The Determination of Blood Alcohol Concentration by Transdermal Measurement

Abstract

A White Paper by

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Introduction

Objective

The objective of this research was to compare the accuracy of readings using the AMS SCRAM Bracelet to alcohol concentrations measured by conventional breath analysis. This was accomplished by establishing a series of objective scientific protocols, as specified in the Methodology section of this paper. This White Paper will also give an overview of the science of transdermal alcohol testing, as well as an introduction to the AMS SCRAM product.

Definition

Transdermal alcohol measurement is defined as the detection of ethyl alcohol in human subjects using an external, non-invasive detection device attached to the skin. A literal translation of transdermal means *transfer through the skin,* or the quantification of alcohol from a vapor after it passes through the skin. Transdermal measurement is the process used to determine alcohol concentration.

Device

Secure Continuous Remote Alcohol Monitor®, or SCRAM®, manufactured by Alcohol Monitoring Systems, Inc., determines alcohol concentration in human subjects by transdermal measurement. The measurement terminology used with the SCRAM is Transdermal Alcohol Concentration™, or TAC™.

Protocol

Breath alcohol tests were collected and analyzed using Department of Transportation-approved evidential and preliminary breath test devices. The following breath alcohol devices were used: DOT Model 5000 Intoxilyzer 68 Series, Draeger 7410 and 7110, and PBA 3000.

The Science

Alcohol in the Body

As alcohol is ingested orally, it is absorbed into the body's blood and distributed via the circulatory system. Alcohol is eliminated from the body by two mechanisms: metabolism and excretion. Metabolism accounts for the removal of greater than 90% of the alcohol consumed, removing it from the body via oxidation of the ethyl alcohol molecule to carbon dioxide and water. The remaining alcohol is excreted unchanged wherever water is removed from the body—breath, urine, perspiration, and saliva. Although excretion accounts for less than 10% of the eliminated alcohol, it is significant because unaltered alcohol excretion permits an accurate measurement of alcohol concentration in the body using both breath analysis and insensible skin perspiration. SCRAM uses this insensible skin perspiration to obtain a transdermal measurement of Blood Alcohol Concentration—or Transdermal Alcohol Concentration.

The Blood Alcohol Curve

When considering all factors affecting absorption, distribution, and elimination in estimating a person's Blood Alcohol Concentration in a particular situation, the result is a graphical representation known as the Blood Alcohol Curve. There are two typical Blood Alcohol Curves: One represents the body's Blood Alcohol Concentration when alcohol is consumed rapidly and immediately (see Figure 1); the second curve (see Figure 2) illustrates the results of alcohol consumed slowly over a prolonged period of time.

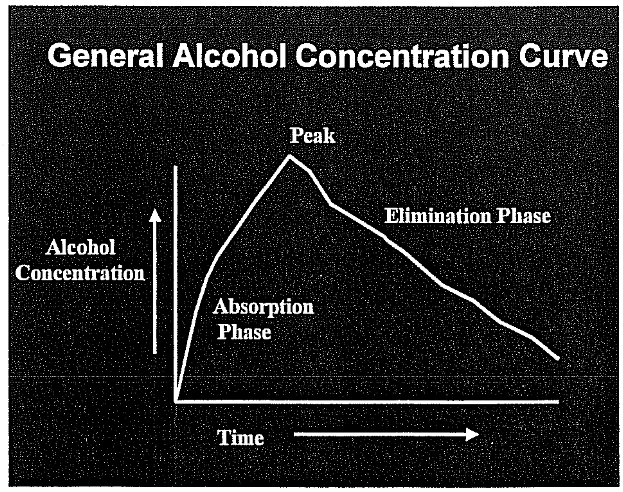


Figure 1
A Standard Blood Alcohol Curve

The Insensible Perspiration Curve

The amount of direct excretion of unchanged alcohol is from 2% to 8% in saliva, tears, urine, breath, and perspiration. Alcohol distributes throughout the body in relationship to each body part's water content.

Insensible Perspiration is the vapor that escapes through the skin when we sweat. It cannot be seen or detected within the normal confines of our olfactory system (nose). An Insensible Perspiration alcohol curve will vary only in a delayed time shift from its

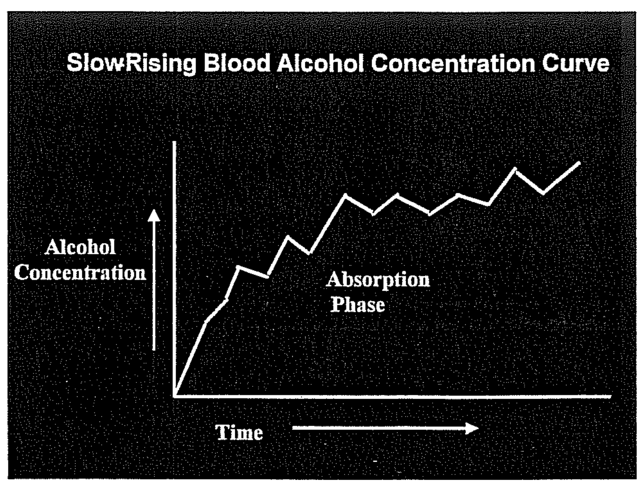


Figure 2
A Slow-Rising Blood Alcohol

comparable breath test curve. Generally, the water concentration in the skin is very low in relationship to other organs of the body. Thus, alcohol migrates last through the skin, resulting in a slightly slower—but ultimately accurate—Blood Alcohol Curve.

Research and testing indicate delays of from 30 minutes to more than 60 minutes for peak SCRAM readings to occur when compared to a conventional Blood Alcohol Curve. However, Insensible Perspiration testing results will directly correlate with breath analysis of a person's Blood Alcohol Concentration, providing an accurate representation of a person's Blood Alcohol Content. In venues where times of absorption and peaking are of no real consequence—where the only requirement is for a person to abstain from alcohol consumption—measuring Insensible Perspiration is adequate and accurate.

Transdermal Alcohol Measurement

Scientists first studied transdermal testing as far back as 1936. In 1982, Dr. Michael Phillips of the Division of General Medicine, University of Connecticut Health Center and Newington Veterans Administration Medical Center in Connecticut, was the first scientist to test transdermal emissions with a sweat patch. Dr. Phillips' research showed a strong correlation between a subject's blood alcohol test and transdermal analysis. In 1985 Daniel J. Brown from the Indiana University School of Medicine studied the excretion of volatile substances through the skin in perspiration, concluding that the concentration of alcohol in Insensible Perspiration is not substantially different from that of breath or blood following complete absorption.

The most recent transdermal testing was in 2000 by Dr. Robert Swift of the Brown University Center for Alcohol and Addiction Studies and the Veterans Administration Medical Center in Providence, Rhode Island.

The SCRAM System

Current Technology

Individuals on probation or parole may be prohibited from consuming alcohol, and many federal, state, and local law enforcement agencies require testing to ensure participants in those court-ordered programs remain alcohol-free.

In general, present-generation remote alcohol monitoring devices used in probation and parole settings are fixed-location breath-testing devices that utilize voice or video identification of the participant. If an offender tests positive for alcohol, the monitoring device then sends a message alerting the monitoring center of a violation, and the monitoring center then sends an alert message to the violator's administrator.

The SCRAM System

Alcohol Monitoring Systems, Inc., was established in 1997 by individuals interested in developing an improved system for long-term alcohol monitoring in the corrections market. The company's objective was to design a device that requires minimal offender intervention. That technology is SCRAM, which offers a new and innovative approach to alcohol monitoring in either a corrections or a parole and probation setting.

Using microprocessors and state-of-the-art sensor technology for alcohol analysis, SCRAM is able to measure the concentration of alcohol vapor venting from the skin, then time-stamps all readings and tamper indications. The heart of the SCRAM System is the 8 ounce SCRAM Bracelet, which is attached to the offender's ankle with tamper-resistant removal detection features. Alcohol readings are taken as scheduled without offender participation, with the data uploaded at scheduled time intervals—or immediately if a positive drinking event or a tamper is detected. Once the bracelet is in place it cannot be removed without destroying the tamper clip, which triggers and records a tamper alarm. In addition, there are a number of anti-tamper features designed into the system to ensure readings are from the proper subject and accurately represent the subject's blood alcohol level.

Unlike other monitoring devices, SCRAM collects alcohol data from the subject on a pre-determined schedule, 24/7/365, regardless of the location or activity of the subject. While commuting, at work, at home, during recreation, in the shower, or sleeping, subjects are passively monitored, allowing for continual, effective monitoring while the subject maintains a normal routine. This ensures that subjects are alcohol-free at all times.

Existing alcohol programs that have used other means of testing subjects for alcohol will likely see an increase in the number of program positives. This is a result of SCRAM's continuous monitoring, rather than the pre-arranged, specific testing times of current monitoring programs. Continuous monitoring eliminates the ability for subjects to manipulate their drinking patterns to avoid detection.

SCRAM is a passive device, so offender participation is not needed in order to obtain alcohol readings. Subjects typically do not know when the sampling will occur, and only the program administrator can change the testing schedule. The SCRAMNET web software allows agencies and service providers the ability to track client compliance in a manner most feasible to them, and the system can be defined to fit the needs of both small and large programs.

The SCRAM System was developed as an alternative to equipment presently on the market for detecting alcohol use and abuse in a variety of venues, including probation, parole, and alcohol treatment clinics.

The SCRAM System features include:

- ✓ SCRAM Bracelet
- ✓ SCRAM Modem
- ✓ Standard communications protocol via the Internet and the SCRAM Modem
- ✓ SCRAMNET web application for data storage, retrieval, analysis, and alert notification and management
- ✓ Increased sensitivity
- ✓ Anti-tamper technology

The SCRAM System benefits include:

- ✓ No collection of body fluids
- ✓ No waiting for laboratory tests
- ✓ Continuous 24/7/365 monitoring and data collection from any location
- ✓ No subject, officer, or laboratory intervention—only passive participation
- ✓ A SCRAM Bracelet that weighs only 8 ounces and is hidden from normal view
- ✓ Tamper-resistant technology to ensure accurate readings representative of the subject
- ✓ Advanced technology—microprocessors, encrypted data links, secure data storage and retrieval
- ✓ The ability for subjects to maintain normal daily routines, including work, counseling, community service, family obligations, and recreation
- ✓ Easy, web-based, secure access for the monitoring authority to each subject's data

The SCRAM Bracelet

SCRAM is an alcohol detection device housed in an ankle bracelet and is the first portable testing device that allows for continuous testing at any location (see Figure 3). The SCRAM Bracelet consists of two parts: One part contains the internal detector, which senses and measures ethanol concentration; the second part contains a myriad of electronics for security, tamper detection, temperature sensing, and data collection and transfer. A tamper-detection circuit acts as the electronics link between the two parts.

Figure 3
SCRAM Bracelet

SCRAM Alcohol Testing

Prior to SCRAM, blood, breath, and urine have been the primary body fluids used to determine ethanol concentration for forensic and correctional purposes. SCRAM measures ethanol as it migrates through the skin, or dermis, to determine alcohol concentration. The SCRAM Bracelet can be activated on a preset schedule deemed appropriate by the supervising officer. The activation of the SCRAM Bracelet causes the collection of an alcohol test. The results of the test are then stored in a flash memory chip within the SCRAM Bracelet. The stored data is transmitted by radio frequency to the SCRAM Modem and then, via a secure telephone network, the data is transmitted to SCRAMNET for analysis, generation, and management of alerts. SCRAMNET is the AMS-hosted website where all data is permanently stored.

Methodology

This section highlights the testing methodology utilized by the author of this White Paper to verify the functional specifications of the SCRAM System.

- Each subject was tested to make sure they were alcohol-free before testing started.
- Each subject was dosed with a specific amount of alcoholic beverage over a prescribed time period. Using the Widmark Formula, the author was able to mathematically calculate expected BAC over time.
- Each subject was measured to obtain height, weight, age, and food intake.
- Each SCRAM unit was initialized by attaching the device to subjects 12 hours before the start of testing.
- Each breath tester was checked for accuracy before and after each drinking episode.
- Tamper tests were conducted to verify SCRAM cannot be "fooled" into giving a negative reading on a positive subject without a tamper alert.
- Studies were conducted to make sure SCRAM does not give positive readings on alcohol-free subjects.
- Ethnicity differences were studied by attaching SCRAM Bracelets to individuals of different racial groups in an effort to ensure that SCRAM does not give false positive readings because of race or ethnicity.
- Other tests conducted include wear-ability testing, waterproof testing, hot and cold testing, interference testing, and dermatological testing.

- Ultimately, all testing was designed to ensure SCRAM would give an accurate and reliable test of a person's alcohol concentration without causing a false positive due to issues unrelated to their transdermal skin alcohol concentration.

Results

Hundreds of SCRAM tests were conducted from October 2000 through June 2002. Early tests resulted in modifications to the prototype SCRAM units. Modifications were made to enhance the SCRAM unit's precision, comfort, communication software and data links, detector clearance, and waterproof packaging.

Research was conducted on more than 100 different individuals providing thousands of SCRAM TAC to BAC comparisons to form the scientific basis for this White Paper. Attachment 1 is a representation of what can be expected from SCRAM technology and shows how SCRAM TAC results compare to breath alcohol test results.

Conclusion

There is a reliable correlation between SCRAM Transdermal Alcohol Concentration and conventional breath test results over varying periods of time on typical individuals under varying degrees of alcohol intake.

The SCRAM system will collect tests on subjects 7 days a week, 24 hours a day, 365 days a year with precision and accuracy. SCRAM will not give a False Positive reading on a true alcohol-free subject. Additionally, all tests specified in the Methodology Section above met the required testing objectives.

This independent research establishes SCRAM technology through its ability to provide accurate, continuous blood alcohol tests on clients who would have normally tested negative in a random testing program. Where random tests during the day might not detect an offender's drinking event, SCRAM's continuous testing will catch the event.

SCRAM technology and its underlying science will assist in providing the connection between testing technology, subject alcohol results, and the legal system.

Attachments

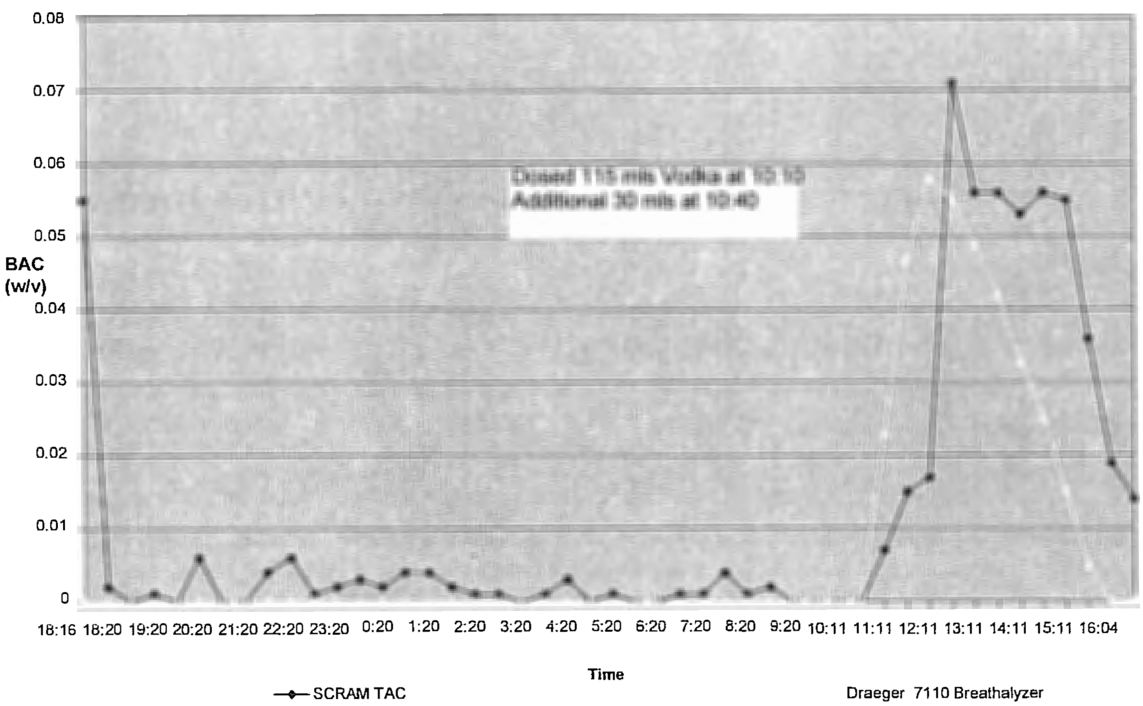
Attachment 1—SCRAM/Breath Analysis Test Results

Test 41181801

Subject: 39-year-old, Caucasian Female, 5'1", 135 lbs.

Subject was dosed with 115 ml of Vodka (40% w/v) at 10:10 and an additional 30 ml of Vodka at 10:40. Breath and Transdermal readings were taken every ½ hour. Peak breath reading was 0.058 and peak SCRAM reading was 0.071.

SCRAM Unit 411 Results for Test 8-18-01



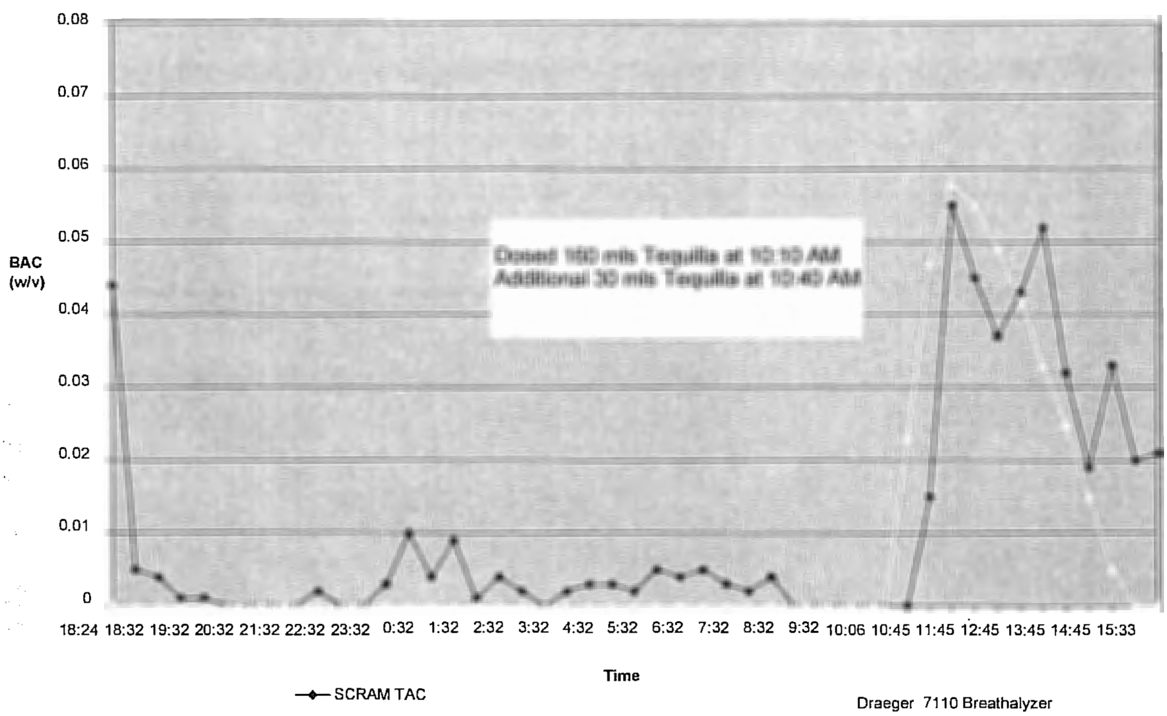
This chart shows the subject consumed enough alcohol to have a breath alcohol reading of 0.058. This correlated very well with the SCRAM reading of almost 0.071. What is not evident is that if the subject had been on a random program and not been tested until the next morning she would have tested negative for alcohol.

Test 98081801

Subject: 44-year-old, Caucasian Male, 6'0", 190 lbs.

Subject was dosed with 160 ml of Tequila (42% w/v) at 10:10 and an additional 30 ml of Tequila at 10:40. Breath and Transdermal readings were taken every ½ hour. Peak breath reading was 0.058 and peak SCRAM reading was 0.055.

SCRAM Unit 980 Results for Test 8-18-01

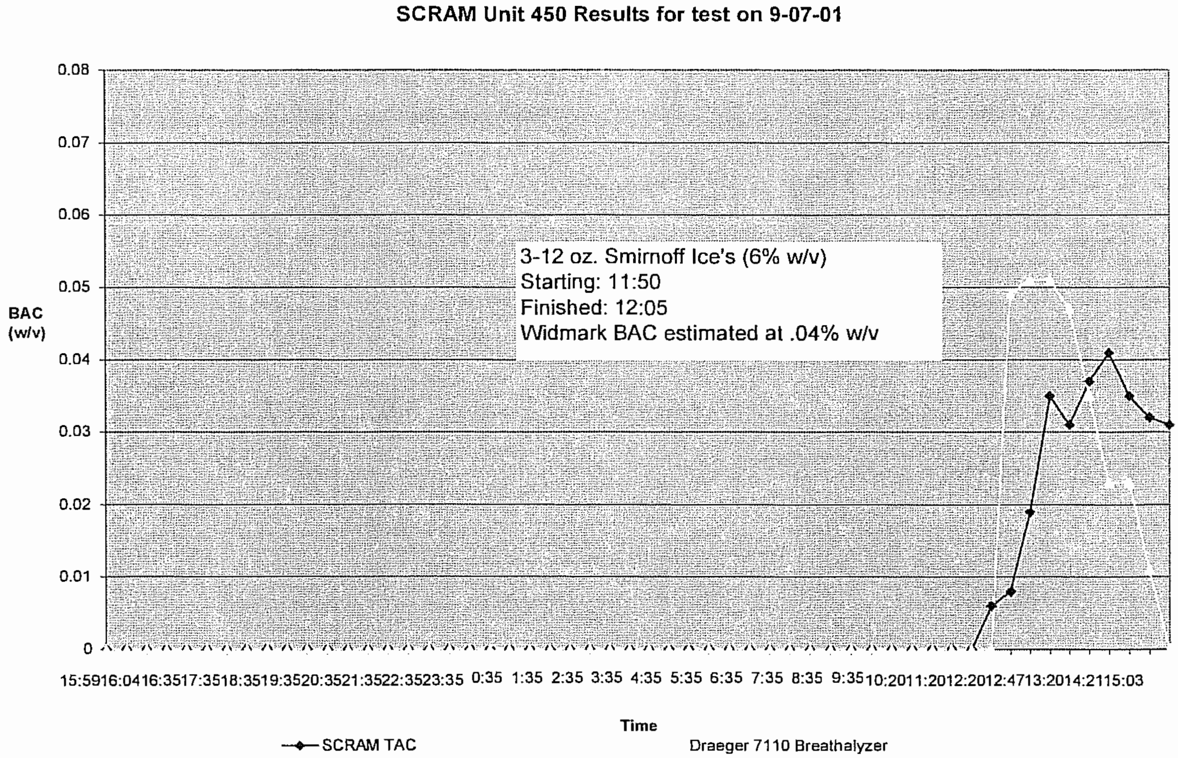


This chart shows the subject consumed enough alcohol to have a breath alcohol reading of 0.058. This correlated extremely well with the SCRAM reading of 0.055. Again, it is apparent that if the subject had been on a random program and not been tested until a number of hours later he would have tested negative for alcohol.

Test 45090601

Subject: 28-year-old, Caucasian Female, 5'4", 130 lbs.

SCRAM was worn on the right leg. Subject was dosed with 3-12 oz. Bottles of Smirnoff Ice (5.9% w/v) from 11:50-12:05. Breath and Transdermal readings were taken every ½ hour. Peak breath reading was 0.051 and peak SCRAM reading was 0.041.



This chart shows the subject consumed enough alcohol to have a breath alcohol reading of 0.05. This correlated very well with the SCRAM reading of 0.04.

Attachment 2—J. Robert Zettl Professional Biography

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Recognized as an expert on most alcohol and drug test equipment, Mr. Zettl has been actively employed in the field of forensic science for over 32 years, specifically in the areas of alcohol and drug analysis as they relate to driving under the influence. Mr. Zettl received his undergraduate degree from Pittsburgh State University—Pittsburgh, Kansas, and his masters in public administration from the University of Colorado. He is a Diplomat of the American Board of Forensic Examiners.

Mr. Zettl has appeared in over 1,100 court cases as an Expert Witness on the impairing effects of alcohol and other drugs on the central nervous system and their effect on a persons ability to safely operate a motor vehicle. He provides consultation, laboratory analysis referral, and testimony in criminal and civil matters for governmental agencies, private attorneys, coroners, medical examiners, insurance companies, and the private sector within the United States. Mr. Zettl has qualified and testified as an expert witness in numerous states on chemical testing processes issues, alcohol test instrumentation, and interpretation of alcohol and drug test results.

Mr. Zettl has presented scientific articles at many symposiums and lectured at numerous forums on the issues related to alcohol testing procedures and protocols. He is a member of several forensic science organizations and has received the following awards: the Borkenstein Award from the National Safety Council, the Ray Abernethy Award from the Toxicology Section of the American Academy of Forensic Science, and the Local Heroes Award from the State of Colorado.