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Identification Of Transdermal Ethyl Alcohol

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The Secure Continuous Remote Alcohol Monitor (SCRAM) is a device used by courts throughout the United States to monitor a subject's abstinence from alcohol consumption over long periods of time. The device is worn over the ankle just above the skin, and the presence of alcohol is determined indirectly by examining the diffusion of alcohol through the skin.

Typically, the device is worn pre-conviction as a condition of bond, or post-conviction as a condition of probation. During this time, if the monitoring agency "confirms" that a subject has engaged in a drinking event then the consequences can be significant, even possibly including incarceration.

The use of SCRAM has increased since its introduction in 2002[1] and is now used in some fashion in at least 44 states. But just as its use has increased, so have the claims of false positive results. Therefore, when evaluating a client's contention that he or she is being falsely accused, it is important to have an understanding of the scientific, technical and legal developments of SCRAM. A review of prior work leading to the development of SCRAM has been presented by Hawthorne and Wojcik[2], and experimental data have been published by Sakai et al[3]. and Swift[4].

It is also important to have an understanding of the methods used by the device to identify alcohol as it passes from the subject's blood through the skin. This requires some knowledge of the physics and physiology that are involved.

Blood-Skin Gas Exchange

SCRAM utilizes fuel cell technology to measure the amount of ethyl alcohol above the surface of the skin.

Ethyl alcohol diffuses from the blood through the skin to the surface of the skin where it is measured.

The exchange process between blood and skin is a combination of diffusion (passive movement from a region of higher concentration to a region of lower concentration) and convection (liquid flow from the sweat glands carrying alcohol from the subcutaneous regions to the surface of the skin). A schematic of the skin is shown in Figure 1. Blood flow through blood vessels delivers alcohol to the skin. The alcohol can then diffuse through the upper part of the dermis and through the epidermis to the surface of the skin. Sweat glands, as shown in Figure 1, help cool the body by secreting liquid to the surface. The sweat then evaporates, cooling the skin. The sweat accumulates alcohol near the bottom of the dermis in the sweat gland and delivers it to the surface with the sweat.

It is interesting to note that the amount of sweat, and, therefore to some extent, the amount of alcohol being moved through the skin, does not remain static. For example, under conditions of exercise or heat, sweat contributes more alcohol to the surface of the skin to assist with the body's cooling mechanisms. That said, the delivery of alcohol to the surface depends on the blood alcohol concentration (BAC), blood flow to the skin, activity level and body temperature.

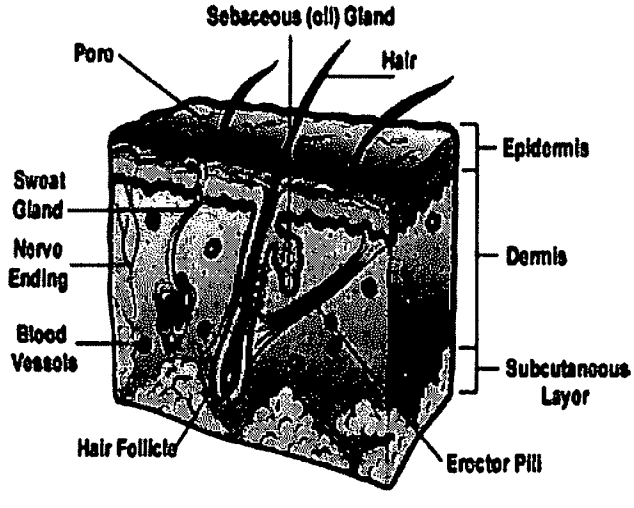

Figure 1. Artist's drawing of the human skin.

Blood Alcohol Dynamics and Metabolism

Consumed ethyl alcohol passes into the stomach where only a small fraction (~15%) is absorbed through the walls of the stomach and into the blood contained in the blood vessels surrounding the stomach. The stomach contents (containing alcohol) then passes into the small intestine (duodenum), which is richly vascularized and absorbs the remaining alcohol. The blood stream distributes alcohol throughout the body and delivers alcohol primarily to the watery tissues of the body (brain, muscle, etc.). The blood circulation also takes alcohol to the liver where it is broken-down (metabolized) and eliminated from the body.

The elimination of ethyl alcohol occurs primarily through the metabolism of it in the liver. Additional trace elimination occurs through the breath, urine, feces, as well as diffusion through the skin (the principle used by SCRAM). The rate of elimination (used interchangeably with burn-off) of BAC occurs at a rate that varies between 0.006 gm/dl/hr and 0.029 gm/dl/hr for 95% of the normal human population. The average elimination rate for males and females is 0.017 and 0.020 gm/dl/hr, respectively[1,2].

The rate and magnitude of TAC elimination is, however, less clear, though it can certainly be said that TAC decreases because the BAC is decreasing. If BAC is greater than the skin alcohol concentration, alcohol diffuses through the skin to the surface of the skin. When the BAC is lower than the skin alcohol concentration, alcohol diffuses from the skin back to the blood. This is a dynamic situation and is influenced by the BAC, properties of the local skin, and the change in BAC with time. There is no equilibrium between BAC and TAC[3]. Consequently, although blood alcohol concentration can be expressed in terms of "gm/dl" or "gm/100ml", supradermal alcohol concentration is expressed as "%".

It is difficult to describe the units of the readout of SCRAM. AMS, which manufactures SCRAM, chooses to assign an average "partition ratio" to the blood/skin of about 1500. Essentially, AMS assumes that the blood/skin partition ratio is 1500 and the blood/breath partition

ratio is 2100, and the TAC scale is adjusted by the ratio of these two. These assumptions require that the TAC scale be adjusted by a ratio of 2100/1500, which equals 1.4. It does appear, however, that like the breath/blood partition ratio, the "blood/skin" varies among different individuals due to a difference in skin diffusion characteristics. In fact, it would be expected to vary even more widely than breath/blood partition ratio because the amount of variation in skin diffusion characteristics is subject to far more variables among the human population than those involved with breath and blood. Therefore, the TAC scale is "rough" at best, rendering the calculation of elimination rates quite inaccurate.

Additionally, the blood alcohol dynamics cause this ratio to change dramatically as the BAC changes. AMS has chosen to use the unit "%". After correction of the TAC to an equivalent BAC (0.020 gm/dl BAC is assumed to be equal to a 0.020 % TAC for an average person). It should be noted that an adjusted TAC will never occur concomitant with the comparative BAC due to the time dependence of the diffusion process. According to AMS, this delay in peak absorption between TAC and BAC may be as much as 180 minutes.

The primary mechanism for the exchange of alcohol through skin in a non-exercising subject is passive diffusion. The alcohol molecules move from a region of high concentration to a region of low concentration. This exchange process has been evaluated in a study by Anderson and Hlastala[5]. The dynamics of skin exchange is illustrated in Figure 2. The straight solid thick lines show an idealized blood alcohol profile with an absorption time of 1 hour and a burn-off rate of 0.018 gm/dl/hr (the peak BAC of 0.050 gm/dl is eliminated at a rate of 0.018 gm/dl). The peak BAC of 0.050 mg/dl is eliminated after about 2.78 hours from peak to zero BAC. The curves labeled "Gas" are TAC (transdermal alcohol concentration) for a variety of subjects with varying skin properties over the range of known measurements in human subjects.

It should be noted that each gas curve is distorted relative to the blood curve because the peak of the TAC curve is reduced in magnitude and delayed relative to the BAC curve. The distortion results from the time that is required for diffusion through the skin. The other point to take from these curves is that the TAC burn-off is linear (a straight line) due to the metabolic characteristics of ethyl alcohol. The slope (change in TAC per unit change in time) varies depending on the characteristics of the skin, but in no case is the TAC elimination greater than the BAC elimination.

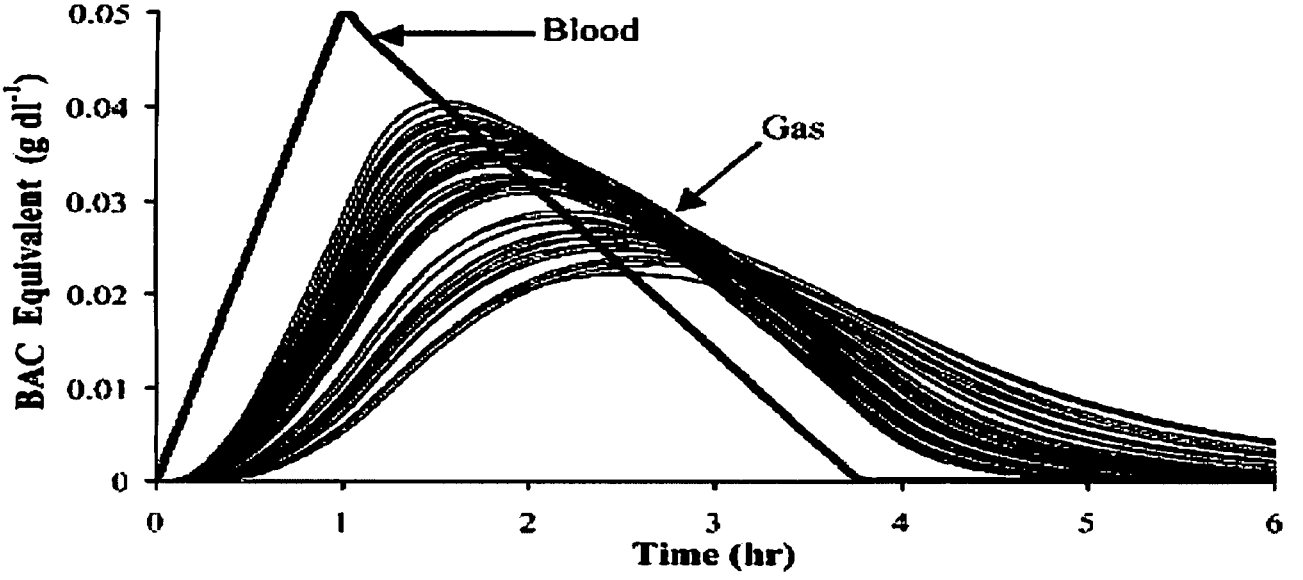

Figure 2. Variation in TAC (Gas) among individuals with differing skin characteristics each having the same BAC profile. From JAP 100: 649-655, 2006, reproduced with permission from the American Physiological Society."

Fuel Cells

The measurement of a subject's TAC by SCRAM is made with a fuel cell, and the numbers produced by these measurements are then used to plot the TAC curve. As a result, it may be said that a TAC curve is only as viable as the fuel cell used to produce it.

Fuel cells are electrochemical energy conversion devices. They produce electricity from external supplies of fuel and oxidant, which react in the presence of an electrolyte. SCRAM fuel cells sample at 60-minute intervals. If a TAC of greater than 0.020 % is seen, SCRAM will sample every 30 minutes. Fuel cells are not specific for ethyl alcohol. They react with any chemical that has a hydroxyl group (-OH), and will therefore react to chemicals other than beverage or ethyl alcohol. Potential contaminating (causing false positives) products include methyl alcohol[6,7] (methanol), n-propanol (propyl alcohol),[8] isopropyl alcohol[9,10,11,12,13] (2-propanol), n-butanol,[14] 2-butoxyethanol[15,16,17](ethylene glycol monobutyl ether), antifreeze (ethylene glycol and propylene glycol) and glycol ether (1-methoxy-2-propanol) [18,19]. All of these chemicals have at least one hydroxyl group and will react with a fuel cell. These contaminants get into the body when an individual is exposed to the product.

One possible reason for a false positive or an incorrectly "confirmed" drinking event is that contaminants can diffuse into the blood through the skin or be absorbed through the lungs due to the inhalation of vapors. Once in the body and the blood stream, the contaminant "behaves" much like beverage alcohol, in that it will diffuse through the skin and come into contact with the SCRAM fuel cell and potentially cause a false positive alcohol reading.

This potential problem is exacerbated by the method used for identification of ethyl alcohol -- it is indirect and based on the elimination rate for ethyl alcohol. The metabolism of ethyl alcohol in the liver is a linear (straight line) process (zero order kinetics) in which the alcohol elimination rate is independent of concentration except at very low concentrations. The alcohol elimination is linear (zero order) and contaminants are exponential (first order). The other contaminating products are eliminated in an exponential manner (first order kinetics) in which the rate of elimination depends on the concentration of the contaminant in the body. In order to identify an apparent drinking event as ethyl alcohol, the elimination must be linear and the elimination rate must be less than 0.025 %hr.

Another potential problem relates to the fact that SCRAM is passive, meaning the wearer is not independently observed or monitored in any way. This is an important fact because although fuel cells are sometimes used for evidentiary breath tests, their limitations are well known. Because of these limitations certain safeguards -- intended to increase the qualitative as well as the quantitative reliability of a positive test -- must always be followed. At a minimum, these safeguards include a 15-20 minute observation/deprivation period and duplicate testing. However, neither of these safeguards is practical for SCRAM, and neither is employed by AMS or any monitoring agency[20]. This fact alone should cast doubt on the reliability of any positive test.

Other Reasons Contaminants are Sometimes Misread as Alcohol

In addition to the "quantitative" identification of alcohol by the fuel cell, SCRAM must also qualitatively determine that it is metabolized alcohol that is being read and reported. To accomplish this task, AMS also uses the absorption rate as the major criterion for identifying and distinguishing ethyl alcohol from any potentially metabolized or environmentally occurring contaminant. According to AMS, the absorption time of ethyl alcohol must be less than 0.50 %hr. However, all contaminating products that are introduced to SCRAM through the skin have similar absorption times due to the diffusion limitation of the dermis. Only contaminants applied on the surface of SCRAM will have absorption times greater than 0.500 %/hr and are susceptible to being identified as contaminants. Thus, the absorption rate does not help to eliminate contaminating products that are absorbed through the skin or lungs into the blood.

The typical patterns of actual drinking events have been determined by AMS in con-

trolled studies as shown in Figure 3. The drinking events conform to the absorption criterion defined by AMS (absorption rate less than 0.5 0 %hr and the elimination less than 0.025 %hr). Notice that the decline of alcohol with time is a relatively linear process.

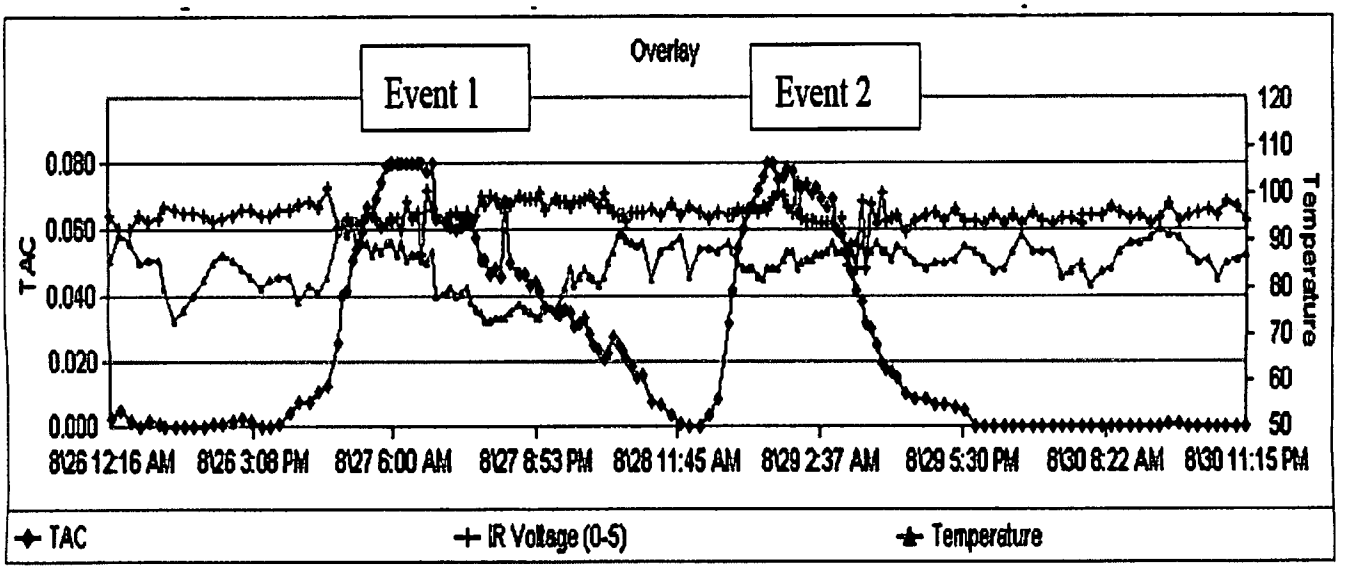

Figure 3. Sample SCRAM curves from an ethyl alcohol drinking subject.

It is also worth noticing the spike (abrupt increase) of approximately 0.020 %hr around *8:00 pm on 8/27.* The occurrence of the spike leads to concern regarding intermittent spikes in SCRAM, sometimes making it difficult to determine the elimination rate. It may be that the electronics are not stable, particularly after prolonged use. It is interesting that the elimination rate for event 2 is greater than that in event 1 in the same individual.

AMS has established a procedure for calculating the elimination rate. They determine the slope of a straight line originating at the peak of the curve and ending when the curve reaches zero. While this method is quite easy to perform, it does not adequately characterize the shape of the curve (linear vs. exponential). This is a particularly important issue in order to accurately determine if the curve is caused by ethyl alcohol. As described above, the elimination of alcohol is a zero-order (linear) process, whereas the elimination rate for all other contaminating gases is an exponential process (elimination rate depends on concentration). As concentration decreases, the elimination rate also decreases. This is why the estimate of the elimination rate of TAC is critical to determining if the curve is caused by ethyl alcohol. Unfortunately, the method used by AMS cannot separate contaminants from ethyl alcohol. Many SCRAM data charts are assumed to be alcohol when they are not.

Sample Cases

To fully understand these concepts, it is helpful to review some sample graphs. Figure 4 is an example of an alleged drinking event. It is important to recognize that the accuracy of fuel cell technology is poor at apparent BAC levels of 0.020 % and below. The alleged drinking event at 4 a.m. on 7/11/07 has two readings that are barely above 0.020 %. In this case, the burn-off calculated from the decreasing points after the alleged event is not sufficiently accurate to quantify burn-off because they are in the inaccurate zone (0.000 % to 0.020 %). The drinking event at 4 a.m. cannot be accurately determined.

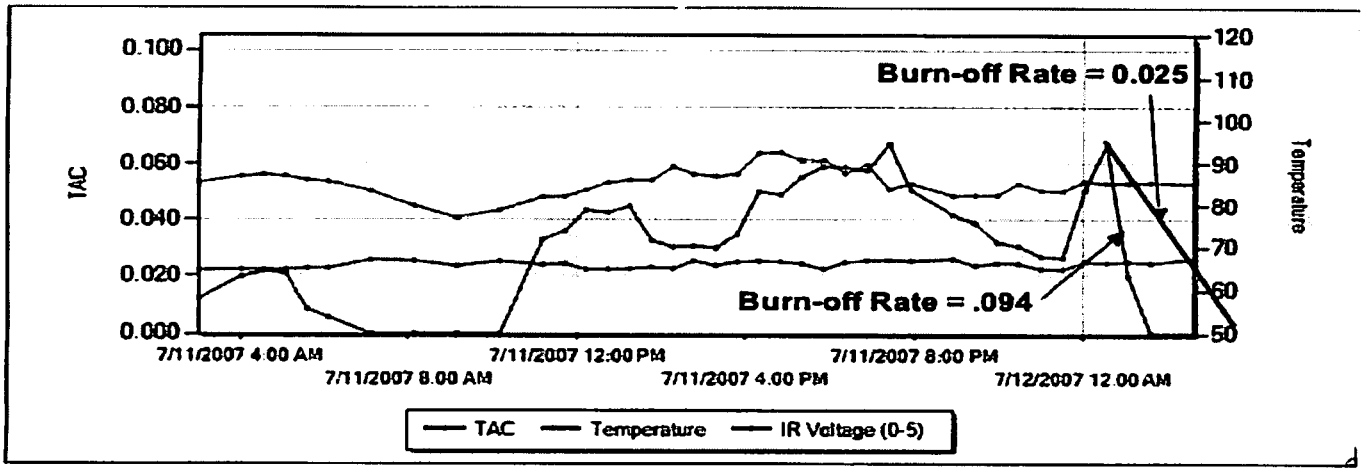

Figure 4. Sample SCRAM curve from a subject.

The second alleged drinking event shown in Figure 4 begins at approximately 10 a.m. on 7/11/07. The TAC rises to a maximum of 0.043 % at about 1 p.m. on 7/12/07. The TAC then decreases to approximately 0.030 % and then rapidly rises to a peak of about 0.060 % at about 7:30 a.m. on 7/11/07. The curve decreases at a rate of about 0.009 %/hr until 11 a.m. on 7/12/07. At this time, the TAC rises rapidly to 0.067 % at 12:30 a.m. and drops to 0.020 after 30 minutes. The elimination rate for the TAC is 0.094 %/hr, much greater than the maximum elimination rate of 0.025 %/hr (shown by the thick black line). Therefore, this alleged drinking event is inconsistent with ethyl alcohol and must be due to a contaminant.

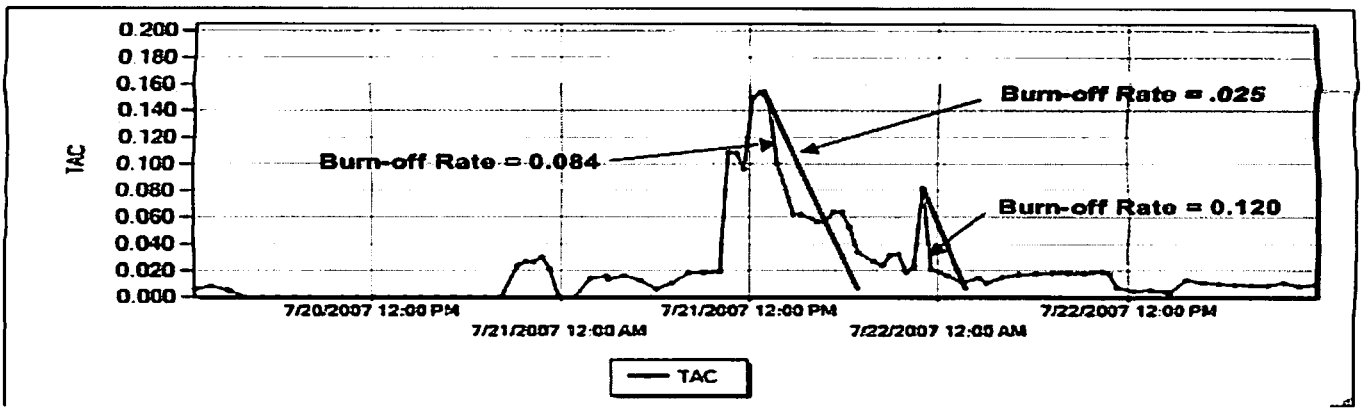

Figure 5. Sample SCRAM data with an alleged drinking event.

Figure 5 shows an example of SCRAM data in an individual who wrapped a SCRAM device with a large plastic bag and then sat in a hot tub. Under these circumstances, the SCRAM was exposed to water due to leakage of the plastic bag as well as increased pressure due to immersion in about three feet of water. The elevation of the TAC in this case may have been due to the water leakage or the increased pressure, or both. Two peaks in TAC are shown at approximately midnight on 7/21/07 and at 11:00 a.m. on 7/22/07. The decrease after the first peak shows an elimination rate of 0.084 %/hr. The TAC profile after the second peak shows an elimination rate of 0.120 %/hr (almost five times the maximum human ethanol elimination rate). Thus, the TAC profile is not consistent with ethyl alcohol due to the high elimination rates.

Figure 6 shows an example of a SCRAM unit exposed to water by an individual who showered daily. Water leakage resulted in sharp peaks with an abrupt rise in apparent TAC followed by a rapid return to zero. The peaks shown in this figure are quite varied in magnitude. Figure 6 illustrates a major weakness of SCRAM, namely sensitivity to the presence of small amounts of water.

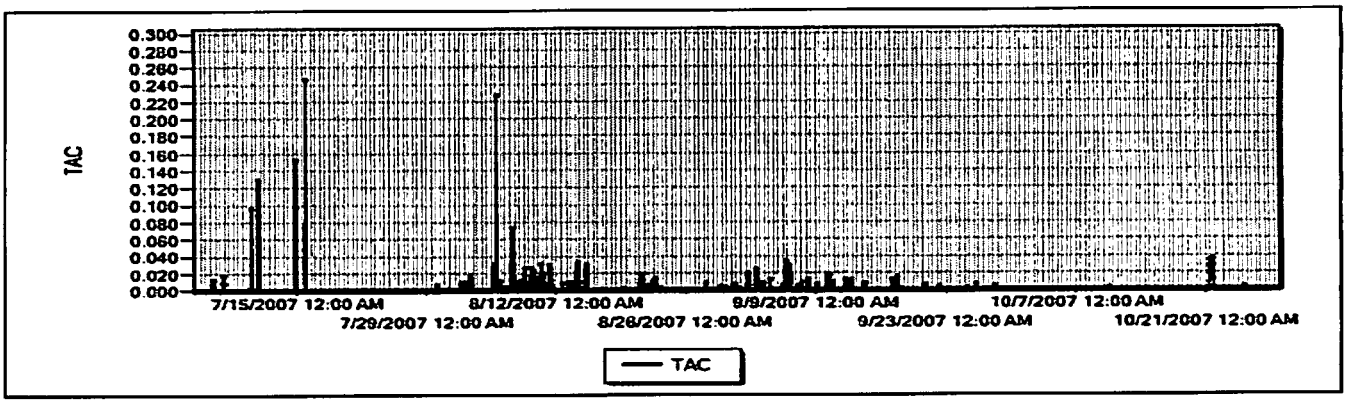

Figure 6. Sample SCRAM data after exposure to water caused by daily showering.

The Discovery Packet and The Defense of the SCRAM Case

SCRAM tracks three separate parameters: the "TAC"; the temperature; and the distance or IR voltage. The latter two factors are used to help determine if any tampering has occurred, and it will often be the case that alleged tampering and alleged drinking occur together. Separate graphs can be produced for each of the three parameters, and a composite graph can also be produced. This composite (Figure 7) has all three factors on the same graph. In most instances, only the composite graph is provided to the defense, and often this will be in the form of a faxed copy. One problem with a composite graph is that it requires color, because each factor is denoted on the graph by a different color. Consequently, black-and-white graphs are very difficult, if not impossible, to appropriately assess.

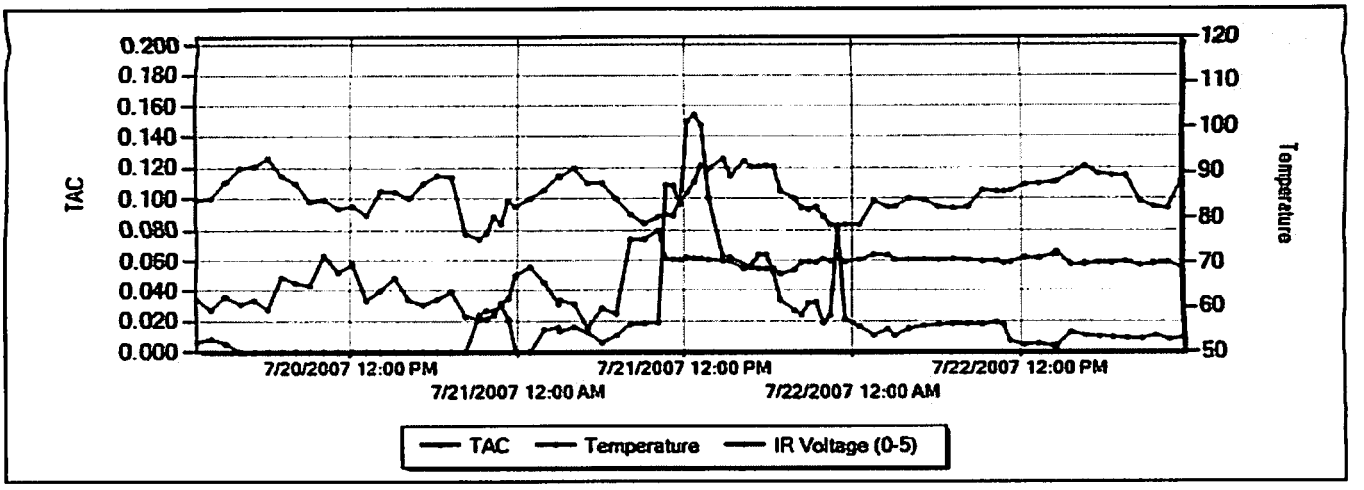

Figure 7. Composite graph with TAC, Temperature and IR Voltage associated with the subject shown

Along with these four types of graphs, also available is a summary of the hourly readings for each factor, and these should also be obtained and reviewed. These hourly (or half-hour) readings are essentially the numbers that are used to plot the graphs themselves. It would also be very helpful to obtain a copy of the written protocol used by AMS to distinguish between a "possible" violation and a "confirmed" violation.

Once these graphs are reviewed, be mindful of the fact that there are no clear methods for identifying ethyl alcohol profiles. In fact, AMS takes some liberty with the identification of ethyl alcohol. Fluctuations in the data are often ignored and an average curve is drawn through the fluctuations to cause the appearance of an ethyl alcohol curve. AMS defines the elimination by drawing a straight line between the peak of the TAC curve to a point where the TAC reaches zero. Using this method converts an ex-

ponential elimination rate to a linear elimination rate. So it is important to carefully examine the data to eliminate the possibility that an alleged drinking event is no more than a contaminant to which the subject was exposed.

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