

## AEIC Annual Fall Meeting

Stanford University  
Palo Alto, CA  
9/2V94

**Mark Platshon:** The meeting was opened at 8:10 a.m. Mark welcomed the group. Dr. Martin Reinhardt, from the Water Quality Research staff at Stanford, also welcomed the group. He reviewed some of their studies that are underway. They have not used immunoassay in their studies but would like to in the future when appropriate.

We went around and introduced everyone. See roster for the attendees.

**Chuck Mihaliak, President:** Chuck reviewed the AEIC mission and what we have accomplished over the last year. At our meetings, we have had 13 invited speakers from several different regulatory levels. Members of the AEIC have spoken at several national meetings and we have two publications. The formal establishment has taken a lot of work. The AEIC has received a lot of respect from several groups which has led to high expectations from the other organizations we interact with. These expectations have led to more potential projects. Chuck stated, "The success of the technology is in our hands." The EPA educational programs are at the top of his list. Other important projects include the UST (Underground Storage Tank) document, symposiums, training programs, international programs, etc.

The meeting was opened for more discussion on future issues and the items Chuck reviewed. Joe Dautlick, Vice President, further explained the UST brochure.

**Pat Nugent, Secretary:** The minutes from the last meeting were approved as distributed. Pat discussed the bylaw changes. The group suspended the bylaw requirement of a 30day pre notification for a vote to change the bylaws. The AEIC voted to adopt the suggested IRS changes necessary for approval of nonprofit status. Unless we submitted the changes to the IRS by the end of September, we would have to reapply and pay additional fees. The AEIC also voted to make the secretary and treasurer a 2 year term.

**Larry Miller, Treasurer:** Larry reviewed the current paid members and membership changes. We have a balance of \$9245.69 in our checking account. Larry reviewed the changes and the work done to date for non-profit status and the differences for a 501(c)(3) and a 501 (c) (6) organization. We will apply for reorganization as a 501 (c) (6) organization. The board voted to approve the use of the CPA firm, Sander, Shifman, and Brannick for help in determining the correct nonprofit status. The CPA firm, Sander, Shifman and Brannick, also recommend that we incorporate. Through the mail, we will distribute the findings and have a final vote on the issue at the next meeting.

Larry also reviewed information from Brinton Miller. Brinton did a logo and name search and found no matches for AEIC. Rick Birkmeyer said he would take care of registering our trademark. Brinton had suggested we needed to revise the format of the bylaws. The AEIC decided to focus its time on other issues at this point.

**Rosie Wong:** Rosie introduced the training session breakout guidelines. The targeted audiences for the training sessions are the Office of Pesticide Programs (OPP), the Office of Ground Water and Drinking Water, the Office of Underground Storage Tanks (OUST), Office of Solid Waste (OSW), EPA regional labs, state labs and contract labs. Topics to be included are: technical background of the techniques, different format of immunoassay (IA), qualitative and quantitative methods, specificity and matrix, data analysis, quality control, case study analysis to include HPLC correlation and hands on demonstration. The regulatory officials have stated they want hard data, such as correlation data. We discussed making a publication of the training module. Data used for training would come with a written script for whomever was presenting. The AEIC decided to focus on OPP and OUST first since they are waiting. Chuck will lead a group to put together the two committees data collection. The EPA has issued a publication on how to do an IA, authored by J. VanEmon and S. Gee. The publication is more a how to instead of correlations. We could develop our training as a compliment to their document. The length of time for a session should be no more than half a day. All meeting attendees joined one of three groups to work on organizing the training sessions. Joe Dautlick headed the sections on technical background of IA and formats of IA. Barbara Young headed the section dealing with specificity of the assay, matrix considerations, sample handling and the kit aspects of data analysis, quality control and validation. Rosie Wong headed the section on data analysis, quality control, validation and case studies / correlations of real world samples. Chuck Mihaliak and Jim Brady were targeted for compiling information specifically for the training for OPP.

**Thursday 9/22/94 p.m.**

**National Laboratory Training Network (NLTN):** Dr. Dan Mills and Dr. Bernie Jilly both spoke about NLTN and the program in place in the U.S. The organization uses individuals and groups such as EPA microbiology inspectors in Cincinnati and CDC. Dr. Jilly talked about the national organization. They organize teleconferences throughout the world for training purposes. Their goal is to improve the nations' efficiency and effectiveness in laboratories. As an organization, they assess and prioritize training needs, identify resources to address training needs, develop training interventions for a company or group, assist in delivery of laboratory training, evaluate laboratory training and build alliances between different organizations. NLTN has a lending library, provides "workshops in a can", stock many of the federal publications and have lab manuals that are available upon request. NLTN maintains a national training base calendar. As part of a training session, they will do publicity and brochures, site arrangements, registration and exhibitors and sponsors. They also can provide CEU, continuing education units. NLTN can also help with the evaluation of the training activity. They went through a set of slides demonstrating some of their training programs in progress.

NLTN operates on a break even basis by using federal funds and grants and charging tuition for a course. For example, the cost for a 3 day wet lab would be around \$300. Mike Conlon has been assigned as an environmental liaison for this group for a one year temporary assignment.

As a potential collaboration, we could come up with a draft and they would review for soundness and content at the level we want to present. The training program can be produced in-house or produced outside. They can arrange it either way.

**Member Update:** Viorica Lopez-Avila spoke to the group about MRI. MRI (Midwest Research Institute) is a not-for-profit organization. The mountain view facility was developed for support of the EMSL-Las Vegas methods development program. They have IA work in progress which includes supercritical fluid extraction(SFE) / LA for use in foods, applications of immunoaffinity chromatography for HPLC and a BTEX badge.

Another project underway is SFE extraction / ELISA detection developed for PCB's in soil. MRI is encouraging the EPA in Cincinnati to use an SFC extraction of pesticides from foods with IA detection.

**C. Mihaliak, Planning:** Chuck discussed the next two AEIC meetings and presented some topics for meetings. The Spring 1995 AEIC meeting will be held in Wilmington at DuPont. SDI and DuPont will organize the site for that meeting and Chris Rankin and Dave Grothaus will organize the program for that meeting. Some of the topics for that meeting included: present training program / 2 sessions, correlation studies and the statistical design of those studies, a member /organization profile, Mike Conlin and his work with the NLTN, AEIC business and incorporation.

The host for the Fall AEIC meeting will be Miles.

Chuck reminded everyone that speaks on behalf of the AEIC to send the Secretary a copy of your slides for distribution and for reference.

**Voting:** Voting by ballot took place for next years of officers.

9/23/94

**8:30 am**

**Jim Rittenburg:** Jim announced the election results. Rosie Wong, Vice President, Joe Dautlick, President, Pat Nugent Secretary and Larry Miller, Treasurer

**Joe Dautlick, Breakout renew:** This session should include reasons why one should use immunoassays and include that they are not always the answer to a problem. Include a slide on cost benefits of IA over existing technology. Validation of LA is necessary as with any other analytical tool. Include here specificity and sensitivity of IA methods. At some place include what an IA is and develop slides that would be to the level and the interest of the audience. We should include a list of assay types and use a direct assay as a

basic example. The level of detail used should also be audience dependent. The formats should be listed and then discussed. Depending on the audience, make it either lab or field based and finally, show examples.

Limitations need to be briefly described such as enzyme reactions are temperature dependent and the lack of multi residue methods.

This session should show how the results are formatted. The output for a qualitative test is usually yes /no. The OPP believes that IA data is quantitative but data submitted to OPP is usually done in the lab. When done in the field, the results are less quantitative. Let each office know why one test can be quantitative and why another format can be a screen. This area needs to be designed at several levels so slides can be interchanged depending on the audience. At the end, slides should be available as a handout.

### **Martin Reinhardt: Stanford /Western Regional Hazardous Substance Research**

Center: Participants in the research center are working to develop alternatives for subsurface transfer and clean up of hazardous substances. The materials they are working on are priority substances such as chlorinated and non chlorinated solvents, pesticides, and metals. The funding comes first from the EPA, the Department of Energy(DOE) and the Department of the Navy. They also have a long list of affiliates that work in cooperation with the research center. The fields of activity include movement and fate of the priority substances in soil, air and water.

At Stanford, the Environmental Engineering and Science department interacts with the Water Resources Department. The Seal Beach study was an example of some of their collaborative research. First, they drilled 30 wells to monitor the movement of the substances. GC/MS was used to analyze water samples. The second set of samples were soil. They have stimulated native organisms to break down contaminants into less harmful products. „Several electron acceptors are being used, N03, O2, S04 and C02. Their challenge is, "just what is needed to optimize the removal?" Do you use a combination of the above or let nature do it and you just monitor the progress? Using a passive technique is longer but much less costly. They haven't obtained enough formation to know if a passive method will satisfy the regulators.

### **Shirley Gee: University of California Davis Development of Rapid Assays for Small**

Molecules: The IA program at UC Davis has 3 graduate students and 6 post doc students. Some of their recent work includes antibodies for monuron, diuron, linuron. They used several conjugates to better study the binding equilibrium. Another study included developing an antibody for chlorpyrifos, 3,5,6-trichloro-2-pyridinol and triclopyr. A sandwich chelate assay has been developed for mercury. The protein chelator complex is coated to the wells. The chelates they chose were dithiocarbamates because they were good chelators. The lower limit of detection is about 2 ppb using sequential addition.

Another area they are studying is recombinant antibodies. Eukaryotic systems don't give a large number of clones but will produce whole antibodies in very large quantities. They are working from hybridoma cell lines and use a baculovirus as a transfer vector.

Baculovirus is used because it produces antibodies with correct folding and it is a well developed technology.

Future directions of the department include: integrating techniques, multi-analyte approaches, immunoaffinity, understanding fundamentals, and new formats applications. They are studying the hapten load on protein with electrospray GC/MS. The biggest thrust is in new formats specifically, biomarkers for human exposure.

Shirley also mentioned that she is helping to organize an immunoassay symposium for the Pacific Rim meeting in January of 1995. They are looking for monetary support for the transportation costs for the potential speakers.

**Barbara Young, Breakout renew summary:** Their slides would include a slide on specificity to include ag-ab reactions, binding site and a 3-D structure to illustrate specificity. Other information to be included here would be matrix considerations, sampling and sample handling and comparisons with traditional methods if possible.

**Rosie Wong, Breakout review summary:** Included here would be standard curve fit methods, (linear, semi-log, 4-parameter, log-logit). Different methods would be described but recommendations won't be made. Discussions would include precision, accuracy, reproducibility, and specificity in an assay. Validation would be the same as any other analytical method. Correlation with other methods and real world case studies would be included. Also included in an evaluation would be blind samples, duplicate field samples and the appropriate amount of samples to analyze. A hands on demonstration would be included.

**Kean Goh, CDFA:** Kean described the work CDFA (California Department of Food and Agriculture) using LA for compliance monitoring of atrazine in California. AB2021 is a California law on monitoring pesticides. CDFA was using a noncommercial LA method to measure atrazine in soil samples collected for compliance monitoring throughout several counties in California. The IA method used showed good correlation to present methods.

**Larry Strattan, National Enforcement and Investigations Center (NEIC):** Larry is on Barry Lesnick's committee for approving IA methods for SW 846. He suggested that a training session would be appropriate at the Waste Testing and Quality Assurance Symposium in July. The NEIC work deals with Clean Water Act violations, Superfund, and RCRA violations. Multi media inspection includes more than one type of violation. They have a project underway for sampling and analyzing ocean sheens. They will measure for petroleum and TPH. Any method can be used for analysis as long as it is scientifically defensible. When working on a project, NEIC objectives are:

- 1) to get the right answer,
- 2) make sure the method is applicable to the project,
- 3) no false positives and
- 4) use screening methods, such as IA, if applicable.

When choosing a method, check first to see if a regulation specifies a method. A permit is a regulation. Negotiations on methods could include using an IA method for a few more analysis. The regulation doesn't say an EPA method has to be used but they might let you use a new method if it is already EPA approved. For enforcement issues, a method must be defensible in court. The Quality Assurance used will be tailored to objectives of the study. Results always depend on the quality of the sample. The NEIC could use IA right now to screen samples in studies such as the one on ocean sheens.'

**Wolfgang Fuhs, CAL EPA:** Today there is a lack resources for independent validation of new technology. The California Department of Toxic Substances Control is doing performance certification to verify the technology works like the manufacturer claims it should work. They view themselves as a protector of the user and the public. Certification has to test the limits of an IA method. Department of Toxic Substances Control is the lead group and works with Air Resources Board, the Department of -- Pesticide Regulation and the State Water Resources Control Board. How do they determine what technologies should be tested? They look at technology and see if there is a definite advantage for using it. Certification is good for 3 years. They are trying to determine if 3 years is appropriate and how renewal should take place. They will look at validations done in other state labs. Dr. Ruth Cheng, also with this group, interacts with the Taiwan EPA. The cost to put a test through the certification process will depend on what department they have to support. Right now it's \$8-\$10,000 per assay. The goal is for the federal EPA and CAL EPA to have identical requirements.

**Meeting Summary: Joe Dautlick reviewed the mission statement.**

A first timeline for the training program is as follows:

1. Come up with program form: Barbara Young, Rosie Wong, Joe Dautlick
2. NOV 1 - have slides done

**American Lab Meeting:**

When: Afternoon of Dec.5 and Dec. 8

What to include: Where someone would use IA, general information, hands on evaluation

Who: Craig McCafferty (Ohrnicron) is responsible for organizing the symposium.

**OPP Presentation:**

When: Finalized by mid March, present at Spring AEIC

Who: Chuck Mihaliak will set up and Jan Sharp will help with site arrangement.

**OSW Training:**

Pat Nugent will contact Susan Sciaratta about training program she is developing.

Barbara Young will contact Barry's group about symposium at solid waste in July 1995.

**AOAC Test Kit Symposium:** Will be held next spring. We should participate.

**Publications:** The papers presented in San Diego, April 1994, Will be published in an ACS Symposium series during the first quarter of 1995. The book title is "Emerging

Technologies in Immunoanalysis of Agrochemicals". The papers were "Guidelines to Validating IA" and "Quality Standards for Test Kits".

Pat Nugent: New trifold, possibly include a cut out to send in for information

Dave Grothaus: Profile of AEIC members, Dave will check into the cost and the format.

Joe Dautlick: UST Booklet

Joe Dautlick: List of kit manufacturers' kit

Jan Sharp and Rick Birkmeyer: Trademark -

**Incorporation:**

The Board will talk to the CPA and will send information to all members. By the next meeting we will make final decision.

**National Lab Training Network:**

Joe Dautlick will investigate trying to work with Mike Conlon in his new role.

**Publicity**

We asked for volunteers for a publicity committee. The committee will consist of Pat Nugent, Jan Sharp, Chris Rankin, and Jim Rittenburg.

The meeting was adjourned at 5 p.m..