

Via email

November 1, 2009

Dear Dr. Sasavage,

This is in respect to the article, "The Pursuit of Traceability, Lab Groups Push for Greater Harmonization, By Bill Malone," which appeared in the October 2009 issue of the Clinical Laboratory News.

As the former Editor of the AACC Division on the History of Clinical Chemistry newsletter and a 54 year member of the AACC, I am interested in historical accuracy, whenever possible. The opening line of the above mentioned article stated that 'It's been 30 years since the legendary Norbert Tietz called for establishing a "comprehensive, coherent measurement system' in clinical chemistry that hinged on traceability."

I want to call your attention the paper entitled "The National Reference Network," which I presented about 40 years ago at the 1969 AACC Annual Meeting in Denver. The authors of the paper were Nathan Radin, Ph.D., Joseph H. Boutwell, Jr., M.D., Ph.D., and Elmer C. Hall, Ph.D.

In July, 1967, I joined the Medical Laboratory Section, at CDC and I became the head of the Evaluation Unit. Guided by the CLIA '67 regulations, the Evaluation Unit was responsible for a clinical

chemistry proficiency testing program. The results we tabulated at that time indicated that much had to be done to ensure that testing results in one laboratory would match those in any other laboratory. In simple language, the National Laboratory Network would consist of Regional Reference Laboratories and one Central Reference Laboratory. The Central Reference Laboratory would have the capability of determining true values, as far as possible. Thus, individual clinical chemistry laboratories through the Regional and ultimately the Central Reference Laboratory have the means to check routine test results against specimens with known desired constituent "true" values. Joe Boutwell and I carefully selected what we thought were the one hundred best clinical chemistry laboratories and sent them 10 samples, in each of six categories. . Concentration levels of glucose, creatinine, urea nitrogen, uric acid, cholesterol, sodium, potassium, total protein, and hemoglobin were requested. The spreads of the results which came back to us was surprising, considering the reputation of the laboratories we selected. This indicated the necessity of lots to do ensure that results of tests in one lab should match, or be very close to other laboratories. This proposal never came to fruition.

Also, in my paper, "What Is A Standard?," first presented in an AACC Upstate New York Section meeting in Albany, New York, September 25, 1964, the need for certified reference samples was discussed. Although the word traceability was not used, the implication that certified reference standards were needed was because the variability of desired

constituent test results among clinical chemistry laboratories was undesirable. Traceability has to depend on the availability of reference samples with known “true” values.

Nathan Radin, PhD