst, Sept. 1999**

President's Message:

Greetings, fellow Bioanalysts:
Thank you for allowing me the opportunity to serve as your president the next two years. These are certainly challenging times for laboratories and laboratory professionals alike. With the recent acquisition of SmithKline by Quest, it make one wonder if eventually there will be just one national lab with lots of local branches. With computerization and automation developing at an increasing pace, all of us must keep abreast with the changes in order to secure our professional futures. That is why it is imperatie to be actively involved in professional organizations such as CAB. Our members participate in the legislative process and keep you informed of developments in law and regulations. Our annual Convention and Mid-year Meetings make available to members required continuing education units. The benefit of membership is the message we must carry to prospective members.

The new CLIA regulations adopted by California (for CLIA exemption purposes) has put additional pressure on Bioanalysis in that new non-doctoral Bioanalysts are not qualified as high complexity laboratory directors. As threatening an obstacle that this poses, it should no altogether stifle the aspirations for career advancement of motivated Medical Technologists. Please let me remind you that several of us licensed after 1965 were not Medicare certified Directors. Later, we were able to get our certification as a result of the legislative process. There is no reason to assume it can't happen again. This reminds me of a saying of the Rev. Robert Schuler and I quote: "Tough times don't last, but tough people do!" Personally, I think you have to be tough to be a Bioanalyst, so we're qualified to outlast the tough times….

Our annual Mid-year meeting will be held in association with the CAMLT state meeting in Sacramento being held September 24 to 27. Please note that our CAB meeting will be held Friday the 24th at 3PM. I'm looking forward t seeing you all there to share fellowship and information.

Best Wishes, Richard Vance
President

P.S. We'd like to keep you up-to-date by e-mail. Please e-mail me with your address at: richardv@whslab.com

The BIOANALYSTS SAGA: Past, Present, and Future

Bioanalyst Bill Reich, shortly before his recent passing, provided CAB with historical detail and commentary on the early days of Bioanalysis. Many thanks to th

California law limits the direction of

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full service Clinical Laboratories to just two professional groups: Physicians and Clinical Laboratory Bioanalysts.

THE PAST:

The profession of Medical Technology was created in California with the passage of the Clinical Laboratory Act in 1937. That law created two levels of clinical laboratory professionals: Clinical Laboratory Technicians and Clinical Laboratory Technologists. In the 1950's the names were changed, Technicians became Technologists and Technologists became Bioanalysts.

The Technologists name has recently been changed to Clinical Laboratory Scientist. In the 1960's an earned master's degree in a biological science was added as a requirement for Bioanalyst licensing.

State law requires bioanalyst candidates, through written and oral examinations to demonstrate knowledge and competence in the clinical laboratory field. In contrast, any M.D. regardless of competence as a laboratorian is, under the statutes, qualified to direct a clinical laboratory. Medicare regulations place some limitations on all Clinical Laboratory directors except for Clinical Pathologists and "Grandfathered" Bioanalysts. Finally, in 1987, a state law was passed which requires that hospital laboratories must be, with rare exception, directed by Pathologists.

California Bioanalyst's have a long and distinguished history beginning before there was an identified laboratory profession, when the powerful medical establishment considered laboratory work to be "Laboratory Medicine". In the early 1930's they started the first blind inter-laboratory testing program in the United States, a sustained informal program which preceded Dr. Sunderman's 1947 publication of such an idea by more than a decade. The program was conceived as an educational tool intended to help in improving clinical laboratory work. The pioneers started an organization called the California Association of Clinical Laboratories (CACL). They were a driving force in the creation of the Clinical Laboratory Act.

In 1951 Lucien Hertert, the man who coined the term "Bioanalyst", helped organize the Council of American Bioanalysts and launched an effort to create a national identity for Bioanalyst laboratory directors. The Council was later merged with the National Association of Clinical Laboratories to form the American Association of Bioanalysts (AAB). In the 1960's, to attract Bioanalysts who were not laboratory directors, they renamed CACL and it became CAB, the California Association of Bioanalysts.

When the Medicare Law was passed in 1965, Bioanalysts were considered professionally inferior by those charged with writing Medicare regulations. Importantly, AAB was an established national organization by that time and it served as a natural base from which to attack the popular assumption that the Doctorate degree equated to a guarantee of professional competence as a Clinical Laboratory Director.

After intense effort, a compromise was reached and federal regulators agreed to "grandfather" Bioanalyst laboratory directors into the Medicare program. The compromise required Bioanalyst directed laboratories to prove their competence through the inter-laboratory testing program functioning in California. Given the circumstances, CAB presented the complete operating system to AAB. Nurtured by AAB, the program has continued to grow and evolve alongside several other such programs. Over time, however, the inter-laboratory testing requirement limited to Bioanalysts was seen as discriminatory and it soon became a requirement for all Medicare approved laboratories. Thus the Medicare Proficiency Testing requirement is directly traceable to the compromise which Grandfathered Bioanalysts into the Medicare program. Beginning in 1991, in the hands of federal regulators, what began in California in the 1930's as an educational innovation has evolved into a highly effective measuring stick for assessing clinical laboratory competence. California Laboratory Field Services has shown proficiency testing can be used successfully for that purpose by developing a program to analyze proficiency testing data received electronically from the national proficiency testing services.

The compromise which Grandfathered Bioanalysts into the Medicare program did nothing to change the fundamental requirement that laboratory directors have doctorate degrees. Since California Bioanalysts were licensed at the master's level the regulations were devastating to the profession.

From 1971 to 1986 there was too little incentive for qualified Medical Technologists to make the effort to become Bioanalysts. If the license was not to disappear, one of two things had to happen. First, in the 1970's CAB tried to establish a doctorate degree in Bioanalysis. A

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curriculum for the degree was created and the University of the Pacific accepted it. The program failed because, despite an extended, wide ranging effort, CAB could not find the required $50,000 in funding.

In 1983, an attack on the federal doctorate requirement itself was begun. Working through Professor Richard Baily of U.C. Berkeley and the Laboratory Field Services Section of California State Department of Health Services, CAB financed a statistical study made by graduate student Michael Kinney. The study, using proficiency test results, was designed to test the assumption that laboratories directed by people with Doctorate degrees performed in a way which was measurably superior to those directed by Bioanalysts. The study, completed in 1984 and referenced below, showed no discernible difference in the quality of results. The study was so scientifically correct that it has never been attacked from any quarter. In fact the study design and its findings were so important that it led to two related federal studies by the same investigator.

Armed with these powerful studies showing professional equivalency and supported by other professional organizations, most notably the California Association of Public Health Laboratory Directors. CAB petitioned Congressman Henry Waxman to address the problem. Congressman Waxman responded and managed to amend the Omnibus Budget Reconciliation Act (OBRA) of 1986 in such a way that the prerogatives of California Bioanalysts were largely restored.

THE PRESENT:

Now is the time for Clinical Laboratory Scientists to dedicate themselves to taking control of their professions, from Phlebotomist and Laboratory Aid through Laboratory Director. The forgoing history shows what can be accomplished by a small, dedicated group. Think, what could be done by a large group or groups, well-organized, well-coordinated, well financed and possessed with a set of integrated, comprehensive goals.

Now is the time for the leaders of all Clinical Laboratory Scientist associations to recognize and appreciate the fact that Bioanalysis is the top of the "career ladder". It is the position with the most stature and every Clinical Laboratory Scientist who becomes a Bioanalyst adds just that much more prestige to the profession.

The leaders must recognize that there are so few new Bioanalysts entering the field that the license is on the verge of extinction. They must understand that Bioanalysts are becoming too old and to few to effectively defend the integrity of the license. They must understand that Clinical Laboratory Scientists individually and collectively need to do all in their power to license more Bioanalysts. Failure to do so will, by default, leave the Physician all alone at the top of the ladder.

THE FUTURE:

Much of what happens to the profession of Medical Technology in the coming years will depend upon public policy decisions by government. It is the responsibility of the profession to position itself to influence those decisions and to respond to the challenges, whatever they may be.

Some assertions about the future can be made with confidence. The rate of technological growth will continue to accelerate. New technologies will appear which will require more licensed laboratorians who are well trained and knowledgeable. Economic imperatives will drive advances in automation and that with the simplification of methodologies will shift much of the routine work load to automation and to unlicensed workers.

As mentioned above, it is possible for Clinical Laboratory Scientists to dominate the profession. To that end, however, they need to become as goal oriented as the pioneers of the 1930's. The challenge is not much different. With specific reference to the Bioanalyst license, if the top of the ladder is to remain an attainable goal and if the barriers to unfettered use of the license are to be removed, two things are necessary. Support by the full weight of the Medical Technology profession and many, many Bioanalyst licensees positioned to perform as directors and clamoring for full professional rights to do so.

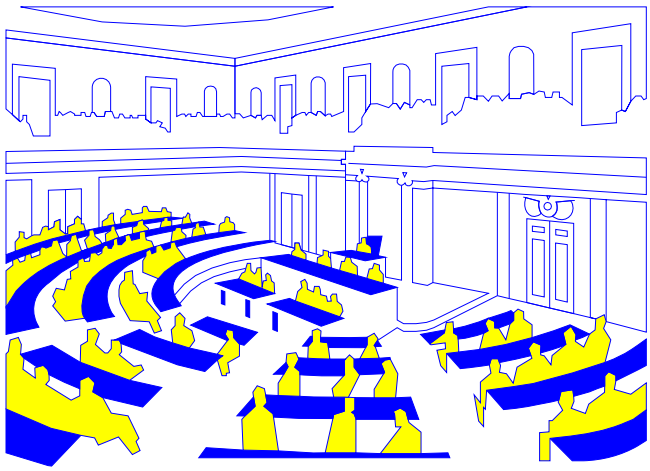
The exemption package, which will ultimately get published in the Federal Register and become law of the land in California, dictates that new Bioanalyst candidates possess an earned Doctoral Degree in order to direct a “High Complexity” laboratory. Master’s Degree candidates passing the California State Bioanalyst examination qualify to direct “Waived” and “Moderate Complexity” Labs.

Laboratory Director opportunities will continue to abound for the new Bioanalyst as more laboratories fall

LEGISLATIVE UPDATE

SB 585 (Chesbro)

1. This legislation expands California's "Physician Performed Microscopy" testing category to resemble CLIA's "Provider-Performed Microscopy."
2. Following amendments secured by CAB and CCLA during the spring, this bill passed the Legislature and was signed into law by Governor Davis on July 6, 1999. It becomes effective on January 1, 2000.
3. On or after January 1, 2000, clinical laboratory tests classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:
   (a) A licensed physician using a microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
   (b) A certified nurse midwife; a licensed nurse practitioner; or a licensed physician assistant acting under the supervision using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.
   (c) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or employee.



The two most significant bills currently being watched are Senate Bill 765 and Assembly Bill 1557. Each of these bills is expected soon to pass the Legislature and be signed into law by Governor Davis. Following is a summary of each bill:

SB 765 (Shiff)

1. Effective July 1, 2000, all biological specimens left in a public location outside the custodial control of the person or entity licensed under the healing arts (presumably for pickup by a laboratory courier) must be secured in a container that is fully enclosed and locked by a padlock, key lock, combination lock, or similar locking device.

2. Containers put into use on or after January 1, 2001, must be labeled with the words " Caution: Biohazardous Material – Please Do Not Touch or Handle," or words of similar meaning.

3. On or after January 1, 2001, the California Department of Health Services (DHS) will provide to all licensed clinical laboratories a form in triplicate to be used by employees, agents, and couriers of those licensed clinical labs to give notice to the person or entity referring the specimens as well as to the California Department of Consumer Affairs when a specimen storage container has been improperly secured as described in #1, above. However, such notification shall not be required if DHS has not provided the appropriate forms.

- These new requirements will not apply to specimens received by mail in compliance with applicable laws and regulations.

- Failure to comply with requirements 1 and/or 2, above, may result in sanctions by the licensing board, including the imposition of a fine not to exceed $1,000.

AB 1557 (Migden)

1. By January 1, 2001, the California Department of Health Services (DHS) must adopt regulations to certify unlicensed personnel in clinical laboratories as a "certified phlebotomy technician (CPT)." The CPT would, at a minimum, be authorized to perform venipuncture or skin puncture to withdraw blood or for clinical laboratory test purposes. Some CPTs (with additional training as expected to be prescribed by DHS regulations) may be authorized to perform arterial puncture, as well.

2. The education and training requirements for unlicensed persons to become a CPT shall include all of the following:
   (a) At least 40 hours of didactic instruction.
   (b) At least 40 hours of practical instruction.
   (c) At least 50 successful venipunctures.

There is no "grandfather" clause. All unlicensed persons performing phlebotomy will have 3 years from the effective date of the regulations adopted by DHS to become CPTs, or they will no longer be authorized to collect blood samples. However, those persons with at least 1040 hours of work experience would be exempted from items 2(b) and 2(c), above, and they would need only 20 hours of didactic instruction rather than the 40 hours specified in item 2(a).

4. It is the stated intent of the Legislature to permit unlicensed persons performing these duties to use educational leave provided by their employers for purposes of meeting these requirements.

5. DHS will adopt regulations establishing standards for approving training programs.

6. DHS will adopt regulations establishing standards for approving national accreditation agencies to administer certification examinations and tests.

7. DHS may adopt regulations providing for the issuance of a certificate limited to skin puncture only.

8. Each CPT must complete at least 3 hours per year or six hours every two years of continuing education or training.

10. Each such person must be found competent in phlebotomy by a licensed physician or person licensed as a clinical laboratory professional in California.

11. DHS will charge fees of no more than $25 for application for and renewal of the certificate.

12. All other existing laws will remain in effect, except:

    (a) Although licensed physicians and bioanalysts will continue to provide, document, and verify appropriate training, they will no longer be authorized to issue phlebotomy certificates as of the effective date of the DHS regulations referenced above.

    (a) CPTs will not be subject to the "5 minute rule" under CBPC 1246 (a)(1). However, until existing unlicensed personnel are in fact certified by DHS, the "5 minute rule" still applies.

Robert I. Footlik
Chair, Committee on Legislation

TECHNICAL UPDATE: HOMOCYSTEINE

Homocysteine (HS) is an amino acid intermediate in methionine metabolism. Although there are genetic enzyme defects which cause elevated plasma HS, it recently has become evident that hyperhomocysteinemia is an independent risk factor for atherosclerosis. Nutritional deficiencies in vitamin cofactors required in the metabolism of HS may promote markedly elevated H?S. Vitamin supplementation can normalize elevated concentrations of HS. It remains to be determined whether this reduction will translate into improved cardiovascular morbidity and mortality.

Measurement of HS in the laboratory can be performed with an amino acid analyzer or mass spectrometer, but are rare in clinical laboratories. High performance liquid chromatography (HPLC) utilizing either fluorescence or electrochemical detection is available. In addition, fluorescence polarization immunoassay (FPIA) is available on an IMX is another option.

By: E.B. Weissman, Ph.D.

NOTICE: C.A.B.'S MID-YEAR MEETING WILL BE CONDUCTED ON FRIDAY SEPT, 24 FROM 2:00pm TO 5:00pm **at the joint meeting of CAMLT/CLMA** at the DoubleTree Hotel in Sacramento.
(For full convention brochure and details contact Richard Vance or Dan Leighton)

HOW TO BECOME A BIOANALYST, A SPECIAL FORUM PRESENTED BY C. A.B., Will be given by Robert Thomas, Bioanalyst, Examiner II, from Lab Field Services.
This program will be conducted on Saturday, Sept. 25, from 5:30 to 6:30 p.m.

This one-hour informational forum is designed for the ambitious medical technologist/ Clinical Lab Scientist seeking career advancement as a laboratory director. Participants will learn the legal/regulatory qualifications and responsibilities of a bioanalyst clinical laboratory director, including the requirements for examination and licensure. **Note: No CE provided; and no registration required.**

Meetings scheduled for the remainder of 1999 are as follows:
⇒ **Saturday, Oct 17th - Earl B. Weissman Ph.D. Speaking on Thyroid Disease**
⇒ **Saturday, Nov 20th - Speaker to be announced**
(Both meetings being held 6:30 PM at Taix restaurant, Hollywood. Mark Alcantar, Meeting Chair.)

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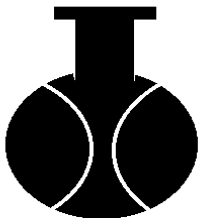

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