

## What Do You Do When CRMs Are Not Available?

**Tuesday, September 15, 2009 1:00 p.m. EDT**

Speakers will provide 15-minute presentations on preparation and use of control materials. A 30-minute Question and Answer discussion with panel members and the session chair will follow.

### **Chair:**

CHAIR: Katherine Sharpless

Analytical Chemistry Division, Chemical Science and Technology Laboratory  
National Institute of Standards and Technology (NIST)  
Gaithersburg, MD USA

### **Speakers:**

Hendrik Emons

European Commission - Institute for Reference Materials and Measurements  
Geel, Belgium

### **Topic: Designing Non-Certified Reference Materials for Quality Control Purposes**

Non-certified reference materials are crucial tools for both internal and external quality control of laboratory performance. IRMM has gained considerable experience in the development and production of such materials, also in the areas of food and feed analysis. This presentation will discuss the major considerations to be respected and crucial activities which have to be performed for obtaining meaningful non-certified RMs. Particular attention will be paid to the interrelation between the specifically intended use of the desired reference material and the required material and documentation characteristics. Moreover the proper understanding of the potentials and limitations of non-certified RMs by the users will be facilitated.

Mark A. Mozola

Neogen Corporation  
Lansing, MI, USA

### **Topic: Validation of Microbiological Test Kits in the Absence of CRMs**

Validation of microbiological test methods, particularly pathogen detection methods, presents unique challenges with regard to selection and preparation of bacterial strains (analytes) to be used for inoculation of sample matrices. While some reference materials are available, bacterial preparations are generally not available in the varieties and forms required for large-scale method validation work. For example, in validation studies of Salmonella or Listeria detection methods, typically up to 15-20 different food matrices are examined. It is customary, and desirable, to use a different inoculum strain (species, serovar, etc.) for each sample matrix. Bacterial strains should be obtained from fully traceable commercial or institutional culture collections. Ideally, strains should be derived from material similar to the test sample matrix and matched with matrices based on historical data relating to known association or isolation rates. Further, bacterial strains used in inoculation studies are preferably subjected to some type of treatment (heat, freezing, desiccation, etc.) to create conditions of sub-lethal injury relevant to the sample type under study. This treatment may be performed on the inoculum culture itself or on the inoculated sample matrix. AOAC International has established method validation guidelines that address some of these parameters. These factors will be discussed and examples presented.

Anthony Fontana, Sneh Bhandari, Tom McKamey and John Budin  
Silliker Inc. USA  
Homewood, IL USA

**Topic: Perspectives from the Independent Laboratory**

An independent testing laboratory will occasionally encounter instances when a certified reference material (CRM) is not available. The challenge to deliver accurate results can be further enhanced by constraints of time and available resources. As such, four alternative approaches are proposed when a CRM is not available: spike approach, use of a substituted reference material, split or collaborative study approach and reference method approach. The spike approach involves comparison of the analytical results from the spiked or non-spiked native matrix or the samples to establish analyte recovery by the method. Use of a substitute reference material approach involves the replacement of the CRM with an alternative matrix reference material matching the matrix of interest as close as possible based on technical or institutional knowledge. The split or collaborative study involves use of a proficiency sample characterized by multiple laboratories using multiple methods or a single method. The reference method approach involves comparing results obtained by the method under investigation with those obtained by another recognized method in the same or another laboratory.

Pieter Scheelings  
Queensland Health Forensic and Scientific Services  
Brisbane, Australia

**Topic: The Development of Reference Materials in the Asia Pacific Region**

Reference materials are generally recognized as essential tools in the development of new analytical methods and the verification of validation parameters of standard methods. The diversity of foods and the array of components, nutrients, toxins and contaminants which may be required to be quantified provide an on-going challenge for both analytical laboratories and commercial CRM providers. The development and certification of suitable reference foods is often difficult, costly and time-consuming. Due to the comparative high cost, tyranny of distance and language barriers, the take-up and use of CRMs and other commercially available RMs by developing country laboratories has been limited.

Through regional networks such as the Asia Pacific Food Analysis Network and OCEANIAFOODS, laboratories from the Australasia region have provided technical and financial support to food analysts from the Asia-pacific region via targeted training programs on methods of analysis, analytical quality control, PT studies and the development of reference foods. Many of these scientists have assumed leadership roles in their own countries by developing national food analysts' networks, PT programs and the development of cost-effective food-based reference materials. The Australian Government National Measurement Institute has more recently adopted an increasing role in preparing reference foods for Australian and regional laboratories.