Performance-based methods

A recent issue of *Analytical Chemistry* carried a news article about the introduction of a congressional bill to "accelerate the move toward performance-based analytical methods" for EPA ("Performance-Based Methods," Feb. 1, 1996, p. 83 A). We would like to point out that the National Institute for Occupational Safety and Health (NIOSH) has followed the philosophy of developing performance-based methods for monitoring the workplace environment for over 20 years.

NIOSH (and the Occupational Safety and Health Administration) methods are evaluated according to a set of criteria. The status of each NIOSH method with respect to those criteria is noted in the *NIOSH Manual of Analytical Methods* (NMAM, DHHS Pub. #94-113). It should be noted that these methods are only recommendations and their use is not mandated by law. The latest revision of the method evaluation guidelines and criteria is available from NIOSH Publications (4676 Columbia Parkway, Cincinnati, OH 45226) as *Guidelines for Air Sampling and Analytical Method Development and Evaluation* (DHHS Pub. #95-117).

Performance-based methods, as the article states, allow greater flexibility and the opportunity to use newer technology. Along with this flexibility to adapt and modify the methodology comes the responsibility of each laboratory to establish that a method meets the appropriate performance criteria. Usually, the primary criterion is a specified accuracy level, although other factors (such as the limits of detection and quantitation, sample storage stability, etc.) may be just as important. If a laboratory is using a method evaluated by NIOSH, it is reasonable to assume that certain tests, such as sample storage stability, need not be repeated. However, other factors that may be dependent on situations beyond the control of the method, such as changes in the desorption efficiency of a contaminant caused by lot variability of the sampling medium, should be verified by the laboratory doing the analysis. With the performance-based method approach, there can be more than one method for a particular analyte, and methods can be updated without rewriting regulations.

The argument that performance-based methods may be more open to legal challenge must be considered in light of the rigorous statistical treatment of the method evaluation data. When the use of a method is mandated by law, the method defines the "true concentration," and in essence, the "true concentration" is that measured by the method. However, all methods have inherent variability and therefore the "true concentration" will also have variability. With the performance-based method approach, this variability in the method result is recognized and is incorporated into the method evaluation criteria.

In the case of NIOSH methods, the accuracy criterion states that an acceptable method must produce a result that is within ±25% of the true concentration 95% of the time with 95% confidence. In the current versions of NMAM and the evaluation guidelines, the accuracy of the method is estimated based on results obtained by defined experiments. This provides the end user with more flexibility in method selection, based on the needs of the monitoring situation.

When ensuring compliance with an exposure standard is the goal, use of the most accurate method is desired. The key issue in this instance is to ensure that the worker is not overexposed to the contaminant being monitored and that one's health is not being compromised.

Martin T. Abell
Eugene R. Kennedy
Methods Research Branch
National Institute for
Occupational Safety and Health
Washington, DC

Mixing business with tenure

I read with interest the recent article on academic trends toward entrepreneurship ("Mixing Business with Tenure", May 1, 1996, p. 311 A). My experiences involving technology transfer and the formation of my business, Advanced BioAnalytical Services, parallel very closely those described in your article. I am happy to report that Cornell has progressed from considerable skepticism to a relatively high comfort level with my business activities. In fact, they are beginning to refer to my example as a model of the way professors can serve both roles with mutually beneficial opportunities.

Jack Henion
Cornell University and Advanced
BioAnalytical Services, Inc.

Your recent feature on "Mixing Business with Tenure" puts a rather positive spin on what many view as a questionable practice. Such arrangements may be an attractive deal for the professor, but are often a Faustian bargain for the students involved. They are shortchanged by having a part-time mentor and may have some career options compromised.

Garry A. Rechnitz
University of Hawaii at Mānoa

Letters to the Editor

We welcome your comments regarding published articles or other topics of interest to analytical chemists. Letters may be submitted by e-mail (analytical@acs.org), fax (202-872-4574), or regular mail (*Analytical Chemistry*, ACS, 1155 16th St., N.W., Washington, DC 20036). Please include your full address, signature, and daytime phone number. Letters should be brief and may be edited for clarity or space.