SUPREME COURT OF NEW JERSEY
September Term 2005
Docket No. 58,879

STATE OF NEW JERSEY,

Plaintiff,

v.

JANE H. CHUN, DARIA L. DE CICCO, JAMES R. HAUSLER, ANGEL MIRALDA, JEFFREY R. WOOD, ANTHONY ANZANO, MEHMET DEMIRELLI, RAJ DESIA, JEFFREY LOCASTRO, PETER LIEBERWIRTH, JEFFREY LING, HUSSAIN NAWAZ, FREDERICK OGBUTOR, PETER PIASECKI, LARA SLATER, CHRISTOPHER SALKOWITZ, ELINA TIRADO, DAVID WALKER, DAVID WHITMAN and JAIRO J. YATACO,

Defendants.

FINDINGS AND CONCLUSIONS OF REMAND COURT

On remand from the Supreme Court of New Jersey: December 14, 2005

Findings and Conclusions Submitted to Supreme Court: February 13, 2007

Jessica S. Oppenheim, Assistant Attorney General, Christine A. Hoffman, Deputy Attorney General, Stephen H. Monson, Deputy Attorney General and John A. Dell'Aquilo, Jr., Deputy Attorney General, appeared on behalf of the State of New Jersey.

Samuel L. Sachs of the firm Sachs & Sachs appeared on behalf of Jeffrey R. Wood and James R. Hausler.

Matthew W. Reisig appeared on behalf of Christopher Salkowitz, Peter Lieberwirth, Raj Desai and Peter Piasecki.

John Menzel of the firm Moore & Menzel appeared on behalf of Anthony Anzano, David Whitman, David Walker, Hussain Nawaz and Jeffrey Ling.

Evan M. Levow of the firm Levow & Costello appeared on behalf of Jane H. Chun, Lara Slater, Elina Tirado, and Frederick Ogbutor.

Jonathan A. Kessous and Christopher G. Hewitt, co-counsel, of the firm Garces & Grabler appeared on behalf of Jairo Yataco and Angel Miralda.

Bartholomew Baffuto appeared on behalf of Daria L. DeCicco.

Arnold N. Fishman of the firm Fishman, Littlefield & Fishman appeared on behalf of amicus curiae New Jersey State Bar Association.

Jeffrey E. Gold of the firm Gold & Laine appeared on behalf of amicus curiae New Jersey State Bar Association.

Peter H. Lederman of the firm Lomurro Davison Eastman & Munoz appeared on behalf of amcius curiae Association of Criminal Defense Lawyers.

KING, P.J.A.D., SPECIAL MASTER

TABLE OF CONTENTS

I. PROCEDURAL HISTORY

The case arises from quasi-criminal actions involving twenty defendants who were arrested in Middlesex County for driving while under the influence of alcohol in violation of N.J.S.A. 39:4-50. Defendants challenged the admissibility and reliability of breath test results obtained from the Alcotest 7110 MKIII-C, firmware version NJ 3.11 (Alcotest 7110).

On October 14, 2005 the Law Division granted the State's motion to consolidate the cases pending as of May 23, 2005 in several Middlesex County municipal courts. Among other things, Judge Cantor denied the State's motion to take judicial notice of the opinion in State v. Foley, 370 N.J. Super. 341, 359 (Law Div. 2003), which ruled that the Alcotest 7110 MKIII-C was scientifically accurate and reliable and that its reported readings would be admitted into evidence without the need for expert testimony. At the time of Foley, New Jersey was using firmware version 3.8.

In her written statement of November 10, 2005 Judge Cantor explained that the Alcotest 7110 MKIII-C was a new instrument adopted throughout New Jersey on a county-by-county basis on a sequential timetable. She emphasized that only the Camden County, Law Division in Foley had found it scientifically reliable and that Judge Orlando, in dictum, had concluded that New Jersey should make certain changes in the instrument's firmware and the instructions given to its users. Ibid. Because the Alcotest 7110 MKIII-C was a novel scientific instrument which had never been vetted by an appellate court or our Supreme Court, Judge Cantor concluded that its scientific reliability remained a justiciable issue.

On December 1, 2005 the Appellate Division granted the State's motion for leave to appeal and denied its motion for a summary reversal. The Appellate Division remanded the matter to the trial court for an accelerated hearing on the validity of breath tests for alcohol, obtained through the use of Alcotest instruments.

On December 14, 2005 our Supreme Court certified the appeal pending in the Appellate Division on its own motion pursuant to

R. 2:12-1. The Court vacated the remand to the Law Division and remanded the matter to retired Appellate Division Judge Michael Patrick King, to preside as a Special Master. The Court ordered the Special Master to conduct a hearing and report his findings and conclusions on an accelerated basis.

The Court ordered the Special Master to:

> 1. Conduct a plenary hearing on the reliability of Alcotest breath test instruments, including consideration of the pertinent portions of the record in State v. Foley, 370 N.J. Super. 341 (Law Div. 2003), and the within matters in the Superior Court, Law Division, Middlesex County, together with such additional expert testimony and arguments as may be presented by the parties;
>
> 2. Determine whether the testimony presented by the parties should be supplemented by that of independent experts selected by the Special Master;
>
> 3. Grant, in the Special Master's discretion, motions by appropriate entities seeking to participate as amici curiae, said motions to be filed with the Special Master within ten days of the filing date of this Order;
>
> 4. Invite, in the Special Master's discretion, the participation of entities or persons as amici curiae or, to the extent necessary in the interests of justice, as intervenors to assist the Special Master in the resolution of the issues before him; and
>
> 5. Within thirty days of the completion of the plenary hearing, file findings and conclusions with the Clerk of the Court and contemporaneously serve a copy on the

> parties and amici curiae, which service may be effectuated by the posting of the report on the Judiciary's website . . . .

The Court also ordered the parties, and permitted all amici curiae who participated in the plenary hearing, to serve and file initial briefs within fourteen days of the filing of the Special Master's report as well as responses, if any, within ten days. It further ordered the Clerk to set the matter for oral argument on the first available date after completion of briefing by the parties. Finally, the Court ordered the stay of N.J.S.A. 39:4-50 proceedings pending in Middlesex County, and directed all Superior and Municipal Court judges before whom such proceedings were pending, to ensure strict enforcement of the Court's Guidelines for Operation of Plea Agreements in the Municipal Courts of New Jersey.

On January 9, 2006 the Special Master granted to the Association of Criminal Defense Lawyers of New Jersey (ACDL) leave to appear as amicus curiae. On January 23, 2006 the Special Master also admitted the New Jersey State Bar Association (NJSBA) as amicus curiae, under R. 1:13-9, in view of the matter's public importance.

On January 10, 2006 the Court sua sponte issued an order addressing issues that affected the prosecution of N.J.S.A. 39:4-50 offenses statewide. The Court ordered all prosecutions and appeals which did not involve the Alcotest 7110 to proceed in the normal course. The Court, however, ordered the stay of prosecutions and appeals involving repeat offenders and the execution of their sentences where the convictions were based solely on Alcotest readings. The Court also ordered that first-offender prosecutions proceed to trial based on clinical evidence when available and on Alcotest readings. It ordered, however, that the execution of sentences for all first offenders be stayed pending disposition of the Court's final decision on the Alcotest 7110's reliability, unless public interest required their immediate implementation.

As explained by the Administrative Director, Judge Carchman, in a clarifying memorandum to municipal court judges dated January 17, 2006, a court could admit evidence of an Alcotest reading, over the objection of defense counsel, without first holding a hearing on the instrument's scientific reliability. He further explained that under N.J.S.A. 39:4-50(a)(2) and (3), the penalty for repeat offenders was the same whether the finding of guilt was based on observation or blood alcohol levels. However, for first offenders, the penalty could vary, making the Alcotest reliability hearing of fundamental importance.

On March 15, 2006 the Court entered an order directing the Special Master to designate an independent expert or experts.

Upon deliberation and consultation with the parties and amici curiae, the Special Master determined that a court-appointed expert was not necessary for proof purposes, especially because of the quasi-criminal nature of the proceedings.

Meanwhile, discovery proceeded. On February 3, 2006 the Special Master entered an order directing the State to give defendants certain information, documents and materials pertaining to the Alcotest 7110's firmware, software, algorithms, electronic schematics, and source codes. Among other things, the discovery order recognized that the exchange of firmware and software might require a protective order to be submitted by the State or manufacturer for court approval. On February 17, 2006 the Special Master entered a supplemental discovery order directing the State to lend three Alcotest 7110s to defense counsel and one to counsel for the amicus NJSBA. Among other things, the supplemental discovery order also allowed the manufacturer Draeger Safety Diagnostics, Inc. (Draeger) to apply to intervene in this matter, especially because of the issue of "trade secrets."

Draeger objected to the discovery orders claiming that they permitted the release of trade secrets and proprietary information. On February 23, 2006 Draeger's intellectual property counsel prepared a proposed protective order and sent it to the State for submission to the court. Draeger's proposal included a request for indemnification from defense counsel. In response to defendants' objections to Draeger's initial draft –– especially to the request for indemnity –– and a revised proposal by the State, the Special Master requested defense counsel to submit a proposed protective order.

Draeger then offered to make copies of the Alcotest 7110's source codes available to the Special Master and explain them to him during an in camera session provided there would be no testimonial record and the data would be returned after his inspection and decision. Again, defense counsel objected, explaining that the purpose of requesting the source codes and algorithms was to allow their expert to review and test them.

On April 19, 2006 defendants submitted their proposed protective order. In anticipation of a court-issued protective order, the State provided to defense counsel and the amicus the four Alcotest 7110 instruments for their inspection.

On April 26, 2006 the Special Master entered a protective order which required all discovery information in which Draeger asserted an intellectual property right so marked. With regard to the marked discovery, the protective order required: (1) that the information could not be disclosed by parties or amici curiae, or by consultants and experts given access to it; and (2) that the information must be returned to Draeger following the conclusion of all litigation. The protective order also extended its terms and restrictions for three years from the termination of litigation or until such time as the marked discovery information entered the public domain, whichever came first, and stated that the violation or breach of any condition would be grounds for court contempt action, civil damages or other appropriate sanctions after a hearing where the accused would be afforded due process under R. 1:10. Additionally, if Draeger did not cooperate with discovery, the protective order allowed the Special Master to draw any appropriate negative inferences in his decision on the Alcotest 7110's reliability. The protective order did not include an indemnification provision.

Shortly after, on April 28, 2006, the State submitted comments on its revised proposed protective order. In part, the State explained that the indemnification provision would require those defendants who received the instruments to indemnify and hold harmless the State from any damage that might result from the firmware's use or installation.

On May 15, 2006 Draeger wrote to the State with its objections noting that it would not cooperate with discovery unless the court entered a "satisfactory" protective order. On May 22, 2006, after consideration of Draeger's expressed objections, the Special Master amended the protective order by: further limiting access to the information disclosed; extending the term and restrictions from three years to as long as the marked discovery information remained a trade secret or until it entered the public domain; and providing that other sanctions might be appropriate in cases where Draeger demonstrated at a hearing that it would suffer irreparable harm and there was no adequate remedy at law.

On June 15, 2006 Draeger wrote again to the State indicating that the amended protective order was an "improvement" but still did not provide adequate protection. Draeger continued to insist that the Special Master adopt an order substantially similar to its initial proposal. For example, Draeger contended: it should be provided with the identity of experts who would be given the marked information in discovery; it should not have to appear before the Special Master at a hearing to demonstrate irreparable harm; it should be allowed to demonstrate its intellectual property rights or prove its need for injunctive relief in a forum other than before Judge King; and it should not be forced to comply with an order essentially based upon a proposal by defendants who did not have any trade secrets or proprietary information to be protected.

Draeger also advised the Special Master and the State that it "recently" had adopted a "new policy" regarding confidential disclosure of the Alcotest 7110's source codes and other trade secrets to those individuals —— including parties involved in the Chun litigation —— who accepted the following conditions: (1) individuals who agreed to sign appropriate non-disclosure and confidentiality agreements prepared by Draeger; (2) individuals who agreed to review the information in a room at Draeger's offices in Durango, Colorado; (3) individuals who agreed to allow a Draeger representative to be present in the room when they reviewed the information; and (4) individuals who agreed not to take photographs, make copies by writing or other means, or make any recordings of the information. To maintain its "non-party status," Draeger again declined the Special Master's offer to meet with him or participate in any conferences. Incidentally, Draeger has no United States or foreign patent protection on the Alcotest 7110.

Neither the State nor defendants expressed any interest in complying with Draeger's fastidious conditions on the source codes' disclosure. The Special Master also declined to further amend the protective order. Consequently, discovery and the exchange of documents and expert reports proceeded without Draeger's participation. This created an anomalous situation: the manufacturer was not a party to the defense of its product. The State had to defend the Alcotest 7110 derivately.

Pursuant to N.J.R.E. 104, the Special Master held forty-one full days of evidentiary hearings which commenced on September

18, 2006 and concluded on January 10, 2007. The parties and amicus NJSBA submitted proposed findings of fact and conclusions of law regarding the scientific reliability of the Alcotest 7110. As further ordered by the Court, the Special Master has issued his findings and conclusions in this matter within thirty days of the completion of the hearings.

II. STANDARD OF PROOF

The key issue is whether the Alcotest 7110 is a scientifically reliable instrument for determining the alcohol content of the breath and blood. The resolution of this question will assist the Supreme Court in determining whether the results of Alcotest 7110 readings generally may be admitted in evidence and support convictions under N.J.S.A. 39:4-50 and cognate statutes.

Under New Jersey's statutory scheme, a driver of a motor vehicle is guilty of a so-called "per se" violation of N.J.S.A. 39:4-50(a) at a "blood alcohol concentration of 0.08% or more by weight of alcohol in the defendant's blood." Thus, New Jersey is a "blood" alcohol jurisdiction as opposed to a "breath" alcohol jurisdiction. See State v. Downie, 117 N.J. 450, 469-71 (1990) (Stein, J., dissenting). A person "under the legal age [twenty-one] to purchase alcoholic beverages" while operating a motor vehicle "with a blood alcohol concentration of 0.01% or more" is subject to special penalties imposed by N.J.S.A. 39:4-50.14 (the so-called "kiddie drunk" law). Operation of a commercial vehicle "with an alcohol concentration of 0.04% or more" is separately prohibited by N.J.S.A. 39:3-10.13. Interestingly, this latter statute defines alcohol concentration either by "blood" or "breath," not by "blood" alone, as does N.J.S.A. 39:4-50. See N.J.S.A. 39:3-10.11. All agree that this "commercial vehicle" section is rarely, if ever, invoked by the police.

The .08% blood alcohol level must be enforced by the several states under pain of withholding of federal highway-aid funds. See 23 U.S.C.A. §§ 163 and 410; 23 C.F.R. § 1225. We understand that New Jersey is in compliance with the federal mandate as of 2004. See L. 2004, c. 8 § 2 (amending N.J.S.A. 39:4-50(a), eff. April 26, 2004); State v. Chambers, 377 N.J. Super. 365, 371 (App. Div. 2005).

To allow the admission of scientific evidence in criminal cases, there must be general acceptance by the relevant scientific community. State v. Harvey, 151 N.J. 117, 169-70 (1997) (citing Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923); Romano v. Kimmelman, 96 N.J. 66, 80 (1984); State v. Johnson, 42 N.J. 146, 170-71 (1964); Foley, 370 N.J. Super. at 349. To establish general acceptance, test results must have "'sufficient scientific basis to produce uniform and reasonably reliable results [which] will contribute materially to the ascertainment of the truth.'" Romano, 96 N.J. at 80 (quoting State v. Hurd, 86 N.J. 525, 536 (1981)). "Proving general acceptance 'entails the strict application of the scientific method, which requires the extraordinarily high level of proof based on prolonged, controlled, consistent, and validated experience.'" Harvey, 151 N.J. at 171 (quoting Rubanick v. Witco Chem. Corp., 125 N.J. 421, 436 (1991)).

Given the rapidly changing nature of modern science, courts recognize that continuing research may affect the scientific community's acceptance of a novel technology. Id. at 167-68. Thus, newly-devised scientific technology essentially achieves general acceptance only after it passes from an experimental to a demonstrable technique. Id. at 171.

General acceptance, however, does not require unanimous agreement about the accuracy of the scientific test or the infallibility of its methodology, techniques or procedures. Ibid. Nor does it require the exclusion of the possibility of error. Ibid.; Romano, 96 N.J. at 80. Indeed, our courts recognize that "[e]very scientific theory has its detractors." Harvey, 151 N.J. at 171.

In a criminal case where defendants challenge the prosecution's attempt to introduce a novel type of scientific evidence, a court may conduct a hearing under N.J.R.E. 104 to determine whether the scientific evidence is generally accepted. Id. at 167. Proof of its general acceptance can be obtained through expert testimony, publications or judicial opinions. Id. at 172-76; Foley, 370 N.J. Super. at 350. The party offering the evidence has the burden to "clearly establish" each of these methods. Harvey, 151 N.J. at 170; Foley, 370 N.J. Super. at 349 ("To establish general acceptance within the scientific community the proponent must meet the clear and convincing standard of proof.").

At a N.J.R.E. 104 hearing, however, proofs need not comply with the other rules of evidence, except that N.J.R.E. 403 may be invoked and valid rules of privilege are recognized. Biunno, Current N.J. Rules of Evidence, comment 4 on N.J.R.E. 104(a) (2006). Thus, hearsay evidence is admissible. Ibid. When a showing of general acceptability has been made, courts will take judicial notice of the scientific instrument's reliability. Romano, 96 N.J. at 80-82 (holding that the breathalyzer's general acceptance within the scientific community demonstrated its scientific reliability and that such reliability was the subject of judicial notice in all cases under N.J.S.A. 39:4-50).

The State must prove by clear and convincing evidence that the Alcotest 7110 is generally accepted in the relevant scientific community —— even if such acceptance is not unanimous —— for the purpose of determining the concentration of alcohol in the blood. If the Alcotest 7110 is a scientifically reliable instrument for measuring blood alcohol, the test results are admissible in evidence only in those cases where the State clearly establishes that: (1) the instrument was in proper working order; (2) the operator was qualified to administer the instrument; and (3) the test was administered in accordance with official instructions and New Jersey State Police protocol for the instrument's use. See Romano, 96 N.J. at 81.

III. THE FACTS

1. Chemistry and Physiology

Scientists have long known the presence of alcohol (ethanol) in the brain causes cerebral dysfunction leading to automobile accidents. The medium through which alcohol reaches the brain is the blood. If we could directly sample blood from the brain, the amount of alcohol it contains could be easily and accurately known. But we can not.

Alcohol comes into the human body through the stomach and passes to the small intestines. It is absorbed into the blood partly in the stomach but principally from the small intestines. Absorption can take place quite quickly or more slowly, depending on the contents of the stomach and the strength and quantity of the alcohol ingested. The alcohol-laden blood then passes to the liver and circulates through all parts of the body. It is found in all water in the body. Freshly formed urine, saliva or other body fluids receive alcohol in proportion to their water content. Blood from many parts of the body, taken after time allowed for absorption, will reflect the alcohol present throughout the body. Urine specimens and saliva samples are not particularly accurate and are difficult to obtain, especially on a repeat basis over a short period of time. They are unsatisfactory for field work.

The taking of blood samples poses some inconveniences but not of great magnitude. With blood the first issue is from what part of the body is the sample taken. The amount of alcohol present in the blood will vary between venous blood from the cubital or elbow vein in the arm, from fingertip capillary blood, or from arterial blood. Even arterial blood will provide different readings on the amount of alcohol present depending on the site where the blood sample is taken.

Arterial blood passes through the lungs into the heart and from there goes to the brain through the carotid arteries. On leaving the brain it travels through the venous system, goes back through the liver, and continues through the heart where it is again pumped into the arterial system and lungs.

Returning to the problem of determining how much alcohol is in the brain, the immediate source of blood supply to the brain is through the carotid arteries. If we could simply and safely draw a blood sample from one of those arteries this would be an excellent measure of alcohol in the brain. Such a procedure is neither simple nor safe.

Blood can be taken from other sites, commonly the finger tips or the cubital vein. Both sites are much more remote from the brain and do not give a precise indication of what is present in the brain at the time. The alcohol content of blood constantly changes as it circulates through the body. It is eliminated through various parts of the circulatory system but gains more alcohol from the small intestines so long as alcohol remains in the stomach.

For multiple tests, upon which the accuracy of blood readings depends, the fingertip blood or capillary blood is not satisfactory. The size of the sample is quite small and there is immediate danger of exposure to the air and evaporation of some of the alcohol, because alcohol is a very volatile substance. Venous blood is satisfactory as to quantity. However, it does not always give an accurate reflection of the alcohol in the brain, especially during the period during which alcohol is still being absorbed through the stomach and small intestines into the blood. All of this has been known to scientists for a long time.

Scientists also have long known that as the blood passes along the alveolar or honey-comb-like cells in the lungs, some of the volatile alcohol in the blood will escape into the breath chambers on the other side of the thin membrane which makes up those cells. This transfer of alcohol from blood to breath in the lungs proceeds, in general, at a fairly predictable rate for most, but probably in no two people is that rate precisely the same. This is because of biological variation.

Since arterial blood passing through the lungs is the most accessible practical spot for testing prior to going through the carotid arteries to the brain, it became apparent that if an accurate form of detecting the amount of alcohol in the breath could be developed and if the breath-alcohol level could be related to an assumed amount of alcohol in the arterial blood which produced it, a prediction could be made as to how much alcohol must be present in the blood flowing through the brain. Thus emerged the Breathalyzer and its progeny: all other breath-alcohol analyzing instruments.

In our view, there is really no problem at all with the technology for measuring the amount of alcohol present in a given sample of breath or vapor. The breathalyzer has been one of a number of scientifically-proven instruments. With proper working order and a trained operator, it can read alcohol in breath quite well and with satisfactorily scientific acceptability. Most all experts agree on this. The problem is converting that breath-alcohol reading or concentration (BrAC) into a blood alcohol concentration (BAC). This outcome depends on the process in the subject's lungs.

2. History

Evidential breath testers (EBTs) have been in use since Robert F. Borkenstein invented the breathalyzer in 1954. In 1984, National Draeger, Inc., the American subsidiary of Draegerwerk Aktiengesellschaft (Draeger AG), acquired Smith and Wesson, the breathalyzer’s manufacturer, partially to gain access to the United State’s market. Draeger AG was founded in 1887 in Luebeck, Germany.

Also in 1984, the National Highway Traffic Safety Administration (NHTSA), United States Department of Transportation (USDOT), issued a notice converting the mandatory standards for EBTs to model specifications and publishing a conforming products list (CPL) of such instruments to assist states in their purchasing decisions. 49 Fed. Reg. 48854 (Dec. 14, 1984). The model specifications also added an alternative laboratory method to test breath sampling capability, eliminating the need to test with human subjects. Ibid. NHTSA defined EBT’s as "instruments that measure the alcohol content of deep lung breath samples with sufficient accuracy for evidential purposes." Ibid.

In 1993, NHTSA published the amended Model Specifications for Devices to Measure Breath Alcohol and an updated CPL to accommodate transportation workplace alcohol testing programs, to meet new zero tolerance laws for underage offenders, and to add testing for acetone interference. 58 Fed. Reg. 48705 (Sept. 17, 1993). The updated CPL listed the "Alcotest 7110." Ibid.

The USDOT Volpe National Transportation Systems Center (Volpe) in Cambridge, Massachusetts performs EBT testing for NHTSA on instruments submitted by manufacturers to determine their accuracy and precision. Ibid. NHTSA, through Volpe, also does special testing for end-users upon request. As Edward Conde explained, Volpe performs an "initial type approval" consisting of eight steps: accuracy and precision testing; acetone interference testing; blank testing; breath alcohol sample simulator (BASS) testing; power variation or voltage testing; temperature testing; post-vibration testing; and electrical safety inspection.

In 1994 Hanseuli Ryser, a key State's witness in this proceeding and Draeger's United States' principal, established the Breathalyzer Division in the United States. Eight years later, the Breathalyzer Division merged with Draeger Interlock, Inc., and the name changed from National Draeger to Draeger Safety Diagnostics, Inc. (Draeger). As vice president of Draeger's operations in Durango, Colorado, Ryser supervises the production, servicing and engineering of evidential breath-testing instruments.

In 1995 Draeger introduced to the United States market the Alcotest 7110 MKIII, which used a dual sensor measuring system consisting of infrared spectroscopy (IR) and electrochemical or fuel cell technology (EC), to analyze breath alcohol results. From November 1995 through February 1996, personnel from the Alcohol Drug Testing Unit (ADTU) of the New Jersey State Police along with then chief forensic scientist, Charles Tindall, Ph.D., and assistant chief forensic scientist, Thomas A. Brettell, Ph.D., performed various tests on four EBTs including the Alcotest 7110 MKIII. They conducted the tests for the purpose of selecting a new breath-testing instrument to replace the Breathalyzer Models 900 and 900A. As Brettell explained, breathalyzers produced "very good, reliable, precise, accurate" results when operated and maintained properly, but they were fast becoming dinosaurs since Draeger acquired the manufacturer and eventually stopped making spare parts, ampules and new instruments.

In addition to the Alcotest 7110 MKIII, the forensic scientists and ADTU members evaluated three other instruments: BAC Datamaster; Intoxilyzer 5000; and Intoximeter EC/IR. They performed validation studies including side-by-side testing for accuracy, precision, linearity, and specificity. They also qualitatively evaluated the instruments for such things as ease of operation, operator dependence, transportability, and printout information. Brettell testified that the results showed the Alcotest 7110 MKIII was capable of providing accurate and precise results. Brettell further testified that he recommended the State select the Alcotest 7110 with the wet bath simulator (Draeger CU34) and a laser-jet external printer, but without the detector for radio frequency interference (RFI) or the breath temperature sensor option.

In January 1996 Volpe successfully tested the Alcotest 7110 MKIII for accuracy and precision, among other things, and listed the instrument on the CPL. 61 Fed. Reg. 3078 (Jan. 30, 1996). Independent laboratories in the Netherlands (1994) and Paris, France and the German government (1998) also successfully tested the Alcotest 7110 MKIII for compliance with the more rigorous standards adopted by the Organisation Internationale de Metrologie Legale (OIML), an international treaty organization established in 1955 to address issues relating to the application of common legal measurements by its 113 members.

Draeger subsequently developed the Alcotest 7110 MKIII-C, which added an internal computer communications capability or modem as a standard feature. NHTSA did not re-test the instrument, concluding that the communication enhancement did not affect the instrument’s accuracy or precision. In 1998

NHTSA amended the CPL to include, among others, the Alcotest 7110 MKIII-C. 63 Fed. Reg. 10066 (Feb. 27, 1998).

In 1998 the New Jersey Attorney General (AG) proposed the readoption, with amendments, of the Chemical Breath Testing Regulations, N.J.A.C. 13:51, which were scheduled to expire on September 16, 2001. 30 N.J.R. 4321(a) (Dec. 21, 1998). The proposed amendments addressed the introduction of new chemical breath testing methods and technology including the Alcotest 7110 MKIII as an improved instrument for testing a person’s breath by chemical analysis. Ibid. After receiving no public comments, the AG approved the Alcotest 7110 MKIII for evidential breath testing in New Jersey. N.J.A.C. 13:51-3.5(a)(2); N.J.A.C. 13:51-3.5(a)(2)(i); N.J.A.C. 13:51-3.6(c). The regulations state in relevant part:

> 2. Infrared analysis and electrochemical analysis, when utilized in a single approved instrument as a dual system of chemical breath testing, is approved as a method of chemical breath testing.
>
> > i. The Alcotest 7110 MKIII, is a chemical breath test instrument which employs both infrared analysis and electrochemical analysis as a dual system of chemical breath testing and is an approved instrument for use in the testing of a person’s breath by chemical analysis.
>
> [N.J.A.C. 13:51-3.5(a)(2)(i).]

The State subsequently commissioned Draeger to develop a version of the Alcotest 7110's firmware to meet its particular needs. In 1998 Draeger delivered the first instruments with firmware version 3.8 to the New Jersey State Police.

On September 6, 2002 Draeger, the licensor, and the State of New Jersey, Department of Treasury, Division of Purchase and Property, on behalf of the State Police, the licensee, entered into a Firmware/Software License Agreement. The license agreement recognized that Draeger owned the firmware and software, and that the State Police had a non-exclusive license to use the Alcotest 7110 MKIII-C under certain terms and conditions. One of the conditions required the licensee to agree not to "reverse engineer, decompile or disassemble the Firmware/Software or otherwise attempt to derive source codes from the Firmware/Software, not shall Licensee allow any other entity to do so."

Meanwhile, New Jersey reviewed and evaluated the operation of the Alcotest 7110, NJ 3.8 in the Pennsauken Township pilot program (pilot program) which took place from December 2000 through December 2001. Sergeant Kevin Flanagan, New Jersey State Police, testified that he loaned two instruments to the Pennsauken Township Police Department which then performed breath tests on 372 subjects suspected of operating a motor vehicle under the influence of alcohol. After the pilot program ended, the Camden County Prosecutor applied to the court for a consolidated proof hearing on the instrument's scientific reliability. Foley, 370 N.J. Super. at 345. The request related to cases pending before the Pennsauken Township Municipal Court which involved prosecutions for violation of N.J.S.A. 39:4-50, N.J.S.A. 39:3-10.13 or N.J.S.A. 12:7-46 (reckless boating). Ibid. The court granted the application and held an evidentiary hearing from September 8, 2003 to October 14, 2003. Id. at 345-46.

In 2003 New Jersey also requested Volpe to perform special testing of the Alcotest 7110, NJ 3.8, including informal RFI testing. Conde performed the tests and found that the instrument conformed to NHTSA's model specifications.

The Foley court also found that the Alcotest 7110 was a scientifically reliable evidential breath-testing instrument. Id. at 351. It found that the test readings produced by the Alcotest 7110 were accurate and admissible in evidence in a prosecution for violation of N.J.S.A. 39:4-50, N.J.S.A. 39:3-10.13 or N.J.S.A. 12:7-46 without the need for expert testimony. Id. at 359.

During the Foley hearings, however, it became apparent there were several functions or features of firmware version NJ 3.8 which required revision. For example, the judge expressed concern about the unusually high number of subjects in the pilot program who were unable to provide the minimum breath sample and were charged with refusal to submit to a breath test. Id. at 345. In response to the 28% refusal rate, the court directed the State to modify the firmware and change the instructions given to individuals who were about to use the instrument. Ibid. The court also ordered that no person who delivered a breath sample of at least 0.5 liters of air during a test on the Alcotest 7110 could be charged with refusal. Ibid.

After Foley, the State asked Draeger to make certain scientific and administrative changes to the firmware. From July through September 2004 Brettell and his laboratory staff performed validation testing on two beta or experimental versions of NJ 3.10. Brettell confirmed that Draeger made the requested changes to the instrument which included: giving operators the option simply to terminate the test rather than record it as a refusal; displaying "error" messages on the LED screen so operators could take them into consideration; automatically truncating the final blood alcohol result to two decimal places; instituting a two-minute lockout between breath tests; and allowing operators to observe the protocol for the twenty-minute observation period instead of locking the instrument preventing use during that period. Draeger also revised the alcohol influence report (AIR) to present all information on one page, including error messages, and New Jersey revised its blowing instructions to ask subjects for deep breaths.

Shortly thereafter, Flanagan and the ADTU operators discovered that four data fields could not be reviewed including the subject's drivers license number, the issuing state, the agency case number, and the summons number. Draeger made these changes, which Flanagan verified, and the State then received current firmware version NJ 3.11. Brettell did not perform additional testing and validation because he believed these changes did not affect the analytical operation.

New Jersey asked Volpe to perform special testing to determine if the Alcotest 7110, NJ 3.11 complied with NHTSA's model specifications. From December 2005 to February 2006, Conde performed tests on the Alcotest 7110, NJ 3.11, retaining only those AIRs which contained data needed for type approval or disapproval. Conde again concluded that the NJ 3.11 met the model specifications and was suitable for use in an evidential environment.

In January 2005 police departments in Middlesex County began to use the Alcotest 7110, NJ 3.11. By December 2005 thirteen of New Jersey's twenty-one counties were using the Alcotest 7110 in place of the breathalyzer for evidential breath testing. In April and June 2006, at the recommendation of the

Division of Criminal Justice and the State Police, the roll-out of the Alcotest 7110 continued in several more counties including Atlantic, Cape May, Passaic and Sussex. The State Police had scheduled roll-outs in October 2006 for the remaining four counties —— Bergen, Hudson, Monmouth and Essex —— but ceased pending decision in this case. To date, New Jersey and its municipalities have bought about 480 instruments with extended four-year warranties for approximately $11,800 each.

At the time of the hearing, at least three other states (Alabama, New York and Massachusetts) and several countries including Germany, Finland, Austria, Italy, Spain, South Africa, Taiwan, Hong Kong, Bulgaria, Guam and the Northern Marianas were using the Alcotest 7110 for evidential breath testing.

3. The Instrument

The Alcotest 7110 is a breath alcohol analyzer used for evidential breath alcohol measurements. It weighs approximately 16.5 pounds and resembles a tool kit. The entire system includes the breath analyzer, a special organizer stand with a drawer, a standard keyboard, an external laser printer, a wet bath simulator, and a temperature probe.

The instrument fits in a metal case with a cover that is removed when in use. On its rear side, there are various interfaces including an exhaust port, an outlet port to deliver air to the simulator, and an inlet port to the IR absorption chamber (or cuvette). There also are power and start buttons, and a tag with the instrument's serial number. The top surface contains a flexible breath hose which is forty-six inches long and heated with two temperature sensors to 43 plus or minus 0.3 degrees Celsius to prevent condensation and overheating of the hose material. A disposable mouthpiece fits onto the breath hose to ensure a better seal, make it easier to exhale, and aid hygiene. The mouthpiece is changed after each breath sample.

The top of the instrument contains a forty-character light-emitting diode (LED) display screen which prompts the operator to take certain actions, describes the operation being performed, conveys error messages, and displays BAC results. The instrument operates in AC or DC modes. It contains an internal printer which uses paper 2 1/4 inches in width and approximately 22 inches in length, but is disabled in New Jersey in favor of an external printer.

While the Alcotest 7110 shares some of the same features as a computer, we find it best described as an embedded system with a very specific, dedicated purpose. The instrument has fairly limited interface sensors and operates by using a very reduced logic code which is sufficient to support its function. Like a computer, however, the Alcotest 7110 contains both hardware and software components.

Hardware components include the IR absorption chamber, EC sampling system, sensors (flow and pressure), a signal processing system, and a microprocessor. Software components include firmware for the microprocessor and software to handle data communications, data retrieval, and operator input.

The Alcotest 7110 is the only evidential breath-testing instrument which uses a dual system of IR absorption analysis and EC fuel cell technology to independently measure alcohol concentration in the same breath sample. Ryser explained that Draeger does not hold a patent for the dual technology because, among other things, it wants to avoid the disclosure of company "trade secrets." Draeger, however, does hold a trademark for the name "Alcotest."

The Foley court accurately described the IR and EC methods this way:

> IR Analysis
>
> Within the instrument a source emits an infrared light which is sensed by a detector. The infrared light from the source to the detector is established in the absence of alcohol as the baseline condition. When a breath containing alcohol is introduced into the chamber some of the infrared light is absorbed by the alcohol molecules and therefore does not reach the detector. The comparison between the presample IR and the sample IR transmission results in a lesser amount of infrared light with the sample present. The quantitative difference in the amount of infrared light reaching the detector is converted by the circuitry into a printed result which equates to the alcohol concentration of the person's breath.
>
> EC Analysis
>
> The instrument also contains a fuel cell which produces an electrical current. In the absence of alcohol the current is flat. When alcohol is introduced the electrons which flow between the anode and cathode on the fuel cell increase. This increase in the flow of electricity is interpreted by the [Alcotest] 7110 as the effect of alcohol in the breath.
>
> [Foley, 370 N.J. Super. at 346.]

While we adopt as fact the descriptions of these two methods as set forth in Foley, we find these additional facts about the Alcotest 7110 in connection with our decision.

IR technology has been available since 1974. In the Alcotest 7110, IR analysis observes a subject's breath from the beginning to the end of its presentation. The solid brass cuvette chamber holds approximately seventy milliliters which is small enough to avoid mixing old and new breath but large enough to absorb energy when alcohol is present. The chamber is heated to prevent condensation on its walls and internal parabolic mirrors. The mirrors are gold-plated to optimize energy reflection and placed at either end of the cuvette, where they deflect the emitted IR light a specific number of times until a detector receives it. Unlike the majority of breath-testing instruments which operate at the 3.4 or 3.5 micron range, the Alcotest 7110 detects alcohol in the 9.5 micron range of the IR spectrum. By only allowing energy at the higher wavelength to pass through the IR filter, the instrument is less susceptible to endogenous interfering substances such as acetone, acetaldehyde and ketones.

EC technology also has been available for many years, at least since the mid-1960s, but has not been used for evidential purposes until the mid-to-late 1980s when the introduction of microprocessors provided the necessary speed. Unlike IR absorption, however, EC analysis waits until the end of a subject's exhalation to take a breath sample out of the IR chamber for analysis.

The fuel cell consists of plastic housing with a vapor inlet port and an exhaust port, and its interior consists of a porous matrix of plastic materials filled with sulfuric acid. Platinum plates on both sides attach to two electrodes or wires which lead to the outside of the fuel cell housing. A small piston assembly draws in a sample approximately one cubic centimeter in volume from the same breath sample in the cuvette.

For a single breath sample to be acceptable, Draeger programmed the Alcotest 7110 with a preset tolerance which requires the IR and EC results to agree within .008 blood alcohol concentration (BAC) or 10% of the IR reading, whichever is greater. Draeger set that particular tolerance so the instrument would be compatible with OIML specifications.

To detect interfering substances, the Alcotest compares the IR and EC readings. Where only alcohol is present on the breath, the readings will be similar but where interferents —— endogenous and exogenous —— are present, the readings will diverge.

Another standard feature includes RFI shielding, which protects the instrument from outside interference which can affect its components. The RFI shielding consists of metal coating underneath the top lid and a metal bottom, both of which prevent electromagnetic waves from entering the instrument. The instrument's five-layer printed circuit board (or motherboard) also suppresses RFI influence. Because of the shielding and special design, Ryser did not recommend that New Jersey purchase the optional RFI detector offered by Draeger. He expressed concern that the RFI detector permitted undesirable penetration of the shield through a small hole. The Alcotest 7110 also successfully underwent informal RFI testing by NHTSA, by laboratories using OIML standards, and Brettell's staff at the State's forensic laboratory. Nonetheless, the ADTU instructs operators to keep portable radios and cell phones out of the room during breath testing.

The State also did not purchase the breath temperature sensor option. The sensor consists of a thermistor placed into the breath hose to measure a subject's breath temperature. For calibration, the temperature sensor requires substantial equipment including two large heated tanks which cost about $15,000 each and two automatic calibration devices which cost about $36,000 each. Draeger is the only manufacturer which offers the sensor. Alabama uses the optional sensor to make downward corrections in the software of 6.58% for each degree that the breath temperature exceeds the standard 34 degrees C; Germany uses it to make both upward and downward corrections.

Draeger designed the Alcotest 7110 to measure samples of alveolar or deep lung air. To provide a valid breath sample in New Jersey, a subject must meet five criteria: (1) minimum breath volume of 1.5 liters; (2) minimum blow duration of 4.5 seconds; (3) minimum flow rate of 2.5 liters per minute; (4) the breath sample must reach a plateau (equilibrium), meaning that the IR reading must not change by more than 1% per 0.25 second; and (5) no detection of mouth alcohol or interfering substances. When a subject fails to meet any of the criteria, the display screen will report an "error" message.

With regard to mouth alcohol, operators in New Jersey must continuously observe a subject for a full twenty minutes, without interruption, before they can begin the breath test. During that time, the subjects cannot have any substances in their mouths nor can they regurgitate or burp. If there are any interruptions, the twenty minutes must start over again. New Jersey also intended for the Alcotest 7110 to institute a two-minute lockout between breath samples to prevent mouth alcohol inside the cuvette from contaminating the second sample. However, Flanagan and Brettell recently became aware that the instrument was not uniformly adhering to the two-minute lockout by about a second or two, and have contacted Draeger about the problem. The instrument's slope detector also provides an additional safeguard against mouth alcohol.

After receiving two valid breath samples, the Alcotest 7110 compares the results of the four readings: two taken by the IR and two by the EC technologies. The two breath samples must be within a specific tolerance of each other for the tests to be considered reliable. If the two samples are not within the tolerance range, a third test is forced.

This court recognizes Brettell's testimony that firmware version NJ 3.11 requires the test results to be within plus or minus .01 or plus or minus 10% of the mean of the four readings (two EC and two IR), whichever is greater. The NJ 3.11 version allows the operator a maximum of eleven attempts to collect two valid breath samples. After the eleventh try, the operator may terminate the test and restart the sequence, terminate the test and report it as a refusal, or terminate the test and give an opinion that the subject was not capable of providing a proper sample. For example, both Flanagan and Brettell stated that women over age seventy would have trouble providing 1.5 liters of breath and should not be charged with refusal. In those cases, the officers may chose to take the women to a hospital for blood tests or issue a summons based solely on observations.

Draeger ships the instruments directly to the police departments which purchased them. Prior to shipping, Draeger calibrates the instruments, simulators, and temperature probes, and certifies their accuracy. Upon their arrival and before the instruments are placed into service, an ADTU coordinator from the State Police verifies the firmware version, calibrates them, sets the tolerances, conducts control and linearity tests, and performs a solution change.

Calibration of the Alcotest 7110 involves a wet bath simulator, the Draeger CU34, and one bottle of 0.10 ethanol alcohol solution. The ethanol alcohol solution is poured into the simulator jar where it is heated to 34 plus or minus 0.2 degrees C. A NIST-traceable temperature probe monitors the temperature of the simulator solution. NIST refers to the National Institute of Standards and Technology, which is responsible for establishing, maintaining and publishing basic standards of measurement consistent with their international counterparts. Each temperature probe has a probe value, which can be changed only by a coordinator using the "black-key" function. When the instrument determines that the simulator has reached the correct temperature, the coordinator hooks up the simulator to the back of the instrument through the rear port of the cuvette. The coordinator then hits the escape key, the function appears on the display screen, the coordinator types in calibrate, and follows the instrument's prompts.

The coordinator then performs a control test to verify that the instrument is properly calibrated to the .10 simulator solution. The linearity test then uses three different simulator solutions of .04, .08 and .16. The instrument performs two tests on each solution. Afterwards, the coordinator uses a bottle of solution from the local police department and generates a solution change report. At that point, the calibration test sequence is complete and the instrument prints a calibration record.

Draeger ships the simulator solutions in lots of 1000, but only after Brettell's laboratory has tested six bottles from each lot to make sure they are within tolerance. For the .10 solution change, Brettell set the tolerance at .005 or 5%. Draeger's default tolerance at .010 or 10%. Brettell's laboratory issues certificates of analysis stating that each simulator solution was within specifications of the target value for the particular concentration. New Jersey protocol requires bottles to be changed after thirty days or twenty-five subject tests, or sooner if the instrument gives an error message that the solution is depleted.

After the initial calibration, an ADTU coordinator will recalibrate the instrument every twelve months, after an instrument is returned for service after repairs, or whenever a coordinator considers it necessary. <u>See</u> <u>N.J.A.C.</u> 13:51-4.3(b). Draeger also annually recalibrates the simulators and temperature probes.

The Alcotest 7110 employs multiple steps in testing an individual's breath alcohol concentration. While the court accurately described the sequence in Foley, 370 N.J. Super. at 347-48, a brief review of the salient facts is presented here.

After the operator explains the process to the individual, the operator removes a new mouthpiece from a sealed plastic bag and inserts it onto the breath hose. The operator then starts the instrument and inputs basic identifying information such as the test subject's name, weight, age, and identifying documentation and license number. The instrument automatically inputs the time and date.

The breath test sequence adopted for New Jersey consists of the following steps: ambient air blank check; control test; ambient air check; breath test one; ambient air check; breath test two; ambient air check; control test; and ambient air check. The purpose of the ambient air checks is to ensure that the air in the instrument's chamber (or cuvette) is free of any interfering substances and registers an alcohol level of 0.00%.

For the breath test, the operator instructs the individual to take a deep breath and blow into the instrument. When ten asterisks appear on the LED screen, the subject has reached the minimum volume requirement of 1.5 liters. However, the ADTU trains operators to encourage subjects to blow up to 3.0 liters (or until twenty asterisks appear on the screen) in order to ensure that the subject has reached deep lung air. After registering at least the minimum volume of air required for testing, the operator instructs the individual to stop blowing.

Upon completion of the test sequence, the Alcotest 7110 prints an AIR on an 8.5 X 11 sheet of paper which contains the individual's identification, date, time, and test results for each stage of the procedure. If the results are within the acceptable tolerance, the AIR shows the successful BAC values to three decimal places. The AIR then shows the final BAC test results as the lowest of the four readings which the instrument truncates to two decimal places. The AIRs are sequentially numbered. The ADTU instructs operators to give one copy to the local police department, retain one copy, and give a copy to the subject.

The Alcotest 7110 has a modem capable of communicating with a central server. Such communication would allow for data to be uploaded daily or weekly from each instrument in the field to a central location for the purpose of data collection. The digital data would be maintained there for a period of time which this court believes should not be less than ten years. Draeger is willing to provide the State with a Microsoft Access database program at no cost.

New Jersey, however, does not use the standard modem. Brettell discussed the issue of centralized data management with the Porter Lee Corporation, the software company which created

New Jersey's laboratory information management (LIM) system. In September 2005 Porter Lee gave Brettell an estimate of $9760 for the transfer of the Alcotest data to the LIM database. The State, however, never proceeded with the project.

As of the time of this hearing, ADTU coordinators download the electronic data in the field onto their laptops. Although the Alcotest 7110 has the option to store 1000 test results, New Jersey protocol requires coordinators to download data at or before 500 tests.

Finally, the Alcotest 7110 relies upon source codes which consist of its own language with syntax, specially named routines, and formatting conventions. An examination of the source codes presumably would reveal if the firmware was properly implementing the intended algorithms and computations, and if the data communication, retrieval and input software was subject to malicious manipulation.

We already have discussed Draeger's grudging attitude and non-cooperation about revealing the source codes during discovery. From the onset of this matter, the parties could not agree about terms for inspection of the source codes. We cannot fault the refusal of defense counsel to permit the Draeger interests to propagandize the court in an _ex parte_ proceeding. _See R._ 1:2-2. Nor can we fault the defense's rejection of

Draeger's proffer of an inspection in Durango, Colorado under very restrictive and sanitized conditions.

But we draw no negative inference against Draeger for its recalcitrant and less than forthright cooperation in discovery in this litigation, which centered upon the integrity of its Alcotest 7110 product. Indeed, Ryser's response to the subpoena served upon him and the Draeger interests during his cross-examination in this case on October 12, 2006, and at this court's suggestion, was substantial and very helpful to this court and the parties. We do not think that this dispute about the source codes has any substantial relevance to our ultimate conclusion, that the Alcotest 7110 instrument is very good at measuring breath alcohol. Further, we conclude that the under-resourced defendants and amici had no way of examining or testing the elaborate source codes at this late point in the litigation. Source code issues arise when the instrument fails to perform properly or its various components fail to interface with each other. We have seen no hint of source code problems or failure throughout this litigation.

IV. EXPERT TESTIMONY

1. Summary of Testimony of State's Expert and Draeger's Principal, Hansueli Ryser

Hansueli Ryser was born and raised in Zurich, Switzerland where he received an electrical engineering degree in 1973 from the Federal College of Technology (19T13).[1] After working several years as an engineer for Seeholzer AG in Zurich, Ryser joined CMI, Incorporated, the manufacturer of the Intoxilyzer (19T16-19T17;19T51). At CMI, he designed electronic circuitries for the Intoxilyzer series (1978-1979), established a quality assurance department (1979-1980), served as director of manufacturing (1980-1982), and ultimately became president when it came under new ownership (1982-1986) (19T16-19T18;19T25-19T26). He then accepted the position of Director and CEO at EyeMetrics Corporation in Switzerland, a firm which specialized in optics and electronic imaging analysis (19T16;19T18;19T27).

In early 1991, Ryser became President of Draeger Switzerland AG, a subsidiary of Draeger Safety AG (19T14-19T16;49T58). In mid-1994, Ryser established the Breathalyzer Division of National Draeger, Inc. in the United States (19T15;49T30-49T31). In 2002, the Breathalyzer Division merged with Draeger Interlock, Inc. (a separate company which sold breath analyzers for installation in cars) and the name changed from National Draeger to Draeger Safety Diagnostics, Inc. (Draeger) (19T14;49T30-49T31;49T104). Draeger has offices in

[1] For designation of transcripts, see Appendix A.

Durango, Colorado (production, servicing and engineering) and in Dallas, Texas (sales and marketing, and the interlock business) (49T104). Ryser is vice president in charge of the Durango operations, where he supervises a staff of thirteen (19T15;49T143;50T9). He holds dual citizenship: Swiss and American (19T60).

Ryser ranked these Draeger entities in their hierarchy: (1) Draeger; (2) Draeger Safety, Inc. (DSI); (3) Draeger Safety AG (Draeger AG) in Luebeck; and (4) the holding company, Draegerwerk Aktiengesellschaft (Draegerwerk AG) in Luebeck (23T4;49T59;49T140;49T142;50T14). According to Ryser, Draeger remained under the "very tight control" of Draeger AG (19T59).

Ryser is a member of several professional organizations including the International Association of Chemical Testers (IACT), the National Safety Council's Committee on Alcohol and Other Drugs, and the National Commission for Alcohol and other Drugs (19T19). He previously testified in Florida on the scientific reliability of the Intoxilyzer 5000, in Colorado on the source code issue relating to the Alcotest 7410 handheld instrument, and in Foley (19T19-19T20;19T24-19T25). The State moved to qualify Ryser as an expert in electrical engineering and breath-testing devices (19T20). He testified over the course of seven days.[2]

In 1984 the Draeger organization acquired Smith and Wesson, the manufacturer of the breathalyzer, partially to gain access to the United State's market (20T49-20T50;20T54). Ryser believed that the breathalyzer's once state-of-the-art technology still was "very proper and correct" (20T51;20T56-20T57). He explained, however, that the breathalyzer differed from the Alcotest 7110 in several major respects: (1) the breathalyzer was more susceptible to an operator's influence; (2) every thirty days, a trooper had to check the breathalyzer in the field; and (3) the breathalyzer recorded data by the operator's hand on a "little paper" (20T51-20T56;51T88).

In 1995 Draeger introduced to the United State's market the first Alcotest 7110 MKIII which was "built" in Durango (49T116). The instrument was tested successfully by NHTSA and by independent laboratories against OIML standards including the MNI Laboratory in the Netherlands (OIML draft three) (1994) and NLA (or NLE) the national laboratory in Paris (OIML draft four) (20T41-20T42). In 1998 the German government also tested the instrument against the OIML specifications, which provided the

---

[2] Ryser testified at the hearings on October 5, 10, 11, and 12, on November 14 and 15, and by telephone on December 12, 2006.

basis for Germany's switch from blood analysis to breath (20T43).

The Alcotest 7110, however, is not included on the OIML certification list (51T101). In fact, the list contained only one breath-testing device which was the Seres instrument made in France by a company that subsequently went bankrupt (51T102). Because of the cost of OIML testing, in excess of $45,000, and the fact that its requirements have been continuously diluted over time, Draeger has not submitted the Alcotest 7110, NJ 3.11 for OIML testing (51T102).

The Alcotest 7110 instrument costs approximately $7300 for the basic instrument or $10,000 for the entire system, excluding extended warranties or other services (19T62-19T63). At the time of the hearing, the Alcotest 7110 was used exclusively by the State Police in New York, New Jersey (except for four counties which are awaiting the changeover), Alabama, Massachusetts, and the Ramah Navaho Indian Reservation in New Mexico, and nonexclusively in California, Rhode Island, New Mexico, Oregon and Illinois (20T43-20T45;20T47;21T11;50T45-50T51).[3] It also is used exclusively in Guam, the Northern

[3] Draeger sold about 240 instruments to Alabama (a "blood" state) and 430 instruments to Massachusetts (a "breath" state) (20T29;25T33-25T34). Draeger also sold the Alcotest 7110 to individual police departments in California along with its hand-held device, which it sold statewide (25T34).

Footnote continued

Marianas, Finland, Germany, Austria, Italy, Spain, South Africa, Taiwan, Hong Kong, and Bulgaria, and non-exclusively in various former Russian or Soviet countries, the Middle East, Australia, and Denmark (20T45-20T47;20T60). New Zealand also used an infrared table-top type instrument, although it was unclear from the testimony if Ryser was referring to the Alcotest 7110 (20T48).

In 1998 Draeger delivered the first instruments to the New Jersey State Police (22T72). In September 2002 Draeger and the State entered into a software licensing agreement (22T74). To date, New Jersey has bought 480 of the instruments with extended four-year warranties for approximately $11,800 each (19T63;21T12;26T34).

Ryser fully described the Alcotest 7110, NJ 3.11, including its various components (19T79-19T148). For a detailed discussion and visual demonstration, we refer the reader to the videotape produced during the hearing (S-26).[4] A brief overview follows.

The Alcotest 7110 analyzes alcohol vapor in the human breath according to an evidential protocol (19T80). The entire system includes a special organizer stand with a drawer, a

---

[4] At the State's request, the videographer also made copies onto DVDs which were distributed to this court, defense counsel, and amici (19T149;S-26A).

breath analyzer, a standard keyboard, an external laser printer, a wet bath simulator used to introduce a known alcohol concentration for accuracy verification purposes, and a temperature probe (19T62-19T63;19T79-19T82).

The instrument's external features include: various interfaces on the back side including an exhaust port, an outlet port delivering air to the simulator, and an inlet port to the cuvette; a power button; a start button which engages a test or wakes up the instrument from standby mode; a forty-character backlit fluorescent display screen; a serial tag; a flexible breath hose which is forty-six inches long (so the subject does not have to bend forward to take the test) and heated with two temperature sensors to 43 degrees C plus or minus 3 degrees C to prevent condensation and overheating of the rubber hose; a mouthpiece for the breath hose which ensures a better seal, makes it easier to exhale, and aids hygiene; and an AC power cord (19T83-19T91;19T120;19T122;21T53-21T57).

The internal features include: an infrared (IR) absorption chamber or cuvette; an electrochemical sampling system (EC) which consists of a fuel cell, pump, and motor; a power supply for direct current (DC) low power voltage to the entire system; a DC pump which purges the air inside the cuvette after a test is completed and provides air to the simulator for control check purposes; a solenoid which sends air to either the cuvette or the simulator; a large printed circuit (PC) board or motherboard which contains all the electronic components including the microprocessor[5] and the electronically erasable programmable read only memory (EEPROM) which stores the firmware; an interface board which contains all the outside connections; an internal printer which prints data on register-type tape as opposed to the easier-to-read letter-size paper used by the external printer; electrical chokes; an AC compartment; a pressure sensor which provides information on breath volume; and a flow sensor which detects and measures the flow rate of a subject's breath (19T82-19T83;19T91-19T93;19T98-19T99;19T101;19T112-19T113). Ryser explained that the Bundesamt, the German governmental entity for legal metrology, required redundant sensors (19T99-19T100).[6]

The Alcotest 7110 is the only breath-testing instrument using dual technology to quantify alcohol concentration in the same breath sample (19T175-19T176;20T21). Draeger does not hold a patent for the dual technology, but holds several patents for certain processes within the system (19T38;20T21-20T22). Ryser

[5] "All incoming signals from the sensors are passed to the microprocessor via a multiplexer and 12 bit A/D converters for further analysis. The microprocessor continuously checks all supply voltages and important components to ensure proper operation. It also has an RS 232 interface to communicate with a computer allowing all stored data to be uploaded with optional communication software" (S-49 at 18).

[6] To open the Alcotest 7110, Ryser released the four safety screws using a security screwdriver made in England (19T122).

believed that Draeger did not aggressively pursue patents, desiring to avoid disclosure of company "trade secrets" (20T22;22T67). The name "Alcotest," however, is protected as a trademark (19T40).

IR technology has been available since 1974 (19T174). In the Alcotest 7110, IR technology acts as the "real time analyzer" because it observes breath from the beginning to the end of its presentation (19T174). The solid brass IR chamber is heated to prevent condensation on its walls and internal parabolic mirrors (19T94-19T95). The mirrors cover the front and back of the chamber, and are gold-coated to optimize IR energy reflection (19T95).[7] The mirrors deflect the IR energy within the chamber a specific number of times before the energy hits the IR detector (19T95).[8] The IR filter (which sits on top of the detector) allows only those parts of energy to pass through the filter that relate to 9.5 microns[9] on the IR spectrum (19T132;21T60). Unlike the majority of breath-testing instruments operating at the 3.4 or 3.5 micron range, the higher

[7] IR energy refers to "[t]he part of the invisible spectrum, contiguous to the red end of the visible spectrum of electromagnetic radiation, which travels through space in waves. Behavior of such waves is similar to that of visible light waves" (S-49 at 8).

[8] "The IR detector converts IR energy to electrical energy" (D-7 at 10).

[9] One micron equals one millionth of a meter (D-7 at 8).

wavelength is less susceptible to endogenous interfering substances such as acetone, acetaldehyde and ketones (19T155-19T158;21T60-21T61). The chamber's inner volume is small enough at 70 ml. to avoid mixing old with new breath but large enough to absorb energy when alcohol vapor is present (19T93;19T153).

EC technology or fuel cells have been used since the mid-1960s for alcohol measurement (19T162). In the mid-to-late 1980s, the introduction of microprocessors provided the speed necessary to allow fuel cells to perform calculations for evidential purposes (19T162-19T163). Unlike IR technology, the fuel cell in the Alcotest 7110 waits until the end of exhalation to take a breath sample out of the IR chamber for analysis (19T175). The fuel cell consists of plastic housing about an inch in diameter with a vapor inlet port and an exhaust port leading to the pump (19T97-19T98;S-28). Its interior contains a porous matrix of plastic material filled with sulfuric acid (19T97). There are platinum plates on both sides which are attached to two electrodes or wires leading to the outside of the fuel cell housing (19T97). A small piston pump assembly draws in a sample approximately one cubic centimeter in volume from the same breath sample, which is already in the cuvette (19T134;19T161).[10]

---

[10] According to Draeger's Instructor Training Manual, "[o]nce

Footnote continued

Another standard feature includes shielding for RFI, which can affect the instrument's components (19T104). RFI refers to interference which enters the instrument from the outside whereas electromagnetic interference (EMI) refers to interference which the instrument generates (23T39;61T19-61T20). Both RFI and EMI are subsets of electromagnetic compatibility (EMC) (23T39). The Alcotest 7110's shielding consists of metal coating underneath the top lid along with a metal bottom, which simulates a faraday chamber by preventing any electromagnetic waves from entering the instrument (19T106;19T129).[11] Ryser also explained that the instrument's five-layer PC board is designed specifically to suppress the influence of RFI (19T107-19T108;23T38-23T39).

Because of the shielding and special design, Ryser did not recommend that New Jersey purchase the optional RFI detector offered by Draeger (19T109;61T43-61T44). To the contrary, he expressed concern that the detector required a small hole in the

---

ethanol reaches the [EC] sensor, a chemical reaction is triggered. The resulting current is used to determine the amount of alcohol in the sample" (D-7 at 5).

[11] A faraday chamber or cage is "a grounded metallic screen completely surrounding a space to protect it from external electrostatic influence." Webster's Third New International Dictionary 823 (3d ed. 1971).

faraday chamber to bring the signal into the processor (19T109).[12]

Instead, Ryser recommended RFI testing in a special laboratory where the Alcotest 7110 would be exposed to different frequencies (19T109). For example, the National Laboratory for Metrology in Holland and the national laboratory in Paris performed RFI testing on the Alcotest 7110 in accordance with OIML standards (19T110;61T57-61T58). The tests were done in a special radiation chamber with an antenna source which allowed for the transmission of various frequencies and modulations (61T58). The tests exposed the instrument to radiation as strong as ten volts per meter and over a frequency span up to one gigahertz (61T58).

To detect interfering substances, the Alcotest 7110 compares the IR and EC readings (19T169). If only alcohol (ethanol) is present, the readings are similar (19T173). If another substance is present, however, the readings diverge (19T173). There is a preset tolerance that requires the results of both readings to be within .008% BAC or 10% of the IR reading, whichever is greater; if the two results exceed the tolerance, the instrument displays an interference message and

[12] Germany does not use the RFI detector, but New York does (61T56-61T57). Ryser could not recall if Massachusetts or Alabama used it (61T57).

aborts the test (19T168-19T169;19T173-19T174). Draeger set the tolerance to make the system compatible with OIML standards (19T169).

Ryser testified that the two samples or four tests (two IR and two EC) must agree within plus or minus .01 BAC of the average of the four measurements or plus or minus 10% of the average of the four measurements, whichever is greater (19T170). If the first two breath samples are not within acceptable tolerance agreement, the Alcotest 7110 requires collection of a third, valid breath sample (D-15 at 13). Recognizing that there had been confusion over the correct tolerance, Ryser explained there was no change between versions 3.8 and 3.11 —— the only two versions used in New Jersey —— but that the language in Draeger's operator's manual for version 3.8 was not correct (22T36-22T38;49T53). This language has been corrected for current use.

Draeger calibrated its evidential breath analyzers based upon the customer's request (19T73). Draeger calibrated the Alcotest 7110 in New Jersey to interpret a certain concentration of alcohol with reference to a blood/breath ratio of 2100:1 (21T70). Ryser understood the ratio in the population was higher and believed that the 2100 figure favored an average defendant (21T70;22T20-22T21). While he could not recall the exact percentage, he seemed to agree that the ratio favored at least 84% of the population (21T71-21T72). He also understood that the ratio differed between individuals and for the same individual from time-to-time based upon changing physiological conditions (21T70-21T71). Draeger recommended that the instrument be recalibrated every twelve months (50T21-50T23).

Ryser also reviewed New Jersey's testing protocol. New Jersey's control test verifies accuracy every time a breath test is done (50T26;50T30). Ryser considered this the most rigorous possible quality control regime.

First, an ambient air blank verifies that the air inside the chamber is free of any absorbing alcohol vapor (19T178-19T179). Essentially, the air blanks force ambient or room air through the chamber to produce a result of .000% alcohol levels (19T178-19T179).

Next, a control test verifies the instrument's accuracy by using a simulator with a known standard of water-ethanol solution (19T179). With a probe to monitor the solution's temperature, the simulator is heated to 34 degrees C to produce a reading equivalent to the targeted value labeled on the bottle (19T181-19T182). The testing protocol requires a bottle of known standard solution of .10, which must be changed every thirty calendar days or twenty-five subject tests (50T85). Periodic calibration inspections use standard solutions of .04, .08, .10, and .16 (50T84). Draeger produces the simulator and temperature probe, both of which are returned to Draeger for recertification and calibration every twelve months (19T67;19T183;19T185;19T189).

Draeger purchases the simulator solution from an independent laboratory called Plus Four Engineering in Colorado and then, sells it to New Jersey in batches of 1000 bottles (19T190-19T191;50T99;50T100-50T101). However, it first ships six bottles —— the first two from the lot, the middle two, and the last two —— to the State Laboratory where Brettell or his associates perform quality control testing (50T102). Each bottle has a "shelf life" of two years (50T103).

Ryser also testified about the margin of error determined by using freshly certified standard solution and a NHTSA-approved simulator (61T65). He explained that the margin of error was the same as the one employed by New Jersey for control testing, and recommended by the NHTSA and OIML specifications (61T65). For the Alcotest 7110, it was plus or minus .005 BAC (absolute tolerance) or plus or minus 5% (relative tolerance), whichever was greater (50T17-50T18;51T64;61T71-61T72).[13] The absolute tolerance applied to concentrations below .10 whereas the relative tolerance applied at or above .10 (50T18-50T19). Therefore, a subject who presented a reading of .08 would have a

[13] We assume that Ryser was referring to the breath result as BAC.

relative tolerance window from .076 to .084 (61T72).[14] However, that same subject would have an absolute tolerance window from .075 to .085 (61T72). Because the absolute tolerance window was greater, all readings would have to be within .075 and .085 (61T73). Ryser was unaware of any state program that automatically reduced an alcohol reading by the instrument's margin of error, although he noted that Alabama apparently recognized it by refusing to prosecute anyone unless they had result of at least .084 (50T19).

Regarding the actual tests, Draeger designed the Alcotest 7110 to measure samples of alveolar or deep lung air (19T191). To accomplish that task, Draeger proposed, and New Jersey accepted, four sampling criteria: (1) a minimum flow rate of 2.5 liters of breath per minute; (2) a minimum blow duration of at least 4.5 seconds; (3) a minimum breath volume of 1.5 liters; and (4) the use of a slope detector to ensure that the instrument waited until the IR absorption plateau is reached (19T191-19T192;20T77-20T79;D-7 at 21). If the sample did not meet all of the minimum criteria, the screen displayed an error message (20T5).

Draeger also designed the Alcotest 7110 to detect potential residual alcohol in the mouth cavity produced by regurgitation,

---

[14] 5% of .08 = .004.

burping, belching, or hiccups (20T5;21T99). Alcohol also can be retained in the mouth in cavities, under dentures or in certain absorbent materials such as chewing tobacco or food (21T99). Absent any direction from NHTSA or the states regarding the conditions under which mouth alcohol detection must occur, Draeger relied upon the OIML specifications to develop its safeguard routine (20T6).[15]

The Alcotest 7110 is manufactured by the parent company in Luebeck (20T9). Draeger in Colorado customizes the instrument to the specific applications requested by each state (20T9). For example, the instrument by default is manufactured to accept a wet bath simulator that can attach to the back but can be modified if a state prefers to use a dry gas standard (20T9). Draeger follows a lengthy checklist to verify that the instrument is calibrated within the specified tolerance and that it is built with the correct firmware according to the

---

[15] The New Jersey User Manual-Technical described mouth alcohol detection as follows:

> Mouth alcohol is characterized by a sharp increase of the alcohol concentration at the beginning of the subject's sample followed by a decrease until the end of the sample. While a breath sample is delivered, the breath's alcohol concentration is continuously monitored. If mouth alcohol is detected, a reference message is displayed and the test is aborted.
>
> [S-49 at 18.]

customer's specifications (20T10). Draeger also verifies the serial number, performs temperature verifications for the breath hose and cuvette, checks the printer, and cleans the instruments (20T14-20T15). After it completes all the quality control and quality assurance steps, Draeger issues a twelve-month certificate of accuracy before it ships each instrument to the customer (20T10).

Draeger offers a standard twelve-month warranty (20T11). It also offers an extended four-year warranty which New Jersey chose to purchase (20T11). Draeger performs all warranty work at no charge for parts and labor (20T12). In 2005 New Jersey returned for repairs three instruments to Draeger from Middlesex County (20T12). The East Brunswick Police Department returned one instrument for replacement of the motherboard, which is manufactured by another company in Germany and delivered complete to Draeger (20T13-20T14;21T29-21T30;S-33). Because the motherboard basically held the "entire electronics real estate," Ryser acknowledged that anything stored on the random access memory (RAM) chip, mounted on the motherboard's surface, could be lost (20T15;50T42;50T59-50T61). He noted that the motherboard had been sent to Luebeck where it probably was undergoing repairs in the service department (50T63;50T80).

The East Brunswick police also returned an instrument for replacement of the printer cable, which essentially required a new connecting wire between the motherboard and the receptacle for the external printer (20T16;S-34). New Brunswick also returned an instrument which showed an error —— its memory was exceeding capacity (20T17-20T18;S-35). In the last case, Draeger cleared the memory and performed the requisite tests to confirm that the instrument was functioning properly (20T18).

The Alcotest 7110 consists of "core" software that has never been changed since the first units were built in Durango in 1995 (49T116;61T66). The core software contains the essential routines relating to how the instrument measures and analyzes alcohol vapor (23T58;24T55;24T58). These routines or critical functions include the IR and EC systems, the temperature sensors on the breath hose and cuvette, pressure sensor, flow sensor, AC/DC analysis, and general processor controls (24T58;24T60-24T65;D-99). Despite vague earlier testimony, Ryser insisted that the Alcotest 7110's core software was the same everywhere (49T119-49T120). Among other things, Ryser modified his earlier statements that the core software in Alabama's instrument had been changed for breath temperature sensing and fuel cell fatigue, claiming they were customized features which did not affect the way the unit read alcohol (25T17-25T18;49T119;61T66-61T68). We think this was no more than a dispute bout nomenclature.

The Alcotest 7110 also consists of customized software or firmware (20T18-20T19;24T55). Firmware consists of the binary code of the "compiled source code," and contains all the instructions or routines necessary for the instrument to operate according to precise guidelines and specifications (20T19). Ryser noted that firmware constantly changes (20T33). Such revisions can by initiated by the customer or the manufacturer (if laws or regulations change, or tolerances change) (20T33;49T81-49T82). For example, since 1998 Draeger has made approximately twenty-seven revisions to the Alcotest 7110's firmware in Alabama's program which Ryser described as very complex (25T12;25T15;25T29-25T30;D-100). As an aside, Ryser indicated that Draeger will have to update the firmware in 2007 to make its instruments compliant with the new daylight savings time structure (20T33;25T41-25T42). Draeger, however, will not make firmware changes that affect the measurement of alcohol (20T31-20T32). Draeger also will not make changes which may affect an instrument's compliance with the NHTSA specifications without first advising the customer (20T32).

Each time the firmware changes, Draeger assigns a new firmware number which initially is accompanied by a letter designation (20T33). After the engineering department performs a quality assurance test, the instrument is given to the technical writing department which runs control tests and writes a new manual (20T34). The instrument then goes to the service department where the instrument is checked again for quality control and assurance (20T34). Draeger then instructs its customers to perform all the necessary tests to assure that it has successfully embedded the requested changes (20T35). Only after the completion of successful testing by the customer will Draeger remove the letter designation (20T35). The new firmware version then is installed and recorded in the instrument's EEPROM (20T35).

Unlike Alabama and Germany, New Jersey did not purchase the optional breath temperature sensor (20T72;22T20). While Germany uses the sensor to make both upward and downward corrections, Alabama uses it to make downward corrections in the software of 6.58% for each degree that the subject's breath temperature exceeds the standard 34 degrees C programmed into the instrument (20T72;61T58). This rise in breath temperature causes the BAC reading to increase to this extent.

The sensor costs about $1300 if ordered at the time of manufacture or $1600 if retrofitted to the top of an instrument (19T64). For calibration, the temperature sensor requires substantial equipment including two large heated tanks which cost about $15,000 each and two automatic calibration devices which cost about $36,000 each (61T62).

While Draeger offered the sensor in its literature and Ryser admitted that it makes the Alcotest 7110 a better instrument, he does not "loudly" market it for several reasons: (1) Draeger is the only manufacturer that offers the feature and if he pushed it too strongly, it might reflect on the reliability of other breath-testing instruments; and (2) the 2100:1 ratio already "took into account" this variability in breath temperature (22T23-22T28;61T40;61T58).

The Alcotest 7110 stores approximately 1000 tests (20T37). After the memory is full, the data can be removed by an upload procedure to a computer (20T37-20T38). If the tests are not removed, they will be erased on a first-in, first-out basis (20T38). New Jersey's instrument also has hardware capable of communicating with a remote computer —— similar to the Alcotest 7110 system used in Alabama —— but Ryser said the State claimed it did not have the financial resources to install dedicated telephone lines to allow frequent data uploads (20T38-20T39;49T87). If New Jersey did download data via computer or modem to a central computer, Draeger could provide a program that used Microsoft Access to "grab" the information relevant to New Jersey's breath-testing program in a readable format (20T40-20T41). The program would be limited to 255 fields, instead of the current 310 fields in New Jersey's current software (61T55-61T56).

The source codes for the Alcotest 7110 consist of 53,744 lines or approximately 896 pages (20T106;22T22;D42). Software engineers in Luebeck wrote the code in C+ or C++ computer language which is humanly viewable but only meaningful to a programmer (20T106-20T107;22T117;23T68). The codes, however, cannot be understood without access to the Alcotest 7110's algorithms and hardware (20T109). Because Draeger puts a "tremendous amount of effort" into the development of its breath-testing instruments, it views source codes as highly proprietary (20T20;22T113). Specifically, Draeger believes that release of its source codes would give its competitors a chance to duplicate its "state-of-the-art" technology (20T24). Ryser explained that Draeger was the technology leader in the breath-testing field as, for example, it was the first company to operate a breath-testing instrument at 9.5 microns in the IR spectrum and the only company to use a dual IR and EC system to quantify breath samples (20T20-20T21). Draeger keeps the source codes for New Jersey's Alcotest 7110 in its engineer's locked computer in Durango (49T135-49T136).

In April 2006 Ryser attended an IACT conference in Anaheim, California where he presented Draeger's new instrument, the Alcotest 9510 (20T113).[16] At the conference, he approached

[16] The Alcotest 9510 measures alcohol the same as the Alcotest

Footnote continued

representatives of several competitors about their source code policies including CMI (which would not discuss the issue due to ongoing litigation), Intoximeter (which refused to release it), and National Patent (which invited attorneys to its factory in Ohio to examine the code) (20T27;20T112).

At Ryser's suggestion, Draeger changed its policy to adopt the approach taken by National Patent (20T28). Since then, it received one inquiry from attorneys in Massachusetts (20T28-20T29). To date, Draeger has not released source codes to any of its customers (20T30). Nor has Draeger apparently released the actual algorithms although it has provided customers with explanations of how the Alcotest 7110 determines mouth alcohol (20T20).

During the hearing, Draeger and defense counsel by negotiation reached a tentative agreement in principle relating to the source code issue and techniques to insure the Alcotest 7110's scientific reliability (61T5-61T6). Defense counsel agreed to forego further cross-examination of Ryser and to limit its direct case to concerns about hardware issues (61T7). In return, Draeger agreed to: (1) submit the source codes and algorithms for the Alcotest 7110, NJ 3.11 to a jointly

---

7110, but communicates through an intranet computer network (23T33). Ryser described the Alcotest 9510 as a "computer" with endless memory, easy accessibility to communication tools, USB connections, and nicer housing (23T34).

acceptable independent software house for examination; (2) program the software to include a self-reporting tamper feature to prevent any modifications except for intentional ones which Draeger would report; (3) allow a laboratory in the United States to verify that the next revised firmware version of the Alcotest 7110 (possibly NJ 3.12) satisfied OIML specifications; and (4) sell the instrument to defense attorneys and experts on the same terms that they sell them to the State of New Jersey (61T8-61T11;61T14;D-232). Ryser understood that these terms would be included in the Special Master's recommendations and findings of fact (61T7;61T17). Of course, he recognized that Draeger's license agreement with the State required the latter's approval before the instrument could be used by someone other than a state representative (61T18).

Ryser also testified at length about the documents produced in response to a subpoena issued to him in court on October 12, 2006 addressed to Draeger and Draegerwerk AG (49T23;49T139-49T140;D-175;D-220). Draeger produced 578 pages of documents which referred to New Jersey's software (49T132). Draeger AG, the German "parent" company, did not respond to the subpoena, claiming that it did not have any offices or employees in New Jersey, and did not do any business or sell any products in the State (50T15). Ryser's testimony about these documents is incorporated where appropriate throughout this summary.

Finally, Ryser briefly addressed the "sucking" issue, i.e., where a subject sucks air back into the instrument (61T36;61T63). He was unaware of similar complaints from other users and was unable to duplicate the problem when Durango tested three instruments (61T38;61T64). Because the subjects in New Jersey apparently sucked the air into the instrument through the port by the breath hose, Ryser thought the problem could be a hardware issue (61T64). In the event, the "sucking" issue could not result in a wrongful conviction because the BAC reading is .000.

Based upon his training and experience, Ryser was 100% convinced that the Alcotest 7110 accurately read alcohol in human breath within the specified tolerances and was scientifically reliable (20T49).

This court finds that Ryser was a candid, forthright, and most cooperative witness. He seemed understandably uncomfortable at his company's secrecy and reluctance to disclose information. He was a very credible and thoughtful witness and the court could detect no evasive or deceptive quality in his testimony.

2. <u>Summary of Testimony of State's Expert, Thomas A. Brettell</u>

Thomas A. Brettell holds a Ph.D. in analytical chemistry from Villanova University (33T7). He is certified as a forensic laboratory director and a public manager by the State of New Jersey, and as a laboratory inspector by the American Society of Crime Laboratory Directors (33T8-33T9). He also is a certified Diplomate for the American Board of Criminalistics, which encompasses the collection, preservation and analysis of trace evidence (33T17). Brettell has certificates for breathalyzer and Alcotest 7110 training (33T9).

In March 1976 Brettell began working for the Office of Forensic Sciences, Division of the New Jersey State Police, as a forensic chemist and, in August 2001, became forensic laboratory director (33T9-33T10;33T13). At the time of the Alcotest hearing, Brettell supervised 250 personnel and had administrative and technical responsibilities for the State laboratory system, including: three regional laboratories for drug, toxicology and fire debris analysis; the criminalistics laboratory for drug and toxicology analysis; the full service laboratory for nuclear and mitochondrial DNA; and the equine testing laboratory (33T9-33T10;33T13). He planned to retire on December 31, 2006 (33T19;34T30).

Brettell is a member of the American Chemical Society, the International Association of Chemical Testing, and various forensic science associations, and has published numerous articles on basic chemistry, toxicology and drug analysis (33T15). He has testified as an expert more than seventy-five times in administrative, municipal and Superior courts in New Jersey on such subjects as drug analysis, forensic toxicology, and forensic chemistry, and testified on the scientific reliability of an evidential breath tester (EBT) in Foley (33T16-33T17). The State offered him as an expert in forensic chemistry and breath testing; the defense agreed that he was eminently qualified (33T17;33T35).

Over the years, Brettell worked closely with the Alcohol Drug Testing Unit (ADTU), which administers and manages the State's breath-testing program (33T13-33T14;33T36;34T109;41T43). While Brettell performed the scientific studies and validation of the instruments, the ADTU staff supervised the testing protocols, trained the operators, set up the instruments in the field, performed periodic testing including calibration and linearity checks, and gave testimony in court when needed (33T36;34T109). The ADTU, however, did not perform any actual maintenance on the Alcotest 7110 instruments, which were returned to Draeger for repairs (36T77;48T44).

From November 1995 through February 1996, Brettell assisted Dr. Charles Tindall (then chief forensic scientist) and members of the ADTU in the selection of an EBT to replace the breathalyzer in New Jersey (33T31;33T35-33T36;D-185). Brettell believed that the breathalyzer produced "very good, reliable, precise, accurate" results when operated and maintained properly, but explained that it was no longer produced and parts were increasingly difficult to find (34T23). The breathalyzer also depended upon operators to follow a checklist, perceive the movement of the pointer on the galvanometer, take a visual reading from the scale, and record the reading by pressing down the marker on carbon paper to make an imprint (34T23-34T24;39T20-39T21). We gather that this imprint was rarely used and produced in court. The visual reading usually was simply recorded by the operator.

The group selected four instruments which were considered "state-of-the-art" at the time, and had been successfully tested by NHTSA and placed on the conforming products list (CPL) (33T37). The instruments were the Alcotest 7110 MKIII, BAC Datamaster, Intoxilyzer 5000, and Intoximeter (33T36-33T37;D-185). They tested the instruments to determine which would fit best into New Jersey's program (33T38).

For each instrument, Brettell and Tindall performed validation studies including side-by-side testing for accuracy (how close the measurements were to the true value), precision (how close the measurements were to each other), linearity (how close the plotting of test results from solutions of increasing concentrations were to a straight line), and specificity (how the measurement of ethanol compared to other organic compounds) (33T38;33T41-33T42;33T49;34T35-34T37). The group also qualitatively evaluated the instruments for ease of operation, operator dependence, transportability, ticket printout information, computer compatibility, and integrity (D-185).

For accuracy, Brettell and Tindall took six known standards of simulator solutions ranging from .016 to .320 ethanol and ran twenty tests on the instruments (33T41;33T50). Using the same solutions, they also tested for precision by determining the standard deviations of the measurements, and for linearity by measuring the instruments' responses (33T41-33T42).

For specificity, they checked for interferents including acetone (a metabolite which appears on the breath of diabetics), isopropanol (rubbing alcohol), methanol (wood alcohol), and methyl tertiary butyl ether (MTBE) (an antioxidant found in oxygenated fuels and gasoline) (33T42-33T43;39T54-39T55). They checked for interferents by relying upon the instrument's use of dual technologies, EC or IR, to measure the same breath sample (33T45;42T14-42T15). If the two technologies deviated by more than .008 or the EC reading deviated 10% or more from the IR reading, the instrument signaled an interferent error (33T45;37T145).

For example, Brettell explained that the fuel cell did not respond to acetone, but that the IR spectrophotometer would detect acetone if the concentrations were high enough (33T46;39T52). By designing the Alcotest 7110 to detect IR absorption at the 9.5 micron range, Draeger eliminated the potential for acetone to interfere with the ethanol reading (39T52;39T57-39T58). Brettell said that his laboratory detected acetone at a frequency of maybe 10%, very infrequently detected isopropanol, and never detected methanol or MTBE (33T43-33T44).

Brettell found the Alcotest 7110 MKIII was reliable for breath testing, performed accurately with precision and specificity, and gave a good linear response up to .320 ethanol (33T48). He liked the dual detectors which produced two readings and the built-in safeguards against RFI and mouth alcohol, and the minimum blowing criteria (34T25-34T26). The evaluation group and the ADTU coordinators in particular found the instrument easy to operate, portable, essentially operator independent, computer compatible, and tamper-proof (33T48;D-185). The group also found it complied with the standards in OIML Draft III (47T54-47T55;D-185;D-186). Deputy Attorney General Hoffman represented to the court that the OIML historically had approved only one breath-testing instrument, which was made in France by the now-defunct Seres Company (47T57-47T58).

New Jersey selected the Alcotest 7110 with the wet bath simulator (33T52-33T53). The simulator contained the solution and vapor, was separately maintained, and was attached to the breath hose (41T126;45T73). The State also chose to use a laser-jet external printer so the AIRs would contain all the information customized to the State's program (33T53). Brettell explained that New Jersey did not select the RFI detector because the instrument already was shielded and had successfully been informally tested by NHTSA and OIML-approved labs (33T53-33T54). His lab also did some informal testing with walkie-talkies, radios and "things like that," and found no variation from the expected outputs using known concentrations (33T54). Brettell was convinced there was no interference from radio frequencies (33T54).

Brettell decided that New Jersey did not need to purchase the breath temperature sensor option (33T55-33T56;35T72-35T73;35T119). The sensor consisted of a thermistor placed into the breath hose to measure the temperature of breath as the subject blew into the tube (33T56). In Brettell's opinion, the temperature sensor was not generally accepted in the breath-testing community based upon the lack of peer-reviewed scientific publications and the absence of its use in programs throughout the country, except in Alabama (33T56;35T73-35T74;35T120;35T122;44T70). Most vendors did not offer a similar option nor did they recommend setting the simulator temperature to anything other than 34 degrees C (33T56-33T57).

He mentioned that the purchase of sensors would impose additional costs on municipalities, but maintained that cost was not a factor in his decision (35T72-35T73).

Brettell was aware of research showing that changes in body temperature influenced the breath alcohol reading (37T186-37T187;51T55). As temperature increased, more ethanol molecules entered the breath, changing the partition coefficient (37T187-37T188;51T55-51T56). It was generally accepted that for every degree centigrade above normal body temperature, the alcohol reading in breath could vary by about 6.8% upwards, requiring an adjustment (33T60-33T61;51T55-51T56). Alabama used the sensor to make only downward corrections; Germany corrected both upwards and downwards (35T102;37T184). In Brettell's opinion, however, there was no need to correct for breath temperature (33T63). He explained that the important temperature was in the deep lungs, not the bronchial tubes (33T61).

Brettell further explained that the Alcotest 7110 took into account such temperature variation by using a blood-breath ratio of 2100:1, which was lower than the actual ratio of 2300 or 2400:1 reported recently by A.W. Jones (33T62;39T85).[17] By doing

[17] We assume that Brettell was referring to A.W. Jones and Lars Andersson, Variability of the Blood/Breath Alcohol Ratio in Drinking Drivers, 41 J. Forensic Sci. 916 (1996) (D-19). Although he made repeated references to the "partition" ratio, Brettell later said that he actually meant blood-breath ratio

Footnote continued

so, the instrument underestimated alcohol in the blood by 9 to 10% (33T62). The 2100:1 ratio was not programmed into the software but was based upon the fact that when the simulator solution turned from a liquid to a gas it would be in the ratio of one gram per 210 liters (34T106-34T107). If the State wanted to reduce the ratio to 2000:1 to benefit more defendants, Draeger would only need to change the solution (34T107-34T108).

Draeger subsequently developed the Alcotest 7110 MKIII-C, which added a communication port (33T51-33T52). The communication consisted of a modem, which allowed the instrument to obtain data over the telephone (44T44-44T45). New Jersey purchased the instruments and customized the firmware (33T64). Prior to its use in the field, the Alcotest 7110, NJ 3.8, was tested successfully by Brettell and Lt. Tom Cambria, now retired, and by NHTSA for accuracy and precision (33T88-33T89). Brettell did not recall working with firmware version 3.6 (39T9-39T10).

New Jersey then engaged in the Pennsauken pilot program which began in December 2000 and continued for one calendar year; this tested 372 subjects in the field (33T64;33T89;34T31;34T39-34T40). Brettell reviewed and analyzed the data, and testified about the results in Foley which raised

---

(37T183).

several issues, including: the instrument was not reporting the lowest breath alcohol concentration when it went to a third test; the minimum volume of 1.5 liters possibly was too high and should be lowered; the operator did not have the opportunity to terminate the test without charging refusal, resulting in a high "automatic" refusal rate of 28%; the blowing instructions were "a concern" and should be changed; and an operator had to use the "black key" to set the instrument to truncate the final BAC result to two decimals (33T90-33T92;34T83).

There is a probe value on the black key which matches a particular temperature probe (35T47). The coordinator enters the probe value into the instrument (35T46-35T47). The probe values differ and are used to ensure that the simulator reads at the proper temperature (35T48;35T56;47T44-47T45). The probes are periodically returned to Draeger for recertification (36T70;36T72). Brettell was aware that Draeger also had a yellow key which apparently inhibited incrementing the sequential file numbers and setting the calibration file number, date of calibration, and storing of the calibration record (46T74-46T75; D-175 at DS168).

After the Foley decision, the State asked Draeger to make certain firmware changes to include more information on the AIR and add error messages, among other things (33T64;33T93). Draeger subsequently produced firmware version 3.9, which New

Jersey never saw (33T65;47T79). Instead, in June 2004, Draeger gave the State a beta version 3.10Y for testing and validation (33T65;33T79;33T104;43T82;D-175 at DS174).[18] All requests for software changes —— scientific and administrative —— required Brettell's approval (43T88-43T89). And Brettell, not the ADTU, tested the firmware (43T117).

Among other things, NJ 3.10Y incorporated the following changes: (1) operators had the option to terminate the test, rather than record it as a refusal; (2) the instrument automatically truncated the final blood alcohol result to two decimal points; (3) the instrument added the safeguard of a two-minute lockout between breath tests; and (4) the instrument allowed the operator to follow protocol for the twenty-minute observation period, no longer automatically locking the instrument (33T96-33T99;33T102;42T71-42T72). With regard to the latter, if a subject regurgitated, burped or belched or was not continuously observed for twenty minutes, Brettell explained that the change allowed an operator to test another subject in the interim and restart the process again for the initial subject after a full twenty-minute observation period had elapsed (33T99;37T25;40T11). He further explained that local

[18] For dates, we are relying upon Draeger's internal memorandum outlining the New Jersey Alcotest 7110 firmware timeline (D-175 at DS174).

police departments had discretion to determine when the observation period began, either on arrest or on arrival at the station house (36T47;46T23-46T24).

At Brettell's request, the revised firmware also addressed the high refusal rate in Foley by displaying error messages on the screen so that operators could take them into consideration (33T96). The State also changed its training protocol to teach operators to instruct subjects to blow deep breaths (33T96). The new instruction stemmed from the assumption that breath at the end of a deep exhalation accurately reflected alveolar or deep-lung air (39T66). Additionally, Brettell requested changes in the AIR including the presentation of all information on one page, whenever possible, and the inclusion of error messages (33T103;34T71).

From July 22, 2004 through September 17, 2004, Brettell's laboratory performed validation testing on four instruments with firmware version NJ 3.10Y (33T104;40T52;47T79). During that time, Draeger made additional changes to the firmware at Brettell's request and, in September 2004, upgraded beta version NJ 3.10ZH remotely onto the units in the Hamilton Township laboratory (44T12;46T80;47T79;47T104-47T105;D-175 at DS174, DS187).

In his report dated December 2004, Brettell confirmed that Draeger made the requested changes including, among other things: modifying the AIR to reflect the location where the instrument was installed; allowing the operator the option to hit terminate, refusal or continue when the error message "blowing not allowed" appeared; and reporting the final error message on the AIR and then reporting "test terminated" (40T54-40T55).[19]

In August 2004 forensic scientist Nirmal Sawhney and Flanagan informally tested the four instruments with beta version NJ 3.10Y for RFI (33T104;41T86;D-120). The following items were placed in the room at various times near the Alcotest 7110: RCA TV/VCR/DVD; State Police Motorola portable radio; Durabrand AM/FM cassette recorder; State Police Motorola pager, and Motorola cell phone (33T104-33T106;D-120). At all times, the Alcotest 7110 performed properly and gave the expected results without any suggestion of interference (33T107;47T114-47T115;D-120).

New Jersey accepted firmware version 3.10 but subsequently, Flanagan noticed during training classes that operators could not review four data fields including the defendant's drivers license number, issuing state, case number, and summons number (33T79;33T107;D-175 at DS528). Draeger made these changes, and the State then received current firmware version NJ 3.11

---

[19] See "Validation of Firmware NJ 3.10[Y] Draeger Alcotest MKIII-C Evidentiary Breath Testing Instrument," a copy of which Brettell attached to his expert report (43T61-43T63;C-13).

(33T79). Flanagan verified the changes (33T109;40T53). Brettell did not conduct another validation procedure for NJ 3.11 (40T53-40T54). He believed the changes in the historical data fields were only administrative and did not pertain to the analytical operation of the instrument (40T55-40T57).

NHTSA, however, successfully tested the Alcotest 7110, NJ 3.11 for accuracy and precision (33T109-33T110). Brettell reviewed NHTSA's data and report, which related that the instrument and revised firmware were operating properly (33T110).

At Brettell's recommendation, NJ 3.11 kept Draeger's default criteria because they were reasonable and generally accepted throughout the scientific community (33T88). These criteria included: a minimum breath volume of 1.5 liters; a minimum blow time of 4.5 seconds; a minimum flow rate of 2.5 liters; and an IR absorption plateau with no change of more than 1% per 0.25 second (33T88;36T16;39T42).

NJ 3.11 followed the same testing sequence implemented in NJ 3.8: ambient air check; control test one; ambient air check; breath test one; ambient air check; breath test two; ambient air check; control test two; and ambient air check (33T80;39T14). In NJ 3.11, however, the firmware changed to allow the subject a maximum of eleven attempts to provide two valid breath tests (33T80). The revised firmware only allowed a maximum of three valid samples in the breath test sequence (42T93-42T95;D-175 at DS247, DS248, DS313, DS314). If the three valid breath tests were not within tolerances, the instrument would automatically abort the test and the operator would have to start over again rather than pursue a fourth test, as with the breathalyzer (42T96-42T97;D-175 at DS247, DS248, DS313 and DS314).

The purpose of the control test was to check the instrument for accuracy by using a known concentration of ethanol vapor (33T81). The Alcotest 7110 set the tolerance for the control test at plus or minus 5% (33T81;34T36). For example, if the control test ran with .10 ethanol solution, the acceptable tolerance range would be .095 to .105 (33T81;40T50-40T51). The purpose of two breath samples was to ensure a valid result by protecting the subject against potential interferents, RFI or mouth alcohol (33T81).

Regarding the acceptable tolerance between two breath tests or four readings (2 IR and 2 EC), Brettell set the tolerance in firmware version NJ 3.8 as .01 or 10% of the highest and lowest of the four readings, whichever is greater (33T82;33T94). He determined the tolerance based in part upon his understanding that Downie required two breath tests to agree within .01 of each other, which he believed actually meant that the tests had to be within 10% of the then per se level of .10 (51T61-51T62). He changed the Downie tolerance to include 10% of the highest and lowest readings, explaining that there was uncertainty in any measurement so it was best to select a tolerance that expanded as values increased (33T82-33T83). Brettell was not aware of any other state that used an absolute .01 as a tolerance (51T62). In Foley, 370 N.J. Super. at 355-57, the judge inadvertently doubled the overall range to 20% stating that the results had to be within .01% or plus or minus 10% of the average of the highest and lowest IR and EC values, whichever was greater (35T35-35T36;43T27-43T28).

Brettell further widened the tolerance in NJ 3.11. While there were certain inconsistencies throughout Brettell's testimony with respect to his expression of the standard, he actually set the acceptable tolerance as plus or minus .01 or plus or minus 10% of the mean of the four readings, whichever is greater (34T78;36T26;37T145-37T148;37T214). He doubled the tolerance from NJ 3.8 to reduce the number of subjects who had to blow third tests, an issue raised in Foley (35T13-35T15;43T31;51T62-51T63). According to Brettell, the "plus or minus .01" —— below the level of .10 BAC —— was consistent with the National Safety Council's recommendation of .02 and what Alabama uses, and the "plus or minus 10%" was consistent with what the State of Washington uses (45T90-45T91;51T63). While no other state used the exact same tolerances as New Jersey, Brettell noted that Germany also used a hybrid standard which was .04 milligrams per liter or plus or minus 10%, whichever was greater (51T63).

Brettell explained that tolerances did not affect the accuracy of the Alcotest 7110's measurements, but affected its precision and uncertainty (51T61). Unlike the breathalyzer which took two breath tests and two readings, the Alcotest 7110 takes two breath tests and four readings; it also reports only the lowest reading, which it truncates to two decimal places, thereby accommodating, to some extent, the doubling of the tolerance (35T15-35T17;51T61).

Brettell extensively analyzed the breath-testing data collected in Middlesex County in 2005 (33T110;36T15). This was the "universe" selected by Judge King for the empirical data base in this Chun case. The data came from twenty-seven instruments and 1865 subjects (33T111;34T19). Of these twenty-seven instruments, evidential testing data came from twenty-five but electronic data came from all of them (34T119-34T120). The coordinators went to every police department in Middlesex County to download the electronic data onto the hard drives of their lap tops and then made copies which Brettell analyzed in excel format (3T111). Brettell reviewed all data including the hard copy AIRs and 300 plus fields of electronic data (33T111-33T112;45T113;48T34).

Brettell compared the electronic data and AIRs from all instruments in Middlesex County except two, and found no discrepancies (33T116).[20] He concluded that NJ 3.11 worked properly except for six valid breath tests which did not allow the two-minute lockout (33T119;51T73). After speaking with a Draeger representative, Brettell learned that there was a problem with the firmware (33T119-33T120). The internal clock apparently did not start running at the end of the first breath test, actually taking less time by about a fraction of a second (33T120-33T121;47T89-47T92;51T73). Brettell wanted the full two-minute lockout to ensure that all the breath was expelled from a subject's mouth before the second breath test was taken, and intended to correct this problem on the next firmware change (33T122;35T125;47T93-47T94).

Brettell concluded that all of the other problems with the AIRs were due to human errors (37T17). For example, he mentioned two cases involving the Milltown Borough and Plainsboro police departments where the coordinator failed to set the control-test tolerance to 5% when he installed the instrument, causing it to revert to Draeger's default tolerance of 10% (33T123;51T71-51T72;S-47;S-48). In other cases,

[20] The two exceptions came from Helmetta (where Brettell thought the instrument might have been recently installed) and East Brunswick (where certain electronic data was lost when the motherboard failed) (33T117-33T119).

coordinators recalibrated instruments and failed to push the quick reset button, causing the test to abort and move to the next sequential file number without a printout (33T123;51T72-51T73;D-57;D-58). Other AIRs provided examples of operators who failed to reset the instrument before inputting; made transcriptional errors such as entering the wrong date, year or time; incorrectly hit the "Y" key when reviewing data; or failed to follow the twenty-minute observation period (33T125;37T17-37T18;37T22-37T24;51T65-51T67;D-131;D-132;D-134;D-135). These "human errors" did not produce any misleading BAC readings which might cause a wrongful conviction.

Brettell also explained that two AIRs with 0.00 readings indicated the subjects were sucking instead of blowing through the breath tube (35T28;39T45-39T52;51T64;D-129;D-130). Brettell personally performed tests where he repeatedly sucked in air through the breath tube and replicated these results, as did Flanagan (36T85;48T42;51T64-51T65;51T78). In another case, Brettell concluded that the AIR showed subject refused and control test failure because the State Police operator selected the refusal option and the instrument ran a control test after the simulator solution had depleted (51T67-51T68;D-137).

Some of the alleged errors involved decimal place issues. For example, two AIRs properly reported control test failures even though the test results at three decimal places looked like they were within tolerance due to the fact that the instrument actually read to the fourth decimal place, at which the results were out of tolerance (51T68-51T69;D-138;D-139). On another AIR, the instrument correctly issued a simulator temperature error because the second decimal place read over 34.2 degrees C (51T69;D-60). Other errors implicated keyboard malfunctions or instances where the operator pushed subject refused but then continued the test (51T69-51T71;D-63;D-140;D-142). None of the AIRs showed any problems with the firmware itself (51T73). Again, these "errors" did not result in flawed BAC results capable of improper convictions.

With regard to the refusal issue, Brettell found that 405 of the 1865 subjects in Middlesex County were charged with refusals and tests terminated (33T126;33T135). Of those subjects, 396 actually were issued refusal tickets resulting in a 21.2% refusal rate (33T126;33T135). As Brettell pointed out, the Middlesex County rate was lower than the refusal rate of 28% from the Pennsauken data in Foley, or the 25% cited as the national average by NHTSA (33T127).

Brettell also looked at the issue of minimum breath volume to determine who would be affected if the State lowered the criteria to 1.0 liter (33T128). He found thirty-seven subjects who blew between 1.0 and 1.4 liters, and 302 subjects who blew all tests less than 1.0 liter of whom 256 did not blow anything

(33T129;33T137;34T4;S-37). Of the thirty-seven subjects between 1.0 and 1.4 liters, he concluded that only eight or .4% of all 1865 subjects would not have been charged with refusal if the minimum volume had been reduced (33T129-33T130;33T132;34T6-34T7).

Under the wider tolerance adopted for NJ 3.11, Brettell observed that there was only one subject in the Middlesex County data who required a third breath sample (35T18). He also found that only twenty-six subjects or about 1.4% of the total subjects from Middlesex County had reported mouth alcohol error messages (34T12;37T29).

Brettell also conducted an independent breath volume study using 179 volunteers who went to his laboratory and blew into an Alcotest 7110 (34T7-34T8;S-39). The volunteers included 106 females and seventy-three males who ranged in age from fourteen to eighty (34T8). Each subject provided at least two breath samples (34T9;S-39). Breath volumes ranged from about .1 liters to 5.1 liters of air (33T9). For the first breath exhalation, two of the 179 volunteers blew less than 1.5 liters and both of them were females over the age of seventy (34T9). The second time, only one female over age seventy was unable to blow 1.5 liters (34T10;S-40). Brettell concluded that the cooperative subjects could meet the minimum volume requirement except that women over seventy might have difficulty (34T11).[21]

In Brettell's opinion, the Middlesex County data and his breath volume study indicated that the 1.5 liter minimum volume was sufficient (34T11). He believed that a reduction to 1.0 or even 1.4 liters would make it difficult for subjects to give a true deep lung air sample, thus requiring more blows into the instrument (34T11;36T16-36T17;36T22;39T42;45T71).

Brettell did state, however, that there should be some consideration given to elderly women, but did not specify a minimum volume (34T11). Brettell thought that Draeger could easily change the software to lower the minimum breath volume —— if only for individuals over a particular age —— and that, in any event, the slope detector would still ensure that the subject gave deep alveolar air (35T100-35T101). Brettell generally agreed with the old adage that "the longer you blow, the higher you go," but said that a person who blew more than 1.5 liters would get a truer value of BAC, not an overestimate (36T23-36T24;37T97).[22] In other words, the old adage applied only where

---

[21] The last revision of the OIML recommendations (OIML R-126-1) specified that the exhaled volume should be greater than or equal to 1.2 liters (35T93;AB-46 at 8). Alabama has a minimum requirement of 1.3 liters (35T89;36T17).

[22] Brettell never saw a volunteer blow more than 5.5 liters of air (37T97).

Footnote continued

a subject's exhalation had not yet reached the plateau and the curve still was increasing (37T98). For his study, the average breath volume was 3.1 liters (37T97).

Although New Jersey did not use the instrument's modem for downloading or monitoring data, Brettell was working with a vendor to develop a program which would allow daily remote transfers of electronic data collected statewide by municipal police and state troopers to a central data base (3T113-3T114;35T105).[23] The vendor, Porter Lee Corporation, was the same software company which created New Jersey's laboratory information management (LIM) system and Brettell wanted the breath-testing data to interface with LIM (33T115;37T6-37T7;44T42;48T48-48T49). In September 2005, Porter Lee gave him an estimate of $9780 for the data collection project (48T47-48T48;D-214).

Brettell said there were logistical problems related to the running of dedicated telephone lines to the barrier islands and the processing of the data (33T114-33T115;44T46-44T50;48T50-48T51). Brettell was aware of a Draeger-based program, but said that he was looking for one that was more user-friendly and would allow him to do more (37T7;37T11-37T12;44T45;44T52-44T53).

---

[23] Alabama uses the modem to communicate with a central computer (44T56).

He did not know when New Jersey would be ready to move forward on the data collection project (35T108-35T109;44T54).

Coordinators from the ADTU inspect the Alcotest instruments when they are installed and then, annually or on an "as-needed" basis (34T13). Brettell relied upon these inspections to verify that the instruments worked properly (34T13). Unlike New York where the State Police bring the Alcotest 7110 instruments in for testing every six months, New Jersey conducts its annual inspections in the field (34T14). Because New Jersey uses control tests on each subject, Brettell made the decision that annual calibrations were sufficient (34T14;51T43).

The coordinator inspects or calibrates an instrument using standard solutions purchased in lots of 1000 from Draeger which, in turn, purchased them from Plus Four Company which puts Draeger's labels on them (34T17;47T21;48T94;51T12). Although Draeger certifies the solutions, New Jersey performs its own tests and Draeger will not ship a lot until it receives the State's approval (34T18;47T50).

Specifically, New Jersey tests six bottles from each lot, including the first two bottles, middle two bottles, and last two bottles (which are numbered 1, 2, 499, 500, 999 and 1000), which Brettell claimed gave a confidence level of 96.5% (34T19;47T21;48T94). Brettell's laboratory tests each of the six bottles three times using head space gas chromatography

(34T19;48T94;48T96). If there is depletion from freezing during shipping or otherwise, the calibration process and control tests will detect this because the results will be out-of-tolerance (34T19). In any event, depletion of the simulator solution would have no effect on the reading of the breath test (39T20). Under New Jersey protocol, each bottle should not be changed for thirty days or twenty-five subject tests, unless the instrument gives an error message that the solution is depleted (48T100;51T28-51T29;51T31).

Brettell's laboratory issues certificates of analysis stating that each simulator solution was within specifications of the target value for the particular concentration (34T20;S-41;S-42;S-43;S-44). Brettell does not look at simulators in the field (44T61).

For calibration, the coordinator uses a known standard of .10 ethanol solution (34T15). If the instrument detects that concentration, the coordinator will run three control tests to make sure that the readings fall within the tolerances of that simulator solution (34T15). Next, the coordinator will run concentrations of .04, .08, and .16 through the breath test hose and check the responses for accuracy, precision and linearity (34T16). Finally, the coordinator will take solution from the police department, make a solution change, set the instrument for operation, and do a run to make sure that the instrument gives a response within the tolerance which is plus or minus 5% (34T16). All tests produce reports which the coordinator keeps on record (34T16). The coordinator also issues certificates of accuracy after the instrument successfully completes the calibration and linearity checks (36T68).

Brettell noted that the Alcotest 7110 was programmed to accept 1000 tests and, at 1001, to replace the first test and so on (44T24). He did not recall any instrument that exceeded its memory capacity of 1000 tests (44T24). If an instrument exceeded the limit, however, it still would operate properly but would noticeably slow down (44T25). Brettell believed that the ADTU was downloading data after about 500 tests (48T52-48T54).

Although he was not an expert in physiology, Brettell had a working knowledge of the human body and understood that the Alcotest 7110 depended upon certain physiological assumptions (39T65-39T66). He agreed that respiration involves the passage of air through the nasal cavity, the nasal pharynx, the oral pharynx, epiglottis, glottis, and trachea into the bronchial tubes (39T67). The inhaled air, which is heated as it passes through the upper airways, then moves through different airways of the increasingly narrow bronchial tubes until they end in a very large number of thin-walled sacs called alveoli (39T67-39T68;39T73).

Gas exchange occurs in the alveoli at which time oxygen is exchanged with carbon dioxide from the pulmonary capillaries (39T67-39T68). Gas in the alveolar air is assumed in equilibrium with the pulmonary capillary blood (39T69). During exhalation, the alveolar air passes through the upper airways where heat is transferred from the exhaled air to the mucus lining of the airways and water vapor condenses on the way up to the mouth (39T74-39T75;39T79). Brettell was not aware of any discussion in the literature that the alcohol in breath samples comes primarily from the airways, rather than the alveoli (39T80).

Brettell further explained that the body absorbs alcohol very quickly at first but after a short time, begins to eliminate it (39T88). When absorption occurs faster than elimination, the alcohol concentration continues to rise until it reaches a "peak" where absorption and elimination occur close to the same rate (39T89). Generally, the average rate of "burn off" or elimination of alcohol is .015 in an hour (36T104-36T105).

The rate of absorption varies between individuals and in the same individual at different times (39T90). For example, a body absorbs alcohol more quickly on an empty stomach (39T95). During absorption, blood alcohol content tends to rise and, therefore, the blood-breath ratio will be lower than 2100:1

(39T93-39T94). Brettell was aware that Rod Gullberg's and Jones' studies suggested ratios during absorption as low as 1500:1 and 1700:1, respectively (39T103). Based upon the amount of time that generally elapsed between an arrest and a breath test, Brettell thought most subjects would be in the post-absorptive phase and, therefore, the assumed ratio of 2100:1 was justified (40T36-40T37).

Brettell never asked Draeger for the Alcotest 7110's source codes nor did he ever ask to see source codes for other complicated instruments which he had used in the laboratory during his thirty-year career (34T12). He asked Draeger once for the tolerance algorithms and got a description of them in response (47T63).

Brettell testified that he did not need the sources codes because he determined an instrument's reliability by testing it with known standards and evaluating the outputs for accuracy and precision (34T13;47T93-47T94;51T28). Although he recognized that there was analytical uncertainty in every measurement, Brettell stated that the Alcotest 7110 was "very close to being 100 percent accurate" (36T51;36T54;37T13). While he acknowledged that a forensic blood test was more accurate than a breath test for determining BAC, he stated that New Jersey had the "smallest uncertainty of many of the programs out there, including Alabama's" (36T51;36T55;44T75).

Based upon his training, experience, the scientific literature, the tests that he performed, and his experience with the instrument, to the best degree of scientific certainty, Brettell believed that the Alcotest 7110 was scientifically reliable to produce breath alcohol results in an evidentiary setting with excellent accuracy, precision and linearity (34T22).

However, Brettell recommended the following changes in New Jersey's program: (1) women over the age of seventy who legitimately tried to blow into the instrument and gave a reasonable breath volume "such as one liter" should not be charged with refusal; (2) there should be a full two-minute lockout between valid breath tests; (3) the firmware version should be written on the AIRs so that everyone would be aware of the requirements used to produce the reports; (4) the AIRs should include an error message "tolerance out of range" when a second breath test did not meet the tolerance; and (5) New Jersey should expeditiously create a data collection system to manage and review data in a more timely fashion (33T122;35T124-35T125;35T129;46T57-46T58;48T64-48T65;51T76-51T77). He did not recommend that New Jersey use the breath temperature sensor based upon its lack of general acceptance in the breath-testing field (51T76).

Brettell also recommended changes in the tolerances between breath tests, stating:

> Yes. After going through these proceedings I think I would recommend that the tolerances be tightened up and I would be in favor of using a hybrid such as .01 or plus or minus five percent, whichever is greater. It also may be even clearer and easier for everyone to understand what the tolerances are if we just went to simply the National Safety Council's recommendation of using two tests within .02 of each other all the way across the board.
>
> If the decision is to go to those tolerances, everyone has to understand that when we get to the higher alcohol readings, and I'm talking now out around .3, over .2, that the subject may have to —— several subjects may have to give more than two valid breath tests to fall within those tolerances.
>
> [51T75-15 to 51T76-3.]

Dr. Brettell testified over a ten-day period. He testified patiently and candidly admitted the problems that inhered in implementing the program. He assisted this court greatly in understanding the scientific problems. We fully accept his very credible opinion that the Alcotest 7110 is scientifically reliable in an evidentiary setting but that certain improvements could be made in the program to effect even greater confidence.

3. <u>Summary of Testimony of State's Expert, Sergeant Kevin Michael Flanagan</u>

After serving four years in the United States Navy, Sergeant Kevin Michael Flanagan graduated in 1984 from Glassboro State College (now Rowan University) with a Bachelor of Arts degree in law and justice (52T9). In September 1986 he joined the State Police (52T9). In January 1987, he became a road duty trooper after graduating from the State Police Academy (52T9). In February 1995 he was assigned to the Alcohol Drug Test Unit (ADTU) as a breath test coordinator and since January 2004 has been responsible for the Alcotest 7110 program (52T13;58T73).

Throughout his career, Flanagan has received extensive technical training in the area of alcohol breath testing. In February 1988 he became a certified breathalyzer operator after attending a five-day training course conducted by the State Police (52T9). He subsequently attended Draeger's repair and maintenance training course on the breathalyzer models 900 and 900A (July 1994), a State Police instructor training course (October 1994), a State Police breath test coordinator training program (February 1995), and the Borkenstein course at Indiana University (May 1995) (52T9-52T11).

Flanagan also received instruction from Draeger on the Alcotest 7110 including: (1) a three-day course in Ewing, New Jersey on basic operation (January 1998); (2) a one-day training course with defense counsel in Foley (January 2003); and (3) a four-day training course for ADTU staff on operation and maintenance (October 2004) (52T10-52T11;52T29-52T30).

While serving as a breath test coordinator for Camden County, Flanagan became involved in the Pennsauken Township Pilot Program (52T12). After receiving additional training by Lt. Cambria, he loaned the Township two instruments and implemented the pilot program in December 2000, assuming responsibility for installation, calibration and solution changes for the project (52T12-52T13). When the pilot program ended in December 2001, Pennsauken Township resumed using the breathalyzer (52T13).

Flanagan has operated the Alcotest 7110 thousands of times and, since November 2004, has trained over 5000 operators (52T14-52T16). He has performed several hundred calibrations, demonstrated the instrument to chiefs of police in the seventeen counties which presently use it, and trained municipal prosecutors (52T16-52T17;54T115). He also has conducted seminars for the Institute of Continuing Legal Education (ICLE) and demonstrated the instrument to the Special Master and defense counsel in Chun in February 2006 (52T17;54T98).

During his career, Flanagan has testified numerous times as an expert on the breathalyzer in Municipal and Superior Courts, and as a fact witness in Foley (52T18-52T20). The State moved to qualify him here as an expert in breath testing in New Jersey

(52T19;52T43-52T44). This court recognized that he also would testify as a fact witness (52T19).

Under Flanagan's direction, the ADTU developed a training program for the Alcotest 7110 and coordinated its "rollout" (52T13). Between November 1, 2004 and December 22, 2004 the ADTU trained approximately 900 troopers and police officers in Middlesex County on the new instrument (52T35). On January 3, 2005 Middlesex County became the first county to use the Alcotest 7110, NJ 3.11 for evidential purposes (55T37).

Among his other duties, Flanagan worked closely with Brettell, the director of the forensic science laboratory (57T60-57T61;58T6-58T7). Flanagan assisted the forensic laboratory in performing breath volume and simulator solution studies (52T14). For example, he assisted in performing blind proficiency studies for Collaborative Testing Services, Inc. (CTS) where the ADTU introduced different solutions into a simulator, then introduced them into the Alcotest 7110 in vapor form, and sent the results to CTS for evaluation (52T14-52T15). Beginning in late 2004 or early 2005, Flanagan joined Brettell and others in a working group to discuss various issues relating to alcohol breath testing (58T69-58T70).[24]

---

[24] The working group also included Flanagan's supervisor (Sgt. First Class Bernhardson) or the lieutenant of his unit at the time, Nirmal Sawhney, and Deputy Attorneys General Christine

Footnote continued

Flanagan presently supervises five coordinators who handle inspections and implement the program throughout the State (52T13-52T14;52T24;52T110-52T111;58T49). The coordinators receive two days of factory training by Draeger after which they receive certificates as factory-trained technicians, observe ADTU training classes, and receive field supervision by Flanagan (52T111-52T112;S-73). Coordinators generally put two new instruments into service each day (52T112-52T113).

The coordinators report to Flanagan when problems arise in the field (52T14;52T114). For example, they received complaints about a number of control gas supply errors and upon investigation, discovered that operators were moving the instrument closer to themselves to read the message on the LED screen, inadvertently disconnecting the simulator and causing the error (52T14;52T102-52T103;53T62). Another time a coordinator discovered that an operator was using a solution jar with a cracked top which caused a control gas supply error (52T114). Recently, a police department reported that an instrument would not permit a solution change (52T115). After realizing that the instrument was still in the standby mode, Flanagan advised the operator to "wake up" the instrument, wait twelve minutes, and then change the solution (52T115).

Hoffman, John Dell'Aquillo, and Stephen Monson (58T70).

Coordinators also may contact Draeger for assistance (52T116). Most contact is made orally and the ADTU does not keep a contact log (52T117-52T118). If a problem cannot be corrected, a coordinator downloads the electronic files onto a laptop and then transfers the data onto two non-writeable CDs: one for the local police department and another logged into evidence (52T119;54T34-54T36). The instrument then is taken out-of-service and returned to Durango for inspection and repair (52T117). Coordinators also download data when an instrument has performed 500 tests, a New Jersey policy adopted to avoid the instrument's tendency to slow down as it searches large numbers of files (54T34-54T35). After downloading, all information in the Alcotest 7110 is removed but the sequential file numbers continue (54T36). Flanagan later testified that East Brunswick was the only police department that might reach 500 DWI arrests in one year (54T112).

The Alcotest 7110 also has a modem for remote downloading to a central computer for data collection (55T34-55T35). Flanagan was aware that Brettell wanted the data collection system to be hooked up to the laboratory information management (LIM) system and that he had contacted a company named Porter Lee to look into it (55T34). He did not know the status of the project in light of Brettell's pending retirement (55T33-55T34). He also was aware that there was some concern about the cost of running dedicated telephone lines to the barrier islands for that purpose (58T71-58T72).

Coordinators neither repair the instruments nor open them (52T119). The State only has one special screwdriver to access the inside mechanism of the Alcotest 7110, which Flanagan keeps but has never used (52T119;55T63). Operators also do not perform maintenance other than cleaning the instrument and changing the simulator solutions (52T110). When a police department reports a hardware problem rendering an instrument inoperable, the ADTU instructs the operator to use an Alcotest 7110 in a nearby town and sends a coordinator to see if the problem can be resolved (60T10-60T11). If not, the local police department returns the instrument to Draeger for repair, and keeps all the repair records (52T120).

Draeger also annually recalibrates the simulators and temperature probes (55T73-55T74;58T16). The ADTU recommends that each police department purchase a back-up simulator and probe so that they can rotate them in and out of the factory (58T16).

As mandated by N.J.A.C. 13:51-1.6(b), the ADTU offers a one-day conversion training class taught by its coordinators to police officers who previously were certified as breathalyzer operators (52T44;55T57;58T25;59T76-59T77).[25] To date, the ADTU has not trained any new officers on the Alcotest 7110 and does not plan to offer the initial four-day training course until 2008 (52T44;55T95;57T28). Flanagan explained that the ADTU cannot begin training new officers on the Alcotest 7110 in 2007 due to its other obligations, including the need to bring the last four counties —— Bergen, Hudson, Monmouth, and Essex —— into the Alcotest program as well as a few towns in the seventeen counties which failed to purchase their instruments before the Attorney General stayed the program (54T122;54T124).[26] The ADTU also must recertify approximately 5000 operators who received training on the Alcotest 7110 in 2005, and hold thirty weeks of DWI classes required by the federal government to receive reimbursement for two training positions, including Flanagan's and another sergeant's (57T28-57T30).

---

[25] N.J.A.C. 13:51-1.6(b) provides in relevant part:

> Subject to the requirements of N.J.A.C. 13:51-1.4(c), certification of an operator, whose certification is valid, on an instrument approved by N.J.A.C. 13:51-3.5(a), other than the instrument upon which the operator was previously trained and certified, requires satisfactory completion of a minimum of one day of training as prescribed and conducted by the Division of State Police.

[26] These towns include Buena Borough in Atlantic County and Sea Isle City in Cape May County along with a few unnamed towns in North Jersey (54T116).

The conversion training class first reviews the breathalyzer, which Flanagan believed was still very accurate (52T48;57T23). (This court suggests that the State produce a breathalyzer at argument for the Justices to view.) Like the Alcotest 7110, the breathalyzer measured a subject's end-expired breath, specifically the last 52.5 milliliters of air (54T17). He recognized, however, that it represented older photometric technology, that it was operator dependent, that it required "periodic" inspections (every thirty to sixty days), and that it had a tighter tolerance (57T23;54T31). Instead of a machine-printed AIR, the breathalyzer's operator manually recorded the test results by moving the blood alcohol pointer up the scale until the instrument became balanced and then pushing down on the plastic shield to transfer the ink from the pointer to an overlay of paper (57T24). The breathalyzer also did not reveal a subject's breath volume (57T50). Flanagan expressed concern that there were no spare parts for the breathalyzer, which no longer was being made (57T25). Particularly, the State is running out of ampules leaving police officers in the four counties with only the option of taking a subject to a hospital for a blood test (54T124;57T25). Of course, subjects always have the option of a blood test as well as the right to an independent breath test of their own choosing after the State completes its test (60T90-60T91). New Jersey does not offer the option of preserving a breath sample (60T92).

On the other hand, the Alcotest 7110 uses newer technology and is more transparent because it produces a printout (57T23-57T24). It also eliminates the chance of operator manipulation after the subject begins to blow and only requires annual inspections (57T23;57T27). The Alcotest 7110 gives subjects the benefit of truncating to two decimals the lowest of the four test results (57T32-57T35). Since New Jersey's Alcotest 7110 program is relatively new in comparison with the breathalyzer which has been in use since 1966, Flanagan expected efficiency to increase over time (57T27).

New Jersey does not use portable breath testers in the field (57T27). The ADTU recommends using only the field sobriety test (57T27).

The conversion class relies upon a lesson plan and the User Manual-Operator (operator's manual) to review the "nuts and bolts" of the instrument such as the IR and fuel cell technologies, minimum criteria, acceptable tolerances, temperatures in the cuvette and breath hose, and AIRs, (52T48-52T50;54T17;D-15;D-224).[27] The class also addresses the function

[27] During cross-examination, Flanagan admitted that the lesson plan incorrectly stated that the minimum flow rate was 3.0 liters, instead of 2.5 (54T94-54T96;D-224). The operator's

Footnote continued

of the simulator including the introduction of solution heated to 34 degrees C and the need to change the solution a maximum of every thirty days or after twenty-five test sequences (which include the control tests performed before and after a subject blows) or if depletion occurs (52T50-52T51;53T35;53T46;54T104;60T20). Although Brettell determined the solution change requirements based on his laboratory depletion study, Flanagan testified that the alcohol level in the bottles was depleting before thirty days in the field (58T80-58T81). He also testified that if a coordinator entered the wrong number of days or tests during the calibration process, the instrument would go beyond the maximum limit but that the mistake would be transparent on the AIR (60T20-60T21). Although the ADTU trains everyone to change the solution, it recommends that police departments assign only two or three individuals to do so (52T52).

The conversion class also instructs operators on how to input data (52T53;D-29). Unlike the breathalyzer, there is no checklist; instead, the operators push the orange button and follow the "prompts" (52T54-52T59). Among other things, operators enter a summons number for every arrest and if they later decide not to charge the subject with drunk driving or

---

manual correctly stated the rate (54T96).

refusal, they will issue the summons based on the probable cause for the stop such as speeding, careless driving, reckless driving or broken taillight (52T57-52T58;52T93-52T94).[28] The operators, however, have the option of dashing out the required field for reporting the summons numbers, proceeding with the test sequence, and adding the number later by hand if they get a reading of .08 or above (56T8-56T9;60T28-60T29). This option may apply in cases where there was an inference of intent to operate a motor vehicle and no other probable cause (56T10).

After inputting the data, the last prompt reminds the operators to review the information for mistakes (52T60;52T62). Flanagan recalled one operator who reviewed the data and mistakenly hit the Y key for each field, inadvertently erasing all the information he previously had entered (52T64). He attributed the mistake to human error, noting it had no effect on the instrument's accuracy in breath testing (52T63).

All operators in the conversion class eventually are divided into teams and instructed to perform a minimum of four tests on the Alcotest 7110 including a full sequence of data entry and breath testing (52T65). Each team also must induce errors into the instrument such as minimum volume or blowing

---

[28] State Police protocol considers the arrest time as the time of the stop (55T63).

time too short (52T53-52T54;52T65-52T66). All tests are done without alcohol (59T59).

Additionally, the ADTU instructs operators to change the mouthpiece after each breath sample and read specific blowing instructions to the subject (52T70;52T80). The class provides each officer with a sheet of the instructions, which also are included in the manual and posted on the wall near the instrument at each police department (52T75). The instructions read: "I want you to take a deep breath and blow into the mouthpiece with one long, continuous breath. Continue to blow until I tell you to stop. Do you understand these instructions?" (52T75). The Foley decision prompted the change in the instructions from "normal" to "deep" breath to make sure that a subject provided alveolar or deep lung air (52T76-52T77). Operators coach the subject through the blowing process (52T78). The State Police do not videotape subjects on the Alcotest 7110 (57T53).

The ADTU further instructs operators that the Alcotest 7110 has RFI shielding up to one gigahertz, but that portable radios and cell phones should be kept out of the room during breath testing (52T95;54T102;58T62-58T63). According to Flanagan, the manufacturer did not recommend the use of an RFI detector because it would require the drilling of a hole through the shield (58T61-58T62).

With regard to the issue of "sucking," the ADTU now trains operators to be keenly aware of subjects who suck air from the room through the top port, normally used to draw in air for ambient air checks or purges (53T60-53T61;53T68;54T81). He did not believe that the air was drawn into the instrument through the one-way flapper valve at the back of the instrument (58T54-58T55). Flanagan found that the instrument reported a result of .000 because it could not distinguish room air from breath (53T61). When operators observe sucking, the ADTU instructs them to terminate the test and charge the subject with refusal (53T61;53T67;54T76-54T78).

At the end of their training, operators take a twenty-five question test based on the material covered during the day (52T97). Operators who miss eight or more questions fail the class and do not get certified on the Alcotest 7110 (52T97). They can take the class again on another date but must sit through another entire day of training (52T97-52T98). If they pass, the operators receive a certificate and get their breathalyzer pocket card updated and signed, which certifies them as trained operators on the Alcotest 7110 (60T11;60T14-60T15). The certification remains valid for the rest of the calendar year plus two more years (60T11-60T12;S-71).

To obtain breath samples, Draeger and the ADTU recommend that a subject remain seated during the test (52T67;54T97-

54T98). Flanagan also recommended that subjects wear handcuffs (52T66-52T67). He explained that subjects still were under arrest and did not need the use of their hands to blow into the instrument (52T67). He further explained that it was easier to control a subject who was sitting and handcuffed, and such measures prevented situations where a subject could damage the instrument by ripping out the breath tube, requiring its return to Draeger for repairs (52T67;52T69). The sitting position also made it easier for subjects to give samples whereas if they stood, there was a greater chance of falling or staggering or bending which could restrict their diaphragms and airflow (52T69;54T99-54T100).

An operator may not begin the test on a subject prior to a twenty-minute observation period to ensure that there is no alcohol in the mouth cavity (52T70). In New Jersey, the twenty minutes may begin at the station or immediately after the arrest provided that an officer can testify that the observation was continuous and uninterrupted (52T71-52T72). For example, Flanagan said that State Police ride double and a trooper could sit in the back and properly observe the subject (52T71). However, if any substances enter the mouth or a subject regurgitates, the twenty minutes must start over again (52T72). The twenty-minute period also must restart if there were any interruptions in the officer's observation of the subject (60T10).

After the operator performs the initial data entry, the LED screen displays a message to "please blow/R" (52T72). The operator has three minutes to read the blowing instructions, insert the mouthpiece, and collect a breath sample or the instrument will display the error message "ready to blow expired" (52T73). If the error message appears, the operator must select one of three prompts: (1) terminate; (2) refused; or (3) continue (52T73). When an operator pushes button three, the instrument purges itself and again prompts "please blow/R" and the process repeats (52T73). If the operator pushes the refusal button and then decides to continue the test, he will get the same three choices and can hit the number three button and continue with the process (60T10).

The Alcotest 7110 allows the operator eleven attempts at collecting two valid breath samples (52T74). After the eleventh attempt, the instrument gives only two options: (1) terminate; and (2) refused (52T82). At that point, the operator does not necessarily have to charge refusal (52T90). For example, if a subject has made several unsuccessful attempts, the operator can choose to terminate the test and give an opinion that the subject was not capable of providing a proper sample (52T91-52T93). While Flanagan acknowledged that women over seventy have trouble providing the minimum 1.5 liters, he did not think it was necessary to reduce the breath volume criteria (52T93;58T40). In such cases, he said the police officer could take the subject to a hospital for a blood test or issue a summons based solely on observations (52T93).

If the operator wants to allow a subject more than eleven attempts, he can simply restart the process (52T81-52T82). As Flanagan explained, the ultimate goal is to get good breath samples (52T89).

When a subject blows into the instrument, a maximum of twenty asterisks can appear on the LED screen (52T79;54T105). If ten or more asterisks appear, the subject has reached the minimum volume requirement of 1.5 liters (52T79;54T105). Because a subject must expel all the air in the lungs in order to reach deep lung air, the ADTU trains operators to encourage subjects to blow 3.0 liters or until twenty asterisks appear on the screen (54T107;54T110;57T39;57T41;57T43). A subject may observe the screen at the operator's discretion (57T93-57T95).

If no asterisks appear, the operator knows that a subject is not blowing into the instrument (52T79). The operator also will receive an error message indicating "minimum volume not achieved" with the amount of air actually delivered (52T79). The message remains on the screen for thirty seconds at which time the operator must decide how to proceed (52T79). Flanagan explained that if a subject was providing 1.2 to 1.4 liters, he would give that person numerous "seven, eight, nine" attempts to collect two good breath samples (52T80). But if a subject was providing .2 or .3 liters after three attempts, he would charge that person with refusal (52T80).

The instrument also is programmed to institute a two-minute lockout between breath samples (53T53). Flanagan understood that Brettell instituted the lockout after Foley for quality assurance and to prevent contamination from any mouth alcohol still inside the cuvette from the previous breath test (56T21;60T27;60T68-60T69). NHTSA recommended two to ten minutes between breath test sequences (60T28). When Flanagan and Brettell recently became aware that the instrument was not adhering to the two-minute lockout all the time, Brettell contacted Draeger which explained that there was a problem with the amount of time the pump was taking to purge and that the instrument was performing a correctible, very slight rounding error (59T64).

If a testing sequence is terminated or aborted, the ADTU instructs the operators to retain the documents (52T96). Flanagan emphatically stated that "[e]verything is sequentially numbered. We don't destroy anything, whether it's good or bad. We save everything. They are not to destroy any documents" (52T96). Upon completion of a test, the ADTU recommends that the operator give a copy of the AIR to the subject (57T71-57T72).

The operator manual lists all of the possible error functions with their possible causes and remedies (52T99;D-15 at 24). Such messages include:

1. AMBIENT AIR CHECK FAILED [where instrument detects something in room air that may affect the breath test];

2. BLOWING NOT ALLOWED [where subject blows, stops, and blows again];

3. BLOWING TIME TOO SHORT [where subject blows for less than 4.5 seconds];

4. BLOWING TIME TOO LONG [which never appears as subject cannot blow too long];

5. CTRL GAS SUPPLY ERROR [e.g., where simulator is disconnected from the back];

6. CTRL TEST FAILED [where results do not fall within tolerance of plus or minus 5% of .10];

7. ERROR STORING DATA [which Flanagan never saw];

8. EXTERNAL PRINTER ERROR;

9. FUNCTION NOT POSSIBLE [where access requires black key held by coordinators];

10. INTERFERENCE [where instrument detects interfering substances];

11. KEYBOARD ERROR [where faulty keyboard requires replacement];

12. MEMORY FULL [which never appears because instrument holds 1000 tests and requires downloading at 500];

13. MEMORY NEARLY FULL [which never appears because of downloading at 500];

14. MINIMUM VOLUME NOT ACHIEVED;

15. MODEM ERROR [which never appears because New Jersey does not use the modem];

16. MOUTH ALCOHOL;

17. OUT OF MEASURING RANGE [where instrument measures BAC above .630 at which time operator must take subject to hospital due to possible alcohol poisoning];

18. PLATEAU NOT REACHED [where operator must collect another breath sample];

19. PURGING ERROR [where instrument draws in room air];

20. READY TO BLOW EXPIRED [where three-minute period to collect sample expires]

21. SIMULATOR TEMP. ERROR [where simulator is heated outside the range of 34 degrees C plus or minus .2];

22. SOLUTION CHANGE REQUIRED [where solution is not changed within thirty days or after twenty-five test sequences];

23. SOLUTION HAS EXPIRED [where solution was not changed within thirty-day window)];

24. TESTS NOT WITHIN +/- TOL. [if third test is out of tolerance, instrument automatically aborts]; and

25. WARNING LOW BATTERY [where lithium battery requires replacement].

[52T99-52T110;D-15 at 24-25.]

Flanagan also explained the procedure for putting a new Alcotest 7110 into service. Draeger ships the instrument directly to the police department that purchased it (53T4). Draeger also sends certificates of accuracy with the dates of the calibrations of the instrument, temperature probe, and simulator (53T6;59T9). After the police department receives the equipment, a coordinator assembles the tri-level stand and the instrument (53T5). The coordinator checks the firmware version, calibrates the new instrument, sets the tolerances, performs control and linearity tests, and performs a solution change (53T5;53T39;54T32;59T52).

If an instrument is not using firmware version NJ 3.11, the coordinator does a firmware update (52T10). Each coordinator has a laptop with a CD burner on which Flanagan installs the most recent firmware version (52T11). Because all of the laptops in the field are new, the only firmware burned into them is NJ 3.11 (53T11-53T12).

To calibrate a new instrument, the coordinator must use a black key temperature probe to gain access to the calibration function (53T7;57T74).[29] The coordinator introduces into the simulator a bottle of .10 solution which must be heated for at least one hour (53T10;59T8). To measure the temperature of the simulator solution, the coordinator uses an Ertco Hart digital NIST thermometer (53T8;55T66;S-70).[30] After checking that the simulator temperature is 34 degrees plus or minus .2 degrees C, the coordinator hooks-up the simulator to the back of the instrument through the rear port of the cuvette (54T21). The coordinator then hits the escape key, gets function on the LED screen, types in calibrate, and follows the prompts (54T21). After reviewing the entered data, the coordinator hits the "N" key and the instrument calibrates itself and generates a report (54T22;S-51).

New Jersey purchases the .10 solution from Draeger, which purchases the bottles from a company called Plus Four in Colorado (53T8;56T34-56T35). Draeger ships the bottles to New Jersey year-round on an as-needed basis in lots of 1000 (56T47-56T48;56T55). Prior to full shipment, Draeger sends six bottles to Brettell's laboratory, which uses gas chromatographs to make certain the solutions are within tolerance (56T46).

---

[29] Flanagan was aware that the manufacturer also had a yellow key temperature probe which it used to gain "deeper access" into the instrument (55T68;57T75-57T77).

[30] NIST is the National Institute of Traceable Standards and Technology (57T5).

The coordinator sets the absolute tolerance at .005 and the relative tolerance at 5% for the .10 solution change as established by Brettell (53T13-53T14;53T17). Draeger's default tolerances are wider at .010 or 10% (53T17). The AIR will show if an instrument inadvertently used the default setting (53T19;55T87). For example, in 2005, both the Milltown and Plainsboro Township police departments asked a coordinator to check the solution configuration of their instruments (53T19). In each case, the coordinator found that the absolute tolerance on the solution configuration was incorrectly set at .010 and corrected it to .005, then recalibrated the instrument and prepared a special report stating exactly what had happened (53T19;53T30-53T31;S-47;S-48).[31] In both cases, the readings fell outside of the tolerances and should have been flagged as control test failures (53T31). Despite the mistakes, the instrument performed correctly to the "default" tolerance (53T30).

The purpose of the control test is to verify that the instrument calibrated itself properly to the .10 simulator solution (54T23). The control test analyzes the vapor through

---

[31] Coordinators prepare special reports only if they deem them necessary to explain in further detail what actions were taken in the field (55T5;55T30;55T59). The ADTU has no written protocol regarding such reports and to date, only four have been prepared (55T5;55T7;55T9).

the rear cuvette using a wet-bath simulator (57T65). The coordinator enters "CTRL-TEST," hits the enter key and follows the prompts (54T23). After reviewing the inputted data for mistakes, the coordinator hits the "N" key and the instrument starts running the test through the rear of the cuvette (54T54;58T59). The control test runs three separate testing sequences and generates a report (54T24-54T25;S-52).

Brettell designed the annual linearity test to use simulator solutions of .04, .08, and .16 (54T28-54T29). To conduct the linearity test, the coordinator disconnects the simulator from the rear of the instrument (54T25). The coordinator then removes the NIST-verified temperature probe from the simulator and inserts it into one of the solutions (54T25). Each temperature probe has an assigned value, which can be changed only by a coordinator using the black key function (60T23).

After hitting the escape key and typing in "LIN-TEST," the coordinator follows the prompts to enter his name, badge number, lot number, bottle number, percentage of the solution, bottle's expiration date, the wet bath calibration unit, the simulator model (CU34), and the serial number (54T25-54T26). After the coordinator reviews the information, the Alcotest 7110 performs two tests on the solution through the breath hose (54T27;54T59).

The instrument repeats the same process for each of the solutions (54T27;S-53).

After the linearity test, the coordinator uses a bottle of solution from the local police department, performs a solution change, and generates a report (54T29-54T30;S-54). Upon completion of the solution change, the calibration test sequence is complete and the instrument automatically prints an Alcotest 7110 Calibration Record on the external printer (54T30;D-224). After the calibration, control and linearity tests, and solution changes, the instrument is assumed to operate correctly and will not be inspected again for one year unless a problem arises or the instrument reaches 500 tests (59T11).

Because Brettell opted to use the laser jet desk printer, the instrument's internal printer has been disabled (58T23-58T24). However, it can be reactivated by a coordinator with the black-key function if the instrument is unable to print externally (60T30). If the coordinator switches to the internal printer, the instrument subsequently would be taken out of service for repair (60T30).

The ADTU trains operators that they can not charge subjects under N.J.S.A. 39:4-50 with test results between .05 and .08, unless there are other sufficient strong indicators of intoxication but that they should charge subjects with DWI with readings under .05 (56T7;59T82;59T89;60T28). If an officer or trooper prematurely issues a ticket for a subject with a low reading, the officer must go to court to have it dismissed (56T8).

During his testimony, Flanagan conducted a three-part demonstration of the Alcotest 7110 including: (1) a normal test sequence with no errors using a fresh bottle of .10 simulator solution; (2) a test sequence with induced errors (minimum volume not achieved, blowing time too short, blowing not allowed, sucking, and control gas supply error); and (3) a blind test sequence using a solution with a concentration known only to this court (52T5-52T6;53T41-53T79). For a detailed discussion, this court refers the reader to the videotape (S-69;S-69a).

Of particular interest are the results from the blind test. For this demonstration, the State asked this court to select one of four bottles with concentrations of .04, .08, .10 and .16 (53T70). Unknown to the parties or amici, this court selected the bottle with an alcohol concentration of .16 (53T73;S-63). Before all the testing began, Flanagan performed a solution change with a fresh bottle of .10 solution which included: a purging (which used the internal pump to flush room air through the cuvette and breath hose to make sure there was no residual alcohol); an ambient air check (which tested an air sample from the cuvette using the fuel cell); control test one (which pumped air through the hose into the simulator and then introduced the sample through the rear of the cuvette); a purge; an ambient air check; control test two; purge; ambient air check; control test three; and final purge (53T41-53T45).

For the blind test, Flanagan blew through the breath hose which was hooked up to the front of the simulator, and produced the following results: .151 EC and .153 IR for breath test one; and .151 EC and .155 IR for breath test two (53T73;S-62). At the request of defense counsel, Flanagan repeated the test using the same bottle of solution and produced results of .150 EC and .152 IR for breath test one and .150 EC and .152 IR for breath test two (53T72;S-64). Both tests underestimated the labeled concentration of .16 (53T75).

Flanagan then used the same .16 solution, but introduced his breath vapor through the rear of the instrument as part of the control test (53T79-53T83;55T47;60T52-60T53). Because the instrument was calibrated to read a labeled .10 solution, the control test failed but the instrument still produced a printout showing results of .152 EC and .153 IR (53T85;S-65). Flanagan thought that the low results could be due to solution depletion, which he attributed to blowing six times at over 3.0 liters each (53T85). He also suggested the results were influenced by variation in his blowing time and the fact that he used a training instrument which had not been calibrated since May 12, 2006 (54T5-54T7;60T54).

The following day, Flanagan ran another test using a fresh bottle of .16 solution with the hose pumping air into the instrument through the simulator (54T6-54T16;56T33;56T41;60T29). Before he started the test, however, Flanagan performed a solution change using a fresh bottle of .10 solution, and got results of .097 EC and .099 IR for both control tests one and two, and .098 EC and 0.10 IR for control test three (55T52-55T55;S-58). Next, he disconnected the simulator and hooked up the .16 solution to the back of the instrument (55T55;60T29). After the instrument aborted the control test, it printed out results using the .16 solution of .155 EC and .158 IR (55T56).

When asked to explain why the results were lower than .16, Flanagan again suggested they were caused by depletion (56T41;60T29). He explained that a concentration of .16 tended to deplete more quickly than .04, .08, or .10 because it contained more alcohol (60T51-60T52). Flanagan also observed that he blew for 18.2 seconds the first day whereas the hose pumped air into the simulator for fifty-five seconds the second day when the results were higher (54T13-54T14). On redirect, however, he concluded probably that the readings were higher the second day because he had used a new bottle (56T39;60T29).

Regarding Draeger's optional breath temperature sensor, Flanagan believed that its purchase would create administrative and financial problems (54T41). In New Jersey, each police department buys its own breath-testing instrument (54T37;54T39).[32] In addition to sensors, this option also requires calibration equipment including a square plexiglas chamber which holds fifty gallons of water, weighs 400 pounds, and costs about $32,000 (54T37-54T38;54T74;S-66). Because such a chamber would not be portable, the calibration procedure would have to take place at a central location or the instrument would have to be sent back to Draeger (54T37-54T38). If the instrument was sent to Draeger, the local police departments would have to take their DWI arrestees, in the interim, to neighboring towns (54T72;54T75).

If the State purchased the equipment, Flanagan estimated that it would need more than one chamber to accommodate the anticipated 600 State-wide instruments when the program was fully implemented (54T38;54T73). The State currently has over 400 Alcotest 7110s in the field (54T89).

Flanagan also offered explanations for alleged errors on some alcohol influence reports (AIRS). For example, in the case of an AIR from the East Brunswick police department which allegedly was missing a sequential file number, he explained that the coordinator was doing a linearity test, encountered a

[32] Flanagan explained that the State of Alabama owned the individual breath-testing instruments and kept fifteen spares in the laboratory to rotate with those in the field (54T39-54T40).

problem with the simulator, and hit the reset button causing a sequential file number to be issued but no report (54T45;D-58). In another East Brunswick case where a subject provided a valid breath test but then had two subsequent readings of .000, Flanagan explained the results were caused by sucking air through the instrument (54T46-54T48;D-129;D-130). He gave a similar explanation for an AIR from the Haddonfield police department where a subject had a reading of .000 followed by two other readings of .14 (54T48-54T49;D-130).

In two other cases from Hopatcong and Chatham Borough, Flanagan noted that the officers had reported difficulty in entering times and dates (54T49). In Chatham, the operator could not enter the data because someone had checked the solution earlier and failed to hit the quick reset button, so instead the operator took the subject to another police department for testing (54T50). In Hopatcong, when the instrument would not allow the officer to enter the correct date and time of arrest, the officer intentionally entered the wrong date (54T51). Flanagan noted that the officer failed to follow his ADTU training to hit the quick reset button (54T51).

Flanagan also found that an operator in Middlesex Borough had violated training procedures by not waiting a full twenty minutes after the instrument reported a mouth alcohol error (54T52-54T58;54T67;D-134;D-135). In another case, he found that the number "4" repeatedly appeared on AIRs from Princeton Borough in the serial number space for the calibrating unit due to a problem with the side keyboard (54T63-54T64;D-142). Similarly, in Milltown Borough, he found that a control test failed to abort because the tolerances had been improperly set allowing the instrument to default to 10% (54T64-54T65;D-144).

Flanagan also addressed the issue of tolerance between two breath samples. In October 2005, the operator manual changed the explanation of tolerance to read "plus or minus .010 percent or plus or minus 10 percent of the average, whichever is greater" (57T96-57T97). The earlier manual had omitted the "plus or minus" (57T96;60T16). Prior to distribution of the revised manual, the training class coordinators taught the corrected version and wrote it on the board (57T97). The actual tolerance in NJ 3.11 never changed (60T16).

During the course of his testimony, Flanagan indicated that he would like to see several changes on the next firmware version, including the following additional information on the AIR: (1) the temperature probe serial number and probe value; (2) the serial number of the Ertco Hart temperature device used by the coordinator; and (3) the firmware version (53T36;60T23-60T24). He also recommended that the firmware be locked (meaning that if someone modified the software, it would be reported as modified on the AIR) and that the public receive some form of notice of future firmware changes (60T25-60T26;60T86-60T87).

Sergeant Flanagan was an excellent witness. This court finds him very honest and very reliable. He has an impressive knowledge of the Alcotest 7110 and has obviously worked very hard to master the nuances of the program and the instrument. From his testimony this court concludes that the Alcotest 7110 is far superior to the breathalyzer because it functions independent of operator influence and provides a detailed, accurate contemporaneous printout of all test sequences and results independent of any operator influence or possible subjective interpretation.

4. Summary of Testimony of State's Expert, Edward Conde

The State first presented the testimony of Edward Conde, a chemical engineer employed by Volpe in Cambridge, Massachusetts (1T41). As part of the Research and Innovative Technologies Administration, U.S. Department of Transportation (USDOT), Volpe conducts transportation-related projects including the testing and evaluation of evidentiary breath-testing instruments for government and private entities (1T41;1T81;2T40-2T41).[33] In 1996, 2003, and 2006, Volpe tested different firmware versions

[33] According to Conde, an instrument performs measurements whereas a machine performs work (1T98;1T107).

of the Alcotest 7110 to determine if they met the model specifications recommended by NHTSA (1T82;1T88;1T111;2T40). Conde participated in the 2003 and 2006 evaluations with New Jersey firmware versions 3.8 and 3.11, respectively (1T89;1T110-1T111;2T54;2T92-2T93;2T107;3T66).

Conde holds a Bachelor of Science degree in chemical engineering from Manhattan College (1T41). For twenty years, he has worked at Volpe in a variety of positions culminating in his January 2006 appointment as program manager of the Alcohol Countermeasure Support Laboratory, replacing Dr. Arthur Flores (1T41-1T43;1T101). Conde is a member of the International Association of Chemical Testing (IACT) and the United States working committee evaluating the recommendations for international breath-testing instruments set forth in a document prepared by the OIML (1T44).

The State offered Conde as an expert in the chemistry of breath testing (1T44). This is a summary of his testimony dealing with the NHTSA model specifications and the Alcotest 7110's scientific reliability.

Evidential breath-testing instruments precisely measure the concentration of alcohol from a human subject or a simulator (1T45). Volpe tests these instruments in the laboratory using a simulator or breath alcohol sample simulator (BASS), and does not perform human testing for a variety of reasons including, but not limited, to safety issues arising from alcohol dosing (1T46;1T52-1T53;1T109-1T110;1T112;2T17;3T62).

Volpe's testing protocol conforms to NHTSA's model specifications drafted in 1993 by Dr. Flores in conjunction with the National Institute of Standards and Technology (NIST), the government agency that controls measuring devices (1T47;1T57;2T23). Those specifications revised the 1984 version to accommodate work-place testing, to add testing for acetone interference,[34] and to meet new zero tolerance laws for underage offenders (2T22-2T23;3T52).[35] If an instrument successfully meets the model specifications to measure breath alcohol, NHTSA adds it to the conforming products list (CPL), which is amended periodically (1T49). NHTSA publishes the specifications and CPL in the Federal Register as recommendations to assist states in their purchasing decisions (1T47).

Generally, manufacturers contact NHTSA in writing to request testing of new instruments for type approval or re-testing where changes are proposed (1T76;1T78). Because NHTSA designed the model specifications to determine whether an instrument is accurate and precise, Volpe will only perform re-

---

[34] Acetone is a ketone found on the breath of diabetics and people on severe weight loss programs, which can produce false readings of breath alcohol (1T61-1T63).

[35] See 58 Fed. Reg. 48705 (Sept. 17, 1993).

testing if the proposed changes are likely to affect an instrument's accuracy or precision (2T17-2T18;3T14-3T15). Conde defined accuracy as a measure of how close the results get to the concentration that is being tested, and precision as a measure of the spread of data (1T53). As he explained, "if you're measuring at .080 and you [get] 10 measurements around .075, the instrument may not be accurate, but it is precise because it's giving you the same result every time" (1T54).

If deemed appropriate, NHTSA also will require testing upon special request by a state (1T80). The testing follows the same protocol used on instruments submitted by manufacturers (3T65). Thus, NHTSA requires re-testing of proposed hardware or software changes only if they are likely to affect an instrument's ability to return an accurate and precise result (1T77;1T79-1T80). For example, NHTSA did not require testing of the Alcotest 7110 MKIII-C because the sole change involved the instrument's capability to communicate with a computer (1T88). Conde pointed out that the model specifications encourage end-users to report any problems encountered in the field that may require re-testing (3T35).

Volpe conducts its tests under government contract and without any charge to the manufacturer (2T42). The manufacturer must submit a single instrument, operational and maintenance manuals, and any other relevant information such as basic diagrams or drawings (1T78-1T79;2T41;2T65;2T96). Volpe relies upon the schematics, among other things, to insure that the device remains essentially unchanged over time (1T79;2T27). If Volpe determines that an instrument no longer conforms to the CPL, it may be removed (1T80).

Volpe's protocol consists of eight steps or conditions: (1) precision and accuracy testing at alcohol concentrations of .02, .04, .08, .16, and .30 grams per 210 liters of breath; (2) interference testing for low and high levels of acetone, which can cause false readings; (3) blank testing to insure that a zero breath alcohol concentration does not produce a positive test result; (4) BASS testing to mechanically simulate a human subject blowing into a device at flow rates of .2, .3 and .5 liters per second, with durations of blow at six, ten, and twelve seconds; (5) power variation or voltage testing at 108 and 123 volts; (6) temperature testing at 20 and 30 degrees C for in-door bench-top devices such as the Alcotest 7110 as distinguished from hand-held devices; (7) post-vibration testing at the .080 level at three different orientations; and (8) basic electrical safety testing (1T53-1T54;1T60-1T67;1T69-1T70;1T73;1T77;1T106-1T107;2T46;2T97-2T98). For each condition, Volpe runs a series of ten tests and requires that the measurements be taken to three decimal places, that the mean falls within .005 or 5%, whichever is greater, and that all tests fall within a standard deviation of less than or equal to .0042 (1T74-1T75;3T50).

Volpe also does informal testing for RFI utilizing a Motorola HT 220 police-style walkie talkie operated at 170.4 megahertz from a distance of six feet in all four orientations (1T70-1T71). NHTSA does not require RFI testing because studies performed in the early 1980s found that such interference had a limited effect on breath-testing devices (1T71;2T10-2T13). Conde performed the informal RFI testing in 2003 only (1T72).

Additionally, Volpe tests the wet bath simulators used for control tests that introduce a certain concentration of alcohol into a breath-testing device (1T55-1T58). Control tests generally are performed by the end user who then compares the breath concentration of a human subject with the control test results (1T59). To get the proper concentration, the simulator temperature must be 34 degrees C (1T57).[36] With regard to human subjects, however, Conde acknowledged that a subject with a temperature higher than 34 degrees C who blew into a breath-testing device would tend to have an elevated breath alcohol

[36] On direct, Conde testified that the temperature had to fall within a range of plus or minus .01 (1T57). On cross, however, he said the range was plus or minus .1 (1T117). According to the Aloctest 7110 MKIII-C User Manual-Technical, the water-alcohol solution in the wet-bath simulator must be maintained at 34 degrees C plus or minus 0.2 degrees C (S-49 at 14).

content (1T119). Nonetheless, he did not recommend the use of breath temperature sensors (1T121).

Conde described the Alcotest 7110 as a bench-top breath alcohol device which uses IR and EC or fuel cell sensors to independently measure breath alcohol content in contrast to the Intoximeter EC/IR which uses the IR sensor to check for mouth alcohol only (1T85;1T87). He further noted that the Alcotest 7110 currently operates at a wavelength spectrum range of 9.5 microns in which acetone is virtually unnoticed (1T87).

In 1996, at the request of Draeger Safety Diagnostics, Inc., Volpe successfully tested a generic Alcotest 7110 MKIII (1T82;1T85;1T88;3T42-3T43). In 2003 and 2006, New Jersey requested special testing of the Alcotest 7110 MKIII-C with NJ versions 3.8 and 3.11 (1T89;1T93;3T62-3T64).

Of importance, Conde performed tests on NJ 3.11 from December 2005 to February 2006 (2T92;2T102). With Draeger's assistance, he bypassed the initial data entry field, claiming that it had no bearing on the instrument's accuracy and precision, and relied upon the internal printer so he did not have to do all the typing between tests (2T35-2T36;2T67-2T68;2T107). Conde's tests generated AIRs with sequential files numbers from 00059 through 00189, although some AIRs were not produced in discovery (2T102-2T105;3T10-3T14). With regard to gaps in the sequence, Conde explained that the instrument ejected pages whenever he started to enter data and was interrupted (3T10-3T16). He also discarded AIRs if they did not contain any data needed for type approval such as control test failures or if he did obtain the data point that he sought (3T9;3T21). Conde further explained that the model specifications only required him to retain AIRs which contained data needed for type approval or disapproval (3T11;3T15).

Conde acknowledged that there is a small range of error with any instrument used to measure breath alcohol in terms of discrepancies between an expected result and the one that the instrument actually returns (1T112;2T94;3T24). The model specifications, therefore, allow for some systematic or analytical error to account for any uncertainty with regard to an instrument's accuracy and precision (1T113-1T114;2T111). Nonetheless, Conde concluded that based upon his training and experience and the tests he performed, all three cycles of testing on the Alcotest 7110 met the model specifications, thereby indicating that the device —— including NJ 3.11 —— was suitable for use in an evidential environment to a reasonable degree of scientific certainty (1T93).

This court finds Conde very credible and candid, and was quite impressed with his testimony. This court accepts Conde's explanations that the discarded AIRs were simply incompleted test runs, bearing no relevance to the scientific reliability of the instrument. Conde was vigorously cross-examined by able counsel. His testimony was candid, forthright and impressive in every respect.

5. <u>Summary of Testimony of State's Expert, Rod G. Gullberg</u>

Rod G. Gullberg retired last year from the Washington State Patrol (State Patrol), where he held the rank of sergeant (7T58;7T61). He worked in the crime laboratory division and for twenty-three years, supervised the State Patrol's breath testing program (7T61;8T98). Gullberg currently works for the State Patrol in a civilian position as a research analyst (7T58). He writes curriculum for, and trains technicians in, the use of the Datamaster BAC and CDM, Washington State's breath-testing instrument (7T58;8T108). He also works closely with Barry K. Logan, the Washington State Toxicologist, on the formulation and development of breath-testing policy (7T59). Gullberg collects and analyzes breath alcohol data and prepares reports for police and traffic safety organizations (7T58-7T59).

Gullberg holds a Bachelor of Science degree in animal science from Washington State University (1971), a Master's Degree in public administration from Eastern Washington University (1978), and a Master's Degree in biostatistics from the University of Washington in Seattle (2003) (7T57;C-14, Gullberg CV). He is a member of the Northwest Association of Forensic Scientists and the American Academy of Forensic Sciences —— Toxicology Section, and serves on the National Safety Council's subcommittee on alcohol and other drugs (7T59). Gullberg defined forensic toxicology as a "mandated science," meaning that it was a science practiced within a legal environment consisting of statutes, case law, administrative rules, and policies (11T111-11T112).

He also teaches twice a year at the well-recognized Robert F. Borkenstein course at Indiana University and has written many articles on such subjects as breath alcohol measurement and blood-breath ratios (7T58-7T59;7T60;7T62). He is a qualified breathalyzer operator, technician, and instructor who testified as an expert on the breathalyzer numerous times in Washington state courts and on the blood-breath ratio in Downie (7T58;7T60;8T99-8T100;8T103). Additionally, in 2004, he performed several months of testing on an Alcotest 7110 instrument which Draeger loaned to the State Patrol for evaluation purposes (8T105-8T106;10T76-10T78). He is very competent and experienced in the areas of breath testing and biostatistics.

Prior to 1985, the State of Washington (Washington) used the breathalyzer which relied upon a partition ratio of 2100:1 to convert the alcohol-in-breath reading to an alcohol-in-blood reading, meaning that the alcohol concentration in the blood was 2100 times that in the breath (8T98-8T99;8T107;12T52;13T19).[37] The partition ratio derives from Henry's law, which applies to

[37] In the fall of 2006, the State Patrol planned to begin the evaluation of newer versions of breath-testing instruments including the Datamaster, Alcotest, Intoxilyzer and Intoximeter (8T108-8T110).

closed systems such as a simulator or the deep alveolar region of the lungs (11T90-11T91). Henry's law states that in a closed system and at a given temperature, there is a fixed ratio between a volatile substance, such as alcohol, in a liquid and the same volatile substance in a gas (7T83-7T84;11T90-11T92).

The partition ratio describes the equilibrium which exists when a gas (ethyl alcohol) is placed in a simulator (closed container) containing a solution heated to 34 degrees C with air in the headspace above it (7T84;7T87;11T92-11T94). Because alcohol is volatile, it will partition itself between the solution and air (7T84). The resulting equilibrium is known as the partition coefficient or ratio of the concentration of alcohol molecules in the solution to the concentration of alcohol molecules in the air in the headspace (7T84).

A similar process exists in the alveolar area of the lungs where alveoli (tiny air sacs at the end of the respiratory track) come into contact with capillary blood, which contains alcohol (11T94-11T96;12T21-12T22). At the higher alveolar temperature of 37 degrees C, the partition ratio is 1756:1, or 1756 parts of alcohol in the blood to one part in the air (7T85-7T86). As the temperature rises, more alcohol molecules will emerge into the vapor (11T96). It is noted here that Gullberg was aware of the theory that alcohol in breath samples also came from the airways, not the alveoli (12T46). He noted that interaction of alcohol with the airways was one factor in why breath alcohol concentration could vary (12T46).

While the partition ratio applies to the deep lungs, Gullberg said it does not apply to measurements of end-expiratory breath and venous blood which do not come into contact with each other (8T5). To describe the relationship between those two independent measurements, Gullberg preferred the term "blood-breath ratio" which he described as the ratio of two measurements consisting of blood alcohol concentration divided by breath alcohol concentration (8T5;9T8;13T58-13T59). Because a person's blood-breath ratio varies from time to time and even within the same breath exhalation, Gullberg emphasized that that there was no uniform agreement among populations about this ratio (8T16;9T7;10T103;11T105). Thus, he testified that Great Britain and the Netherlands use 2300:1; Norway and Finland use 2100:1; and Austria and France use 2000:1 (10T101-10T102).

To support his testimony concerning the range of blood-breath ratios, Gullberg cited a single-breath study conducted by Dr. A.W. Jones of 793 individuals in Sweden who were arrested for driving under the influence and found that the mean ratio was approximately 2411:1 with a standard deviation of 205 (8T6-8T7;8T15).[38] Jones' study found that thirty-four individuals or

---

[38] See A.W. Jones and Lars Anderson, Variability of the
Footnote continued

4.3% had a blood-breath ratio below 2100, meaning that their breath measurement overestimated their blood alcohol values (8T7-8T9).

After plotting Jones' raw data on a graph, Gullberg observed that for most of these thirty-four subjects the overestimations were harmless false positives because the breath exceeded the blood and both were over .08 (8T10;12T104). For those individuals with false positive results (such as a breath alcohol reading above .08 and a blood alcohol reading below .08), Gullberg agreed that more weight could be given to clinical observations drawn at and after the time of arrest (8T12).[39]

Over the years, Gullberg has conducted a series of studies on individuals involving the near-simultaneous taking of breath and venous blood samples, the latter of which were read by gas chromatography in his toxicology laboratory (8T22-8T23). In one side-by-side study, a twenty-eight-year old volunteer gave a

---

Blood/Breath Alcohol Ratio in Drinking Drivers, 41 J. Forensic Sci. 916 (1996) (D-19).

[39] In support of his statement that the blood-breath ratio varied among populations, Gullberg briefly mentioned a study in New Zealand which analyzed single and double breaths from 21,000 subjects (8T15). He evidently was referring to A.R. Gainsford, et al., A Large-Scale Study of the Relationship Between Blood and Breath Alcohol Concentrations in New Zealand Drinking Drivers, 51 J. Forensic Sci. 173 (2006).

very long exhalation which showed a rise in the breath alcohol curve with a corresponding horizontal line representing the blood alcohol (8T22-8T23;S-11). In another study, a subject was dosed with a specified alcohol concentration and every fifteen minutes over a seven-hour period, technicians collected duplicate blood and breath samples (8T25-8T26;10T109;S-10).

Gullberg's studies confirmed that the blood-breath ratio was not the same for every individual, that it was not constant within an individual, and that it tended upwards over the course of an exhalation as alcohol was eliminated (8T21-8T23;8T25-8T26). In any event, Gullberg did not consider the ratio to be a fundamental element of the breath instrument or to effect its ability to make accurate measurements (12T128-12T129).

Given the range of extant calculated partition ratios, Gullberg recommended that drunk-driving statutes avoid the blood-to-breath comparison by adopting a breath alcohol standard and if not, that courts give greater weight to the clinical picture at and after a subject's arrest along with the surrounding circumstances (8T11-8T12). In any event, he agreed that the 2100:1 ratio usually underestimated the amount of alcohol in the blood, thereby favoring the defendant (8T15). New Jersey's protocol of taking four breath measurements from two separate samples, selecting the lowest reading, and truncating the results to two decimal places further benefited the defendant by producing more results on the low side, with truncation alone favoring the defendant 90% of the time (9T9;10T63-10T64).

In some cases, however, Gullberg recognized that the 2100:1 partition ratio resulted in readings on the high side (8T18). He was unwilling to predict how often that would happen in a general population, noting that it depended upon several factors such as the analytical methods used (8T18).

Unlike the variation in breath samples, Gullberg testified that blood alcohol sampling was more precise primarily because an individual cannot influence the results (8T61;9T7). Both methods, however, are analytically equal with the gas chromatograph (used to take blood alcohol readings) and the Alcotest 7110 of equal precision (8T61;9T7). With regard to New Jersey's breath-testing protocol, he stressed the importance of ambient air blanks to purge the instrument, control tests which relied on reference standards traceable back to the NIST to insure its accuracy, and two separate breath samples to account for any biological variability, insuring the precision or repeatability of the measurement process (8T59-8T60).

Gullberg further explained that the use of a tolerance standard within the four tests on the two separate samples allowed for the increasing variation that existed in breath alcohol measurement (8T65-8T66;8T68). Gullberg testified that

New Jersey's tolerance or agreement standard varied for values below and above .10 (8T65). Specifically, he stated that the tolerance between four tests (two IR and two EC) with a mean below .10 must be within .01 grams per 210 liters, but at .10 or greater, it must be within plus or minus 10% of the mean (8T63;9T67;12T12). In comparison, Washington's tolerance was plus or minus 10% of the mean of duplicate breath alcohol measurements throughout the entire range (8T63;9T27-9T28).

Gullberg thought that New Jersey's and Washington's tolerances were too imprecise, noting that New Jersey's tolerance of plus or minus 10% was "rather broad" and Washington's tolerance also was "a little too generous" (8T66-8T67;10T72). He preferred a plus or minus 5% standard which would have a greater power to detect errors (10T90;12T15). He noted that the National Safety Council recommended that duplicate breath test results should have an absolute –– as opposed to relative –– tolerance of .02, which other states have adopted (8T68-8T69;12T109;12T120;D-27).

Gullberg analyzed the data from Middlesex County in order to estimate the standard deviation in breath alcohol measurement (8T42-8T43). He examined only those individuals who had acceptable first and second breath tests, which consisted of 1334 duplicate breath alcohol results out of the total sample of about 1900 tests (8T65;9T20;13T5). For those individuals, Gullberg plotted a scattergram showing that 95% fell below .02 and about 5% fell outside of the tolerance of plus-or-minus 5% of the mean (8T70;13T58;S-18). Gullberg explained that subjects whose tests fell outside the tolerance should be retested (13T58).

Gullberg also analyzed unpublished Alabama data to determine minimum breath volume (8T71). Specifically, he examined first and second breath samples taken on an Alcotest 7110 (IR readings only) provided by individuals who were about to be released the morning after their arrests (8T73;10T22). Of the 15,000 subjects who provided the first breath samples and 14,300 subjects who provided the second breath sample, only 4.1% and 2.5% respectively had volumes below 1.5 liters (8T75). Based on the presumption that those subjects willingly provided the samples in anticipation of their release, Gullberg concluded that most people have the biological capability of meeting New Jersey's minimum volume requirement (8T79).

Gullberg did acknowledge, however, that females tend to have difficulty achieving 1.5 liters as they get older (10T34). Specifically, his analysis showed that breath volume of females dropped dramatically around age seventy-five (10T34). He further acknowledged that a study of 4000 subjects in Germany showed that females between the ages of sixty and sixty-nine years produced on average 1.4 liters of air (10T35;AB2). Other biological factors affecting the delivery of a breath sample included lung capacity and how a subject exhaled (12T30-12T31). Washington, like New Jersey, has a minimum volume requirement of 1.5 liters (8T119).

Gullberg also concluded that New Jersey's protocol had adequate safeguards against mouth alcohol, including: a twenty-minute observation period which he considered the most critical; duplicate breaths tests which had to fall within predetermined acceptable limits; and a slope detector which monitored each exhalation (8T82;12T87). Gullberg relied in part on an experiment in which he repeatedly administered mouth alcohol to a single individual who then spit it out and exhaled directly into the Datamaster (8T82-8T83). After collecting several samples, Gullberg found that it took seven minutes for depletion of mouth alcohol in an individual with a reading of .103 (8T86). He concluded that a fifteen-minute observation or deprivation period was more than sufficient (8T87-8T89). He also observed that slope detectors could be "fooled" by someone who had consumed alcohol (12T80).

In addition to New Jersey's protocol for detecting mouth alcohol bias, Gullberg wrote in his expert report that the protocol for detecting RFI, electronic component failure, and interfering substances ensured a high probability of error detection (C-14, Gullberg report at 5). He stated that the instrument's algorithms monitored for the presence of other errors (C-14, Gullberg report at 5). Specifically, he calculated that errors occurred approximately 3.8% of the time (C-14, Gullberg report at 5-6). After quantifying all relevant sources of uncertainty, Gullberg concluded that a high degree of confidence could be assigned to breath test results arising from a full analytical run which complied with all quality control criteria (C-14, Gullberg report at 17). When asked if he agreed with a 1987 article written by Dr. Gerald Simpson who concluded that the error for all subjects in post-absorptive breath alcohol testing was as high as 22% (for 99% confidence) or 15% (for 95% confidence), Gullberg declined to do so without more information on how error was defined (12T114-12T115).

With regard to breath temperature, Gullberg noted that it varied within a population (9T44). He was aware of recent studies showing that normal breath temperature was closer to 35 degrees C, and not the 34 degrees C assumed by the Alcotest 7110 (9T44;11T107-11T108;AB2). Nevertheless, Gullberg considered temperature to be "totally irrelevant" to the measurement of breath alcohol (12T34). Thus, he opined that it was not necessary to subtract 6.8% (used in Alabama) or 6.59% (advocated by Schoknect and Stock) from the recorded breath result to account for a higher temperature because the breath instrument was designed to accurately measure the alcohol concentration in the sample it received (9T13-9T14;9T33-9T34;9T37-9T38;13T60). Thus, both readings —— at 34 and 35 degrees C —— are analytically correct and even if there is some uncertainty in the measurement, they are fit for purpose or appropriate in the context for which they are being used (9T38-9T41;10T102). Indeed, Gullberg testified that there was uncertainty and error in all measurements, and that all technology was limited (11T112;12T103).

As for software-related issues, Gullberg testified that he did not know anything about the technical details and did not care if algorithms varied among instruments (13T8-13T9). He also did not care if software or hardware was different for purposes of evaluating a breath instrument's accuracy and precision (13T55). Instead, he cared about final test results and if they met his expectations after completion of New Jersey's thirteen-step protocol (13T9;13T12;13T14). If a critical error occurred which would affect his confidence in the analytical result, he would expect the Alcotest 7110 to abort the test (13T15). While he did not necessarily care if a record was made, he later admitted that error reports might be useful (13T15;13T50). Prior to the purchase of new breath-testing instruments, however, Gullberg advised that the software should be checked for reasonable integrity by an independent laboratory (13T52-13T53;D-16).

Since the Datamaster's introduction in Washington, Gullberg reported that it had undergone several changes in software and hardware (13T29;13T32). To check the instrument's measurement system for possible errors, Gullberg and others studied information sent to a central computer, reviewed reports from officers in the field indicating possible errors, and performed experimental tests in the laboratory on human subjects to explain invalid samples such as the misidentification of mouth alcohol (13T26;13T29-13T31). National Patent Analytical Systems, Inc., the Datamaster's manufacturer, also provided him with details of its algorithm and, upon request, has provided others with the source codes under protective order (8T110-8T111;13T36-13T38). Gullberg, however, never felt it necessary to examine them (13T55).

Gullberg concluded that test results obtained from the Alcotest 7110 were reliable when all of the criteria were met (8T96). He was confident in the instrument's measurement results based upon his review of New Jersey's protocol, training program, documents, and the printout of test results (13T60-13T61).

This court found Gullberg a very sincere and forthright witness and technically very well-qualified. This court considers him very honest and reliable.

6. Summary of Testimony of State's Expert, Samuel E. Chappell

Samuel E. Chappell holds a doctoral degree in physics from Pennsylvania State University and spent thirty-eight years at the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards, United States Department of Commerce (3T70-3T73). He started working at NIST as a bench scientist in the Radiation Physics Division; he retired in 2000 as head of NIST's Office of Technical Standards Program (3T74). From 1987 until his retirement, Chappell served as the NIST-appointed United States' technical representative on the OIML and vice-president of its international committee (3T75-3T77;3T168). Beginning in 1994, Chappell also served on OIML's subcommittee which developed recommendations for evidential breath analyzers (3T79;3T86).

Chappell currently is a consultant in legal metrology and radiation physics (3T70). He has written more than fifty peer-reviewed technical publications —— albeit none of them addressed breath-testing instruments —— serves on the appeals board of the American National Standards Institute (ANSI), and is an honorary member of OIML's international committee (3T81-3T83). Based upon Chappell's training and experience, this court found he was experienced and competent in the field of legal metrology which includes evidential breath-testing instruments (3T87).

Legal metrology is the study of instruments used for legal measurements (3T70). As our national metrology laboratory, NIST is responsible for establishing, maintaining and publishing basic standards of measurement consistent with their international counterparts (3T73;3T87). NIST also engages in research and development projects for other federal agencies regarding needs for standard measurements (3T73).

Chappell described evidential breath analyzers as instruments that sample a subject's breath to determine the concentration of alcohol (3T87). To obtain confidence in any legal measuring instrument, Chappell outlined a three-step process of metrological control: (1) type evaluation or approval; (2) initial verification; and (3) subsequent verification (3T88).

Type evaluation refers to tests performed on an instrument by an entity in accordance with documented standards (3T89;3T157-3T158). It also involves the preparation of a report which appropriate officials then can use to issue type approvals (3T89). In the United States, NHTSA is responsible for type evaluations of evidential breath-testing instruments including the development of model specifications, the preparation of a report on each instrument it tests, and the dissemination of a conforming products list (CPL) to assist end users such as states which use these instruments (3T89-3T91;3T93-3T94).

Chappell reviewed the summaries of the three type-evaluation tests performed by NHTSA on the generic Alcotest 7110 MKIII, and New Jersey firmware versions 3.8 and 3.11 (3T95-3T97). Successfully passing these tests, the Alcotest 7110 satisfactorily completed the first step in the metrological control process (3T97).

Chappell also offered testimony on international type evaluation and approval standards recommended by OIML, an international treaty organization established in 1955 to address issues relating to the application of common legal measurements by its member countries (3T76;3T97;3T156-3T157). The organization has 113 members with fifty-nine full voting members, including the United States which joined in 1972, and fifty-four corresponding or non-voting members (3T99). Under the OIML certificate system, legal measuring instruments must be evaluated in accordance with certain performance criteria and testing methodology, and results must be reported in a standardized format (3T98).

In 1998, OIML published Recommendation 126, which applies to evidential breath analyzers that automatically measure the mass concentration of ethanol in exhaled breath (D-4). The recommendation incorporated the framework of the OIML certificate system by establishing metrological characteristics required of such instruments, specifying methods and equipment for checking their conformity, and mandating a test report format (3T98-3T99;D-4). To be OIML certified, the evidential breath analyzer must successfully pass the tests performed at one of five OIML-approved laboratories. If so, the International Bureau of Legal Metrology in Paris will include it on the list of qualified instruments (3T99;3T105).

Chappell said that OIML's standards are more stringent than NHTSA's 1993 model specifications currently in use (3T101;3T104;3T170-3T173). For example, Recommendation 126 advises testing for nine interferents; NHTSA tests only for acetone (3T104). Recommendation 126 also recommends tests for RFI or electromagnetic compatibility over a range of electromagnetic frequencies and at specified field strengths, which NHTSA does not require (3T104). Additionally, OIML's recommendation includes tests for such physical disturbances as vibration, mechanical shock, electrostatic discharge, damp heat cycles, and storage ambient conditions, among other things (3T183-3T185).[40]

---

[40] For a full description of all mandatory tests for physical disturbances, see "Annex D" of OIML Recommendation 126 (D-14 at 18-21).

In Chappell's opinion, the international standards reflect the European preference for more rigorous legal measurement and uniformity in metrological control (3T178-3T179). For NHTSA to adopt the more rigorous OIML standards, it would, among other things, have to acquire additional equipment at a significant investment (3T104-3T105). While acknowledging that the OIML standards were more complete, Chappell did not consider an instrument which met the NHTSA standards any less reliable (3T174;3T185-3T186).

A manufacturer, however, may elect at its own expense to have its instrument tested for OIML compliance (3T105). In 1994, Draeger submitted an Alcotest 7110 MKIII —— without NJ firmware —— to the National Measurement Laboratory for the Netherlands (3T106). This OIML-compliance testing was undertaken in accordance with both British regulations which followed the third or 1993 draft of the OIML which, unlike Recommendation 126, required testing for sixteen interfering substances and with Dutch regulations which required testing for an additional seven or so compounds (3T113-3T114;3T163). The Alcotest 7110 passed the more rigorous Dutch OIML test (3T114).

With regard to the second and third steps in the metrological control process, Chappell reviewed documentation concerning New Jersey's breath-testing protocol relating to the initial verification performed on each new instrument and the subsequent verification performed at least once a year or after an instrument has been repaired or a component replaced (3T114; 3T136). The initial verification confirms that the manufacturer is capable of making an instrument that meets the model specifications; the subsequent verification confirms that the instrument did, in fact, meet them (3T115). In Chappell's opinion, New Jersey's verification of the Alcotest 7110 went beyond the normal requirements of metrological control (3T138). Chappell, however, noted that OIML's tolerance recommendation for initial verification was equivalent to New Jersey's 5% requirement for control tests but for subsequent verification, it was smaller (4T33). He also noted that OIML's member nations rejected a proposal by German experts to require breath temperature measurements (4T28-4T29).

Based upon his training and experience, and his review of the NHTSA standards, the OIML recommendations, and New Jersey's protocol, Dr. Chappell concluded that the Alcotest 7110 MKIII-C was suitable for its intended scientific purpose (3T138). His testimony was fully credible in every respect.

7. Summary of Testimony of State's Expert, Barry K. Logan

Barry K. Logan received his doctoral degree in forensic toxicology from the University of Glasgow, Scotland in 1986, and is board-certified by the American Board of Forensic

Toxicologists (4T35-4T36). Since 1990, he has been the Washington State Toxicologist and since 1999, the Director of the Washington State Patrol (4T36-4T37;6T33). For the last sixteen years, Logan also has been a clinical assistant professor in the Department of Laboratory Medicine at University of Washington's School of Medicine (5T10-5T11).

During his lengthy career, Logan has been a member of many professional societies, taught extensively on issues related to drug and alcohol testing, trained personnel throughout the United States in blood and breath alcohol programs, and published numerous peer-reviewed articles on breath alcohol testing as shown on his impressive curriculum vitae (4T38-4T39). One of his recent publications described a proposed proficiency-test program based upon the evaluation of several instruments including the Alcotest 7110 (4T39-4T40). He also has extensive experience in state and federal courts as an expert in blood and breath alcohol measurements (4T36;4T40-4T41).

As the Bureau's director, Logan oversees eight laboratories with a staff of about 180 people who specialize in a range of areas including, but not limited to, forensic science and toxicology (4T36). He manages the laboratory system, works with the state's Legislature on issues relating to blood, breath and drug testing, and writes administrative rules for breath testing (4T37). As state toxicologist, Logan also is responsible for approving protocols used in blood, breath and drug testing programs (4T41-4T42).

Although he is not an expert in physiology, Logan described the various stages of alcohol absorption, distribution, and elimination. After being ingested orally, he explained that the alcohol enters the stomach, is absorbed through the walls of the intestine, and then is carried by the bloodstream to the liver, the right side of the heart, the lungs, and the left side of the heart (4T42-4T44). The arterial system distributes the alcohol to all the water-bearing tissues including organs, muscle, and the brain (4T43-4T44). When it reaches the brain, the alcohol's effect on a person's performance begins (4T45). The alcohol then returns through the venous system in a lower concentration to the liver, the heart, the lungs and back into the arterial system (4T44). Some of the alcohol is excreted in urine (4T45). During the absorptive (pre-peak) phase, the arterial blood going to the brain has a higher concentration of alcohol than venous blood (4T46-4T47). After peak absorption, however, venous blood alcohol is higher (4T47-4T48). Generally, the rate of absorption depends upon a number of factors including the amount of alcohol consumed and the rate of drinking (4T49). The faster the rate of absorption, the more substantial the difference between the arterial blood and the venous return (4T49).

Blood sample alcohol laboratory testing almost always relies on venous blood because it is easier and safer to collect (4T50). Because alcohol remains stable in blood for a long period of time, blood specimens are ideal for legal measurements because they can be retested (4T50-4T51). As with any measurement, however, blood testing is subject to error and variability depending upon the equipment and protocol in use (4T51). Blood is more difficult to collect in the field, requires a trained person to collect the sample, and should be refrigerated prior to testing (4T51). After testing, it should be frozen (4T51). For legal purposes, blood should be drawn in vacuum tubes with anti-coagulant and anti-bacterial agents to avoid contamination (4T51-4T52). Moreover, each time a tube of blood is opened, some vaporized alcohol is lost from the headspace above the liquid (4T52). Blood samples also do not yield immediate results (4T52).

In contrast, breath samples can be taken much more easily using a highly-automated procedure which permits very little, if any, operator influence over the results (4T53). The results are available immediately to police officers who use them to decide whether to charge a subject with intoxication (4T53).

As Logan explained, when blood is forced from the right side of the heart to the lungs any volatile substances such as alcohol will pass through the very thin membranes of the air sacs called alveoli and escape into the inhaled air (4T53). Some of that alcohol eventually passes out through the body when a subject exhales (4T53). The initially exhaled breath comes from a subject's upper airway, i.e., mouth and throat, and typically has only small amounts of alcohol (4T54-4T56). The concentration rises rapidly as a subject evacuates the upper part of the airway, but rises more slowly as the air comes from deeper in the lungs and the rate of increase in the end-expired breath is very low (4T55-4T56;6T44). Breath alcohol concentration never completely reaches a plateau but continues to increase as long as a person exhales (6T42). The actual shape of the curve (or the exhalation profile), however, is influenced by such factors as how fast a subject blows into the breath-testing instrument or the presence of mouth alcohol (6T106;6T109-6T110). To obtain a sample that is as close as possible in equilibrium with the arterial blood, Logan advised using end-expiratory breath (4T56).

Logan preferred the term "blood-breath ratio" to describe the correlation between the concentrations of alcohol in the breath and blood (4T58). He did not suggest using the term "partition ratio" given its meaning in physical chemistry to explain the degree to which a volatile substance will partition between two phases, typically air and water (4T57). Whereas there is a defined air/water partition coefficient for alcohol (or ethanol) in the simulator used to calibrate the Alcotest, many different variables, physiological and environmental, influence the concentration of alcohol in breath verses blood in the lungs (4T57-4T58;6T20). The blood-breath ratio differs among individuals and to some extent from breath-to- breath in the same person (4T58). While researchers generally agree there is a range of blood-breath ratios for the population at large, they disagree about the limits or extremes (6T120).

Logan relied upon two side-by-side (or simultaneous) blood and breath studies conducted on impaired drivers which concluded that the true (or average) post-absorptive blood-breath ratio was approximately 2400:1 (4T59-4T60;4T69-4T71;4T73;6T120-6T121;6T132;7T55). Specifically, he cited a 1996 study by A.W. Jones and L. Andersson which placed the blood-breath ratio at 2407:1, and a 2006 study by Gainsford and others which reported ratios of 2510 plus or minus 256; 2370 plus or minus 240; 2520 plus or minus 280; and 2440 plus or minus 260 (4T73).[41]

Logan testified that the 2100:1 ratio as adopted by the Court in Downie, 117 N.J. at 468, underestimates a subject's

[41] Among others, Logan was referring to the following studies: A.W. Jones and L. Andersson, Variability of the Blood/Breath Alcohol Ratio in Drinking Drivers, 41 J. Forensic Sci. 916 (1996) (D-19); and A.R. Gainsford et al., A Large-Scale Study of the Relationship Between Blood and Breath Alcohol Concentrations in New Zealand Drinking Drivers, 51 J. Forensic Sci. 173 (2006)

true blood alcohol concentration by ten to fifteen percent (4T74). For legal purposes, therefore, a lower conversion ratio favors the accused in most cases (6T123;6T131). By reporting more breath test results on the low side, the lower ratio compensates in part for the range of physiological variables such as length of exhalation time, breath volume, and body temperature (6T118-6T119;6T122-6T132). Logan noted, however, that Jones' study also found that 4.3 percent of his study population had an actual blood-breath ratio less than 2100:1 and for them, the Alcotest overestimated the blood alcohol in their breath (7T33).[42]

Although Washington State uses the Datamaster, Logan was familiar with the Alcotest 7110 and its two technologies: IR and EC (4T74;4T82-4T83;4T86-4T87;6T56). IR technology has been used since the late 1970s and is universally found a reliable technique in evidential breath testing (4T75). The breath sample is placed into a chamber, or cell, where one side admits infrared energy and the other side detects or measures how much of that energy is transmitted through the chamber (4T74). The

[42] The State of Washington does not use the blood-breath ratio because the applicable driving-under-the-influence statute specifies that a per se offense consists of a blood alcohol concentration of .08 grams per 100 mass or a breath alcohol concentration of .08 grams per 210 liters, thereby eliminating the requirement for a blood-to-breath conversion (5T11-5T14;7T29).

alcohol molecules absorb the selected infrared wave length which shines through the cell to a degree proportional to the alcohol concentration in the chamber (4T74-4T75). To reduce the risk of the "only universally accepted meaningful potential interferent," the Alcotest 7110, NJ 3.11 uses an infrared wave length of 9.5 microns which prevents the absorption of acetone by the alcohol molecules (4T76;4T84;4T110;4T112). IR monitors over real time how the breath alcohol concentration changes in the chamber (4T83). Logan pointed out that the Datamaster uses IR technology, but not at the 9.5 micron frequency (7T28).

Likewise, EC technology is a well-established technology used for many years in screening devices (4T82). In the Alcotest 7110, after a sample is measured by IR absorption, a portion of that sample is aspirated or sucked into a one cc chamber containing the fuel cell (4T83). The fuel cell is a porous ceramic matrix containing a carbon metal catalyst which oxidizes or breaks down when it interacts with alcohol and in the process emits electrons which are measured to determine alcohol concentration (4T77;4T83;5T83). As fuel cells wear down over time, they respond more slowly and may become contaminated (5T84). Their performance, however, can be assessed by looking at the data generated (5T85). While recognizing the general reliability of both technologies, Logan also acknowledged that any quantitative measurement has some inherent error given the range of human biological variability (5T16-5T17).

Although he did not personally conduct any testing on the Alcotest 7110, Logan reviewed the reports of test results performed on the instrument by Volpe in 1996, 2003, and 2006 in connection with NHTSA's type-approval (4T86;5T61). He noted that the instrument repeatedly met the requirements during all three cycles of testing, but he did not actually review the underlying data (6T114-6T115). Logan also relied upon the results of New Jersey's testing program using known vapor phase standards from a wet-bath simulator which showed that the Alcotest 7110 was capable of making measurements within 5% of the reference or control value (4T89).

Additionally, Logan assessed the findings of tests conducted in connection with his recently-published proficiency study by an unnamed state jurisdiction on the Alcotest, using various undisclosed concentrations of ethanol including one containing acetone (4T87). According to Logan, the results indicated that the Alcotest accurately read the alcohol in the unknown specimens and was not influenced by the presence of acetone (4T88).

With regard to the instrument's precision, Logan recognized that the Alcotest 7110 tested for two kinds: precision between two readings in the same sample; and precision between four readings in the two samples (7T43). Regarding the latter, he expressed some confusion over the formula but believed that all four results must lie within plus or minus 10% of the mean for results above .10, but within .01 of the mean for results below .10 (7T18;7T53). Because there is greater variability at higher breath alcohol concentrations, Logan recommended using a variable standard to avoid the risk of too readily getting legally inadmissible test results (7T24). Moreover, he thought that the range of 20% around the mean was scientifically reliable given that the variable had a biological component (7T53).

Logan also reviewed elements of New Jersey's breath testing program (4T89). He observed that New Jersey's protocol of conducting control tests during each subject's testing was sufficient to verify the instrument's ability to accurately measure the sample, and was the "best scientific practice" (4T90). Logan also said that New Jersey's practice of conducting duplicate tests was good scientific practice (4T96). For example, he said that the use of two separate breath tests served as a check on accuracy by showing that even with significant biological variation in breath exhalation, the measurement was reproducible within limits (4T96).

Additionally, he said that New Jersey's testing sequence is an automated process over which an operator had very little influence (4T91;4T96). In his opinion, the testing sequence which consisted of five air blanks, two control tests (Washington State does one), and two subject tests was one of the most rigorous protocols in the United States (4T90-4T95).

According to Logan, New Jersey's minimum volume requirement of 1.5 liters was common practice among the states (4T100). While he was aware that Alabama's minimum requirement was 1.3 liters, Logan noted in his expert report that the most comprehensive data set on this issue came from an Alabama study showing that 97% percent of more than 15,000 test subjects were able to provide breath samples of 1.5 liters (4T100).

Moreover, he said that the 1.5 liters requirement ensured that, on average, the breath sample came from a fairly level phase of the exhalation curve (6T45-6T46). Logan reached that conclusion based in part on his study over an eight-to-ten-year period of 100 individuals who provided several hundred breath-exhalation profiles after being administered alcohol in an experimental setting and about a dozen individuals who had been arrested for drunk-driving (6T45-6T51). Of those individuals, approximately forty also submitted venous blood samples for testing (6T52). While acknowledging that breath volume could be effected by a person's size and that a person with a longer exhalation could have a higher reading, Logan maintained the 1.5

liter minimum requirement ensured that the subject was delivering end-expiratory breath (6T118;6T141;7T54-7T55).

He also said that New Jersey's twenty-minute waiting period was "more than acceptable" to allow for the dissipation of mouth alcohol and noted in passing that Washington's "acceptable" waiting period was fifteen minutes (4T104;4T107-4T108;5T32). During that time, however, Logan stressed that there should be face-to-face observation to make sure that the subject does not have access to anything that could influence the test results (6T144-6T145). Logan viewed New Jersey's two-minute lockout between duplicate tests and a slope detection system as additional safeguards to ensure against mouth alcohol interference by allowing time for dissipation and monitoring of abnormal breath profiles (4T104-4T106;7T34-7T35;7T54).

Logan did not believe that there was any reason to monitor breath temperature with a sensor (4T101;6T151). Noting that average breath temperature of human beings had not changed in at least twenty years, Logan explained that it was just one component that explained variability and that it already was accounted for by adopting a blood-breath ratio of 2100:1 instead of the true ratio of 2400:1 (4T102-4T103). He is aware of only one state, Alabama, which measures breath temperature (5T18). Nonetheless, Logan acknowledged that if all other factors are equal between two individuals, the one with the higher temperature would have a higher breath alcohol concentration (6T124).

Logan also did not believe that it was necessary to review the source codes and algorithms in order to determine a breath-testing instrument's reliability (5T23-5T24). Instead, he relied upon the data that the instrument produced (5T24). For example, Logan believed that Washington State's quality assurance program consisting of control tests, linearity tests, and calibration checks provided all the information necessary to determine how an instrument was performing (5T24). Logan assessed an instrument's performance by presenting it with a variety of samples of known alcohol concentrations and then reviewing the results to see if they agreed with his expectations for accuracy and precision (5T73;5T90).

Logan has never asked for the Datamaster's source codes and even if an expert analyzed them, Logan doubted that the exert could tell him whether the instrument would, in fact, provide accurate results (5T24). He noted, however, that on at least two occasions, the manufacturer did provide under court-order copies of Datamaster's source codes to Washington's defense bar and, over the years, provided his state with the algorithms used to calculate various aspects of the test results (5T25;6T57).

Based upon the materials he reviewed, his training, and experience, Logan concluded to a reasonable degree of scientific certainty that the Alcotest 7110, NJ 3.11 was accurate and reliable, and that New Jersey's program was scientifically sound (4T121-4T122). In his opinion, the program had the necessary procedural and administrative elements, including: the collection of data with every breath test showing the instrument was operational; the use of periodic linearity testing demonstrating the instrument was properly calibrated; the agreement of breath test results indicating the instrument's ability to measure reproducibly; and the use of two control tests showing the instrument read accurately and precisely at the time the subject was tested (4T122). Logan was an impressive witness and his testimony was concise, understandable and persuasive.

8. Summary of Testimony of State's Expert, J. Robert Zettl

Zettl has a Bachelor of Science degree in bacteriology with a minor in physical chemistry from Pittsburg State University in Kansas (1964), and a masters degree in public administration from the University of Colorado (1991) (13T64;14T78). For thirty-three years, he worked in the alcohol test unit, later known as the toxicology unit, at the Colorado State Department of Public Health and Environment (13T64-13T65). As the unit's first employee and its chief for many years, Zettl developed rules and regulations relating to the taking of blood, breath and urine specimens which the Board of Health (BOH) promulgated under the state statute for driving under the influence of alcohol or drugs (DUI statute) (13T65-13T66;13T68-13T69;14T95).[43]

After retiring in 1998, Zettl established Forensic Consultants, Inc. to provide assistance in the development and implementation of breath alcohol test programs (13T66). Among other things, his consultant work includes: inspecting laboratories for compliance with the National Laboratory Certification Program; teaching at various venues including the Borkenstein School in Bloomingdale, Indiana where he provides instruction on the Alcotest 7110, Intoxilyzer 5000 EN, Datamaster CDM, and the Intoximeters I and II; and training law enforcement officers, forensic scientists, and attorneys on breath alcohol and other drug-testing devices (13T66;13T70-13T72;15T52-15T55). Robert Borkenstein invented and patented the breathalyzer instrument in 1954 (13T71;15T56).

Zettl belongs to several professional organizations, serves as an executive board member on the National Safety Council Committee on Alcohol and Drugs, and has written six peer-reviewed articles on alcohol testing (13T71-13T73). He has

[43] While the BOH held public hearings as part of Colorado's rule-making process, New Jersey did not hold any such hearings in connection with its adoption of the Alcotest 7110 (13T67-13T68).

testified numerous times as an expert in alcohol-related cases in Colorado (both jury and bench trials) and thirteen other states (13T74). He qualified here as an expert in forensic toxicology specifically relating to alcohol breath testing (13T75;13T90).

Beginning in the mid-1970s, the State of Colorado has used intoxilyzers to measure breath alcohol (13T80). It currently uses the Intoxilyzer 5000EN manufactured by CMI, Inc. in Owensboro, Kentucky (13T96;13T98;14T54). CMI does not reveal its source codes nor did Zettl believe it was necessary to see the code in order to complete Colorado's validation of the instrument (13T96-13T97). In fact, he admitted that he would have no use for it (13T100).

Zettl also has worked with a generic Alcotest 7110 MKIII-C in Colorado and received limited exposure to New Jersey firmware version 3.11 on June 8 and 9, 2006 (13T80-13T81). At that time, Zettl went to the New Jersey State Police Bordentown Station and Forensic Science Laboratory where he evaluated New Jersey's protocol, observed fifteen to twenty tests performed on several instruments, and interviewed selected staff including, but not limited to, Brettell and Flanagan (14T75-14T76;15T21;D-34 at 5). He did not conduct any scientific testing (15T11). Despite exhaustive questioning on cross-examination, Zettl maintained that the Alcotest 7110 was not a computer although it employed computer technology (15T23-15T26).

Zettl assessed the Alcotest 7110's performance primarily by relying on the outcome of calibration tests using known alcohol solutions (13T81-13T82;15T8). If the instrument gave the expected breath alcohol results, he assumed that it was working properly (15T8). He used the analogy of a snow blower to explain that if the machine started when he turned the key, it worked (13T82). Zettl admitted, however, that he also relied in part on the integrity of the manufacturer to provide the instrument it promised (15T9).

Zettl described New Jersey's validation of the Alcotest 7110 as extensive, noting that some states simply buy their breath-testing instruments off the shelf and put them into use without first verifying them through analytical testing for accuracy and precision (13T95-13T96;13T102). On the other hand, New Jersey's validation consisted of a thirteen-step testing sequence, including ambient air checks which ensured that a subject's test results were not unduly influenced by contaminants in the surrounding room air; control tests which required the tolerance between them must be .005 or 5% for a .10 solution, and duplicate breath samples (13T104-13T106).

With regard to the acceptable tolerance agreement between two breath samples, Zettl relied on the Alcotest 7110 manual[44] to conclude in his expert report that when there were two valid sets of breath-testing data, the average of the four readings (two from the IR and two from the EC technologies) must be plus or minus .01 at or below a blood alcohol concentration (BAC) of .10 or plus or minus 10% for BAC's above .10, whichever is greater (13T108;14T110;D-34 at 6-7). During the hearing before this court, however, Sergeant Flanagan informed Zettl that the manual incorrectly stated the tolerance and that the correct formula required the resulting values of the IR/EC duplicate breath samples to agree within .01 or plus or minus 10% of the mean of the four readings, whichever is greater (13T108;14T5;14T110).[45] In any event, Zettl observed that the plus or minus 10% standard allowed for greater divergence

---

[44] We assume here that Zettl was referring to the Alcotest 7110 MKIII-C User Manual-Operator, V 1.1 (Oct. 11, 2005) (D-15 at 13).

[45] There was considerable testimony at the hearing regarding the correct tolerance calculation. Zettl suggested that the confusion might stem from the Law Division's misunderstanding of Brettell's testimony in State v. Foley, 370 N.J. Super. 341 (Law Div. 2003) (14T126-14T128). Brettell testified that the tolerance between the readings (generated by the IR and EC technologies) must be within .01 or 10% of the average of the highest and lowest readings, whichever is greater (14T121-14T122). The Foley court essentially doubled Ryser's standard by finding that the acceptable tolerance was .01 or plus or minus ten percent of the average of the highest and lowest of the IR and EC values.

between the two readings than the .01 standard articulated in Downie, 117 N.J. at 455, 457, thereby making it easier for a subject to give two samples within the acceptable tolerance (14T130). Zettl further observed that New Jersey's range was tighter than the National Safety Council's recommendation that two breath samples fall within .02 (13T107;14T129).

Zettl agreed that there is debate among the breath-testing community about the use of a constant blood-to-breath partitioning ratio for all subjects (14T84). He further agreed the magnitude of variation of the ratio between subjects and from time-to-time within the same subject was important to document whenever blood alcohol concentration was estimated indirectly by analyzing breath (14T84;D-19 at 920). Because an "ordinary" partition ratio was about 2280:1 for potentially sixty to sixty-eight percent of the population, Zettl thought that the use of the lower 2100 figure would substantially benefit a typical defendant (14T27-14T28).

Asked his opinion on breath temperature sensors, Zettl said that he no longer believed that they had any value (14T6;14T94;15T12;15T96-15T97). He readily admitted that he initially was overly optimistic about their potential importance, but that over the years only Alabama had adopted them (14T6). In fact, Zettl suggested that a temperature sensor actually might create analytical and jurisdictional problems related to its addition as another part of the breath-testing equipment (14T7).

While an elevated body temperature theoretically would drive more alcohol off the lungs and into the breath than in the bloodstream, Zettl agreed with Gullberg that the instrument still "reads what it reads" (14T7;14T20-14T21). Thus, a rise in breath temperature is irrelevant for breath-testing purposes unless a state requires a conversion from breath to blood alcohol concentration (14T21). For example, in New Jersey the Alcotest 7110 is set to read an alcohol concentration at 34 degrees C so when the temperature rises, the calculation is thrown off (14T21;14T26).

To avoid miscalculations, Zettl suggested that New Jersey rewrite its statute to eliminate the need for any conversion or compensate by taking a certain percentage off a person's breath alcohol concentration whenever the temperature rises (14T21-14T22). For example, an Alabama study of about 12,000 subjects who used the Alcotest 7110 showed that the average breath temperature was 34.9 degrees C, not the historically accepted 34 degrees C, and concluded that there should be an downward adjustment of 6.8 percent for every increase of one degree (14T24-14T26). Colorado addressed the temperature issue by including a question on its alcohol influence reports which required the officer to ask if the subject was ill, thereby allowing the person to argue in court that she had a temperature which might have affected the reading (14T7).

Additionally, a test result might be affected by how a subject blows into an instrument (14T26). According to Zettl, a long, full exhalation of deep lung air produces a higher breath alcohol concentration (14T27;14T108-14T109). Likewise, a subject who holds her breath will potentially have a higher test result (14T28). On the hand, a test result will be lower if a subject breathes shallowly or hypoventilates (14T28).

For forensic purposes, Zettl was satisfied with New Jersey's minimum requirements. Based upon research and evaluation of other instruments, Zettl opined that 1.5 liters was the minimum volume needed to obtain a "fairly accurate determination" of breath-to-blood alcohol (14T10). He also said that New Jersey's safeguards against mouth alcohol —— twenty-minute observation period, two breath tests a few minutes apart, and a slope detector —— were sufficient to detect contamination from the stomach or extraneous sources which could potentially elevate a subject's presumed breath alcohol concentration (14T10-14T11;14T40-14T41).

Zettl further expressed that the Alcotest 7110's dual system of IR and EC technologies was capable of detecting interferents introduced into a subject's breath (14T11-14T12). He acknowledged, however, that certain interferents, such as acetone and acetaldehyde, would not be detected in healthy individuals to any measurable degree (14T53-14T54). For example, he never saw a positive acetone reading from a normal subject despite testing approximately 10,000 to 20,000 subjects on the Intoxilyzer 5000 (using IR technology) and reviewing another 4000 to 5000 monthly records in Colorado (14T53-14T54).

Some people, however, have unhealthy conditions that can impede their ability to metabolize food causing very high levels of endogenous or naturally occurring interferents such as acetone, acetaldehyde, and ketones (14T61-14T62;14T65-14T66). In particular, Zettl observed that diabetics and people on special diets can have those substances present in sufficient concentrations to generate spectra in the presence of IR light (14T62). To detect their presence, the Intoxilyzer 5000EN used five points on the spectrogram —— unlike the one point used in New Jersey —— to test for five major interferents including, but not limited to, acetone, acetaldehyde, and ethyl methyl ketone (14T57-14T58). In Zettl's opinion, the more points of identification the greater the likelihood that interfering substances will be detected (14T58). He recognized, however, that New Jersey used 9.5 microns to detect such endogenous interferents along with an IR detector which took measurements 128 times a second, and an electrochemical detector (14T63-14T64). Moreover, he pointed out that New Jersey's ambient air checks would detect the presence of exogenous interferents in room air (14T65-14T66).

Regarding RFI, Zettl said that the Alcotest 7110 had a number of safeguards including: a built-in radio frequency detection; minimal non-scientific testing by the state and federal governments; extensive testing by the manufacturer; a requirement by the NJSP that no communication devices be present in the room during the administration of a breath test; and a thirteen-step protocol which would detect such interference and abort the testing sequence (14T12-14T13;14T30;15T30-15T33;15T64). Zettl acknowledged, however, that he would have more confidence in the field instruments if New Jersey collected the data in a central computer, as in Colorado (15T15). Specifically, he said that the Alcotest 7110 was capable of having data remotely reported to a central computer, that data retrieval was useful in determining a field unit's "reliability, accuracy, failure rates, down time," and that the technology needed to download the information was available (15T16;15T18-15T19).

Overall, Zettl thought that the State Police had maintained a high standard of quality assurance by checking the instrument upon delivery to make sure it was fit for service, by implementing the thirteen-step testing sequence each time a subject was given a test, and by periodically checking it in the field to make certain the instrument was accurately reading the alcohol concentration (14T14). Specifically, he said that New Jersey's periodic inspections were sufficient and that the Alcotest 7110 accurately measured breath alcohol samples (15T107-15T108). He concluded that New Jersey's program was "probably one of the top in the United States" (14T14-14T15). This court finds Zettl a very credible and helpful witness.

9. Summary of Testimony of State's Expert, Patrick M. Harding

Patrick M. Harding holds a Bachelor of Science degree in biochemistry from the University of Wisconsin (26T39). He has been a chemist at the Wisconsin State Laboratory of Hygiene (Hygiene Lab) for many years and currently supervises the Toxicology Section which is responsible for blood alcohol testing (26T40-26T41;26T46). Since 1983, Harding also has served as a scientific consultant for the breath alcohol testing program administered by the Wisconsin Department of Transportation's Division of State Patrol (State Patrol) (26T41). In that capacity, he has conducted research, evaluated breath-testing instruments, drafted statutes, revised the administrative code, recommended testing protocols, and trained breath test program supervisors and operators (26T42). Since

December 2002, Harding has been on the faculty of the Robert F. Borkenstein Course on Alcohol and Highway Safety (26T42-26T43).[46]

Harding is a founding member of the International Association for Chemical Testing (IACT)[47] and belongs to several other professional organizations (26T43). He has published three articles in peer-reviewed journals and numerous articles in IACT newsletters (26T44-26T45). Harding has testified many times as an expert in Wisconsin, Florida, Michigan, and New Jersey in Downie (26T45). The State offered Harding as an expert on breath testing and forensic chemistry (26T45).

Wisconsin has a per se statute which relies upon blood or breath to define the offense of operating while intoxicated (OWI) (27T14-27T15;27T17;28T98). Under that state's implied consent statute, the arresting officer or the suspect may request a blood test after the breath test has been completed (28T70;28T72-28T73). In either case, the police officer must take the suspect to a hospital for the blood test (28T75). The blood standard ranges from .08 grams of alcohol per 100 milliliters of blood for first, second and third offenses, .02 for fourth and higher offenses, .01 for absolute sobriety, and

[46] This summary incorporates facts and opinions from Harding's expert report dated June 27, 2006 (C-14).

[47] Harding described IACT as an organization for government employees whose job responsibilities include alcohol testing (27T42).

.04 for commercial drivers (27T14). While blood testing offers greater accuracy, Harding noted that it required the withdrawal of a sample, a central laboratory, expensive equipment, and a lot of court time by the eighteen analysts who work in the Hygiene Lab's toxicology section (27T62-27T63).

Wisconsin uses the Intoximeter EC/IR for evidential breath testing (26T106;27T84). It previously used the Intoxilyzer 5000 (1984 to 1999) and the Breathalyzer 900A (pre-1984) (26T84;26T106;26T109). Following the recommendations of Harding and the National Safety Council Committee on Alcohol and other Drugs, Wisconsin's breath testing program requires that two breath readings agree within plus or minus .02 (26T118;29T10). For duplicate analysis of blood, Wisconsin adopted a tolerance criteria of plus or minus .005 or 5% (26T118-26T119).

Harding has participated in two blood and breath comparison studies, which led him to conclude that the average blood-breath ratio was higher than the 2100:1 ratio used in the United States (26T62-26T67;26T98;27T66). One study consisted of a joint NHTSA and IACT multi-state research project, which involved six breath-testing instruments (three Intoxilyzer models, BAC Datamaster, Alco Monitor, and Alco Sensor IV), four states, and subjects dosed with alcohol on five different occasions (26T63;26T94-26T95). In addition to measuring breath alcohol, the study simultaneously collected two venous blood samples from each subject (26T63;26T95-26T96). The blood samples were sent to laboratories in Wisconsin (the Hygiene Lab), Colorado, Iowa, and Arkansas (26T63-26T64). The results indicated that all the instruments generally underestimated the blood alcohol using the 2100:1 ratio and that the average blood-breath ratio was around 2300:1 (26T65;28T104;29T11).

In another study ongoing since 1983, Harding has worked with the State Patrol in their breath testing operator training courses where the participating police officers were dosed with alcohol (26T66;26T97). Over the years, Harding compared breath tests administered by the Intoximeter EC/IR, Intoxilyzer, Alco Sensor IV, and Breathalyzer with blood samples taken almost contemporaneously (26T97). The officers were given about an hour to imbibe in a controlled setting (26T102). In about thirty minutes, blood samples were taken (26T101-26T103;27T12). At that point, the alcohol concentration in the breath was generally lower than in the blood, with a corresponding ratio of approximately 2300:1 or higher (26T103). The study revealed that all instruments underestimated the blood alcohol concentration in ten to eleven percent of the cases and overestimated in one to two percent of the cases (26T97-26T98).

Harding was familiar with a 1995 peer-reviewed article by by M.D. Taylor and B.T. Hodgson which similarly found that three breath-testing instruments —— Alcotest 7110, Intoxilyzer 5000C, and Breathalyzer 900A —— underestimated blood alcohol concentration by about eight percent (27T63;29T14-29T15;29T20-29T21;AB-12).[48] Eighteen subjects were given measured amounts of alcohol and then tested on all three instruments for a period up to five-and-a-half hours after their last alcohol consumption (29T14). Blood samples also were taken about an hour apart (29T15). Among other things, a comparison of the breath and blood results, using linear regression analysis, revealed there was no statistical difference between the performance of the Alcotest 7110 and the Breathalyzer (29T15;29T20).

Harding described the three phases of physiological absorption of alcohol into the bloodstream (26T100;27T10). During the absorptive phase, the body is absorbing alcohol faster than eliminating it (27T111). The actual rate of absorption, however, varies in the same subject from time to time and under similar conditions depending upon various biological factors, such as the amount of food in the stomach (27T13). During this phase, the concentration of alcohol in arterial blood is higher than that of venous blood (28T104).

---

[48] See M.D. Taylor & B.T. Hodgson, Blood/Breath Correlations: Intoxilyzer 5000C, Alcotest 7110, and Breathalyzer 900A Breath Alcohol Analyzers, 28 J. Can. Soc'y of Forensic Sci. 153 (1995) (AB-12). This study did not employ the Alcotest 7110 MKIII or MKIII-C, but an earlier model that only used IR technology (27T75;18T52).

Controlled studies that compare blood-breath alcohol concentrations in the absorptive phase generally dose subjects with fairly large amounts of alcohol in short periods of time, and then test them shortly afterwards (26T100). In non-controlled settings, however, drivers are unlikely to be in the absorptive phase by the time they get to the second breath test given the time elapsed since their arrest, transport to the police station, and twenty-minute observation period which, in Wisconsin, takes place at the station, not in the car (29T25). Arrestees also generally consume alcohol over a longer period of time before driving (26T100). Thus, laboratory studies tend to produce greater differences between breath and blood alcohol readings (26T100).

In the peak phase, alcohol concentration reaches its highest level when it exists at a plateau where absorption and elimination occur at the same rate, in equilibrium (27T11). Harding found that under controlled conditions, peak alcohol concentrations were reached about thirty minutes after the subjects stopped drinking (26T102). At that point, subjects enter the post-absorptive phase when their bodies are eliminating alcohol faster than absorbing it, thereby producing a more realistic estimate of a blood-to-breath comparison

(26T102;27T11-27T12).[49] Approximately 95% of the alcohol consumed is metabolized in the liver while the remaining 5% is eliminated by excretion, some through the breath (27T21-27T22). During post-absorption, alcohol concentration in venous blood (used for drunk-driving cases) is higher than arterial blood (usually used only for forensic research purposes) (28T104-28T105).

Harding was aware of the Alcotest 7110's dual technology (26T104). He noted that IR technology has been employed in commercial breath-testing instruments since the 1970s and that the Alcotest 7110's use of one wavelength at 9.5 microns was more specific for ethyl alcohol and eliminated the need for tests at multiple points on the IR spectrum (26T105-26T106). He further noted that EC technology was introduced for evidential purposes in the 1990s and that the small size of the fuel cell permitted use in hand-held screening devices, as well as in evidential breath testers (26T106). While the Alcotest 7110 is the only instrument that uses both technologies to provide a documented analytical result, Harding pointed out that the Intoximeter EC/IR relied upon EC technology to detect alcohol and the IR component to monitor the breath sample (26T106).

[49] This court believes that Harding was referring to the fact that by the time drivers typically are tested following their arrest, they are in the post-absorptive phase.

Harding reviewed NHTSA's initial type evaluation for the Alcotest 7110 in 1996 and its subsequent evaluations of New Jersey's firmware changes in 2003 and 2006 (26T108). Although he was unaware that some AIRs from the 2006 evaluations were missing, Harding did not consider it necessary for purposes of his testimony to know why these reports had been discarded or why these tests had failed completion (26T140-26T141). He also reviewed New Jersey's protocol and concluded that it was essentially the same as the one he had written for Wisconsin (26T109). Specifically, he found that the ambient air checks and quality control tests, and the requirement that two breath samples agree within predetermined criteria were sufficient to show that there were no aberrant errors in the instrument and that there was no inconsistency in the sampling process (26T116-26T118).

Harding defined the acceptable tolerance in New Jersey as the greater of plus or minus .01 or 10% of the mean (26T118). In Wisconsin, however, the tolerance or agreement criteria for breath samples was plus or minus .02, and for blood was plus or minus .005 or 5%, whichever was greater (26T118-26T119).

Asked his opinion on RFI, Harding stated that all breath-testing instruments were protected against electromagnetic interference (26T120). For example, in Wisconsin, the Intoximeter EC/IR –– like the Alcotest 7110 –– did not include an

RFI detector but had its case redesigned to shield it from such interference (26T120). For RFI to remain undetected, it must adversely effect every single test the same way (26T123). Thus, Harding said that New Jersey's use of ambient air blanks, control tests, and two breath samples made RFI "astronomically" unlikely (26T123-26T124). He also said that New Jersey's use of dual technology would detect exogenous interferents, and that endogenous compounds were unlikely to affect the Alcotest 7110 or any other breath-testing instrument based upon the results of two literature surveys he conducted with Dr. Kurt Dubowksi[50] for the Committee on Alcohol and Other Drugs, most recently in 1999 (26T124-26T105;27T80-27T81).

With regard to the issue of mouth alcohol detection, Harding thought that New Jersey's twenty-minute observation period, its two-minute lockout between breath tests, and its use of a slope detector were sufficient safeguards (26T128;28T11). He reached this opinion based in part on a peer-reviewed study that he performed with the Intoxilyzer 5000 in conjunction with three dentists and his co-author, Mary McMurray (26T127;27T81;D-109).[51] The study gave measured amounts of brandy to twenty-five

---

[50] Among other things, Dr. Dubowksi was the Director of Tests for Alcohol and Drugs for the State of Oklahoma when he testified in 1989 in Downie.

[51] See P.M. Harding et al., The Effect of Dentures and Denture
Footnote continued

subjects with various combinations of dentures and adhesives, and essentially found that dentures did not retain alcohol (26T128;26T146;27T82). The study further found that mouth alcohol could be ruled out after fifteen minutes (26T128).

Harding testified that it was sufficient for the two breath tests to be taken two to ten minutes apart, and that it would not matter if the lockout was several seconds short (26T129-26T130;27T10;28T11;29T18). However, he considered the slope detector less accurate on subjects who actually had been drinking when the alcohol in their bodies exceeded the amount in their mouths (27T96-27T97;28T13-28T14;28T17-28T18).

Harding also testified that Wisconsin, like New Jersey, used a minimum breath volume of 1.5 liters (27T69). Unlike New Jersey, Wisconsin collected and stored data in a central computer (28T55).

Harding confirmed what other experts found with regard to breath temperature; it was not necessary to measure (28T99-28T100). Specifically, he said that there were no studies showing a direct correlation between breath temperature and blood alcohol concentration and, in any event, the 2100:1 ratio already accounted for temperature variability by measuring

---

Adhesives on Mouth Alcohol Retention, 37 J. Forensic Sci. 999 (1992) (D-109).

breath alcohol at a lower level than the corresponding blood alcohol concentration for most people (28T99-28T100).

Based upon his training and experience, his review of tests performed on the Alcotest 7110 by NHTSA and New Jersey, his observations during a two-day visit in June 2006, and his review of relevant documents and scientific literature, Harding concluded that the Alcotest 7110 was a scientifically reliable instrument (26T131;27T85). He further concluded that New Jersey operated the Alcotest 7110 as part of a scientifically acceptable program which followed guidelines commonly used by other jurisdictions throughout the world (27T85;28T43). Harding offered his opinions to a reasonable degree of scientific certainty (28T42-28T43). This court finds Harding a very credible witness and was impressed with his qualifications, experience, and lucidity.

10. Summary of Testimony of State's Expert, Norman J. Dee

Norman J. Dee graduated from the Juilliard School with a Bachelor of Arts degree in music (30T7-30T8;30T54). After teaching at the University of New Hampshire and working as a professional musician for several years, he received a certificate in computer programming from New York University (30T7-30T8;30T29;30T33). He has worked as a computer professional for the last twenty-eight years (30T14).

Dee currently works as a senior consultant for the CMX Group (CMX), a boutique of system programmers who specialize in capacity planning, performance analysis, system audits, and the process of data management (30T9;30T14). CMX specializes in finance industries especially Fortune 1000 companies (30T15). Dee also has served as chief technology officer for such companies as Scholastic Publishing in its internet division and 1-800-Flowers (30T22). He previously taught COBOL and Assembler business languages at Pace University (30T23;30T44;30T46).

Dee holds several professional memberships, gives numerous presentations, and publishes mostly "white papers" for marketing promotion purposes (30T24-30T25;30T50-30T51). He is certified in the industry standard of IT Infrastructure Library (ITIL), in systems management from the IBM Systems Sciences Institute, in MICS installation and maintenance, and in Sybase FastTrack (30T9-30T13;30T31;30T40). Dee considers himself a specialist in cost recovery and the business side of planning, cost accounting, and data processing (30T24;30T48).

Prior to this hearing, Dee never testified in court on technology matters nor did he have any experience in breath testing (30T25;30T40;30T52-30T53). The State offered him as an expert in computer science, particularly in systems auditing and computer measurement (30T25). This court qualified him as an expert in data management business systems (30T60-30T61).

As a systems programmer, Dee evaluates and audits computer hardware and software, and reviews source codes (30T15-30T17;30T37). He described source code as "human-friendly" language which is put through a compiler to generate machine executable code (30T69-30T70). The computer's operating system then loads the machine language into memory (30T69). There are multiple languages of source code ranging from English (Cobol) to mathematical expressions (C or C++), each with its own syntax (30T69-30T70). Computer applications (which are developed using source codes) are considered proprietary because they cost a lot to develop (30T78).

When a system works properly and produces the expected results, an external review by a customer of the source code is not necessary (30T73). A manufacturer, however, may want to review the source code to ensure that the programmers followed the correct standards (30T73).

Source code review becomes necessary when a system fails to produce the expected outputs (30T73). As Dee explained in his report, source code review may be warranted when there are performance issues (such as slow responses or the persistence of overly high utilization), integration complexities in getting several systems to interface with each other, or inaccurate results (31T22;C-13,Dee report at 5).

If a particular function was not operating properly, a customer generally would contact the vendor or manufacturer to find out why the anomaly happened (30T83;31T22-31T23;31T65). The manufacturer could ask the programmer who wrote the code to look at it, could ask an independent programming team from another department to look at it (sometimes called "walk-throughs"), or could use an independent outside agency (31T21-31T22).

It is a time-consuming process to review a source code for its actual function and execution, especially if the review is undertaken to "debug" a system (30T82-30T83). Source code review also can be confusing especially where a programmer, in dealing with the hardware, has to change the code to respond to predictable results (30T137-30T138).

In complicated applications (or programs), Dee explained that he would search for the component that was not performing as expected and then proceed to a further "drill-down" into the suspect area which often would reach the source code level (30T73). Specifically, he would get computer dumps (stacks of hexadecimal code) which would lead him to various areas in the operating system where there were faults (30T17). After finding a failing instruction (which was represented in the hexadecimal code), Dee would look it up on the microfiche card containing the assembler or source codes (30T19). Dee would report the problem to the vendor, who might ask him to put in a "patch" or a "hot fix" to get around the area (30T20). Dee acknowledged that errors in coding were rampant and for that reason, a lot of systems had self-checking capabilities (30T83-30T84).

Dee also said it was the expectation in the industry that no one shared source codes (32T52). In cases where sources codes were made available, it was fairly common practice for the review to take place in a segregated area at the manufacturer's location without cameras and copying devices (32T50-32T51).

Unlike multiple-function computers, an embedded (or targeted) system has a sole purpose (30T62). It operates by running a very reduced logic code which is sufficient to support what it has to do and has fairly limited interface sensors (30T63-30T64). Dee described the Alcotest 7110 as an embedded system with a very specific dedicated function even though its display screen allowed some input and output, and it used a printer like a computer (30T64;32T71). He explained: "You can't play Atari games on it. Can't browse the Internet on it. You can't do word processing on it. It's a very focused instrument for one purpose and, therefore, it is a black box" (32T71). Specifically, he treated the Alcotest 7110 as a black box because it had "highly certified" known inputs whose outputs could be evaluated (30T105;30T144-30T145;32T67-32T68).

To evaluate the Alcotest 7110's single-function technology, Dee used the black-box testing approach which he compared to a "truth table-type evaluation," meaning that if the instrument produced accurate results, he concluded it was working (30T64;30T66;30T84-30T85). He determined how the Alcotest 7110 operated by reviewing six controlled inputs and seeing if they produced the expected outputs (30T55-30T56;30T66-30T68;30T145-30T146). Dee also reviewed the process of administering the breath tests and the environment in which the Alcotest 7110 was used (30T85-30T87;32T69).

Dee determined that New Jersey used the Alcotest 7110 in a controlled environment which allowed no deviation from the testing sequence (30T88). He further determined that there was no way to change or alter the instrument's database, thereby ensuring data integrity and access security (30T89-30T90). The use of certified bottles of simulator solution for the calibrations also ensured the instrument's baseline performance (30T91). Dee then set up scenarios to test the system by putting in data which did not fulfill the requirements, and found that the instrument would not allow certain things to happen such as incomplete or interrupted blowing and that everything was recorded (30T91;30T94).

Based upon his training, experience, and the actual system testing that he performed, Dee concluded that the Alcotest 7110 was accurate and produced predictable results (30T95). He further concluded that the breath tests were administered in a well-defined process, most of which was automatically controlled by the instrument (30T95). Because the inputs to the Alcotest 7110's single-function system produced the expected and desired results, Dee concluded that source code review was not necessary (30T69;30T84).

This court finds Dee's testimony very credible and reliable. Dee helped greatly in understanding the function of the electronic processing and computer aspects of the Alcotest 7110.

11. Summary of Testimony of State's Expert, Stephen B. Seidman

Stephen B. Seidman is a mathematician by education with a Ph.D. from the University of Michigan (16T17;16T26). After receiving his degree in 1969, Seidman taught mathematics and computer science, and worked in administrative positions at various academic institutions (16T20-16T21). He currently serves as dean of the College of Natural Science and Mathematics at the University of Central Arkansas in Conway (16T21). For the last ten years, he also has engaged in academic consulting primarily in the area of computer science education (16T21-16T23).

Seidman considers himself a specialist in software architecture (16T23). He is a member of the Institute of Electrical and Electronic Engineers (IEEE), the IEEE Computer Society, the Association for Computing Machinery (ACM), and the American Association for the Advancement of Science (16T17-16T18;16T25). He also is an IEEE Computer Society Certified Software Professional (16T17-16T19). Seidman has published extensively on mathematical and software-related issues as listed on his curriculum vitae (16T23-16T24). Although he never testified previously as an expert, This court found him qualified in the areas of software engineering and computer science (16T26;16T60-16T61;16T69).

Seidman has no experience with breath-testing instruments (16T28;16T59). His only contact with an evidential breath tester occurred when he visited the New Jersey State Police Laboratory in August 2006 to evaluate the Alcotest 7110 (16T28). Seidman believed that the State retained him to testify as an expert based upon his IEEE certification as a software professional (16T64-16T65).

Seidman described a computer as a device that can be programmed to do things by and for the user (16T71). It consists of a central processing unit (CPU) (which does the actual computations), memory, and some way of communicating or interfacing with the outside world (16T79;17T40).[52] Seidman distinguished a computer from an embedded system, which can be found in many aspects of contemporary life ranging from microwave ovens and televisions to braking systems in cars (16T71-16T72). Unlike a computer, an embedded system contains a computational component used to control other machines, has a specific purpose, often is pre-loaded with operating software, and does not allow communication to introduce new functionality (16T71-16T72;17T42). Seidman described the Alcotest 7110 as an embedded system because it performed a particular task (16T115;17T40;17T42).

A computer (or an embedded system) contains hardware and software components (17T43). On the Alcotest 7110, the physical components comprising the hardware (internal and external) include a signal processor, microprocessor, motherboard, memory, optics (an infrared absorption cuvette), sampling system, sensors (both flow and pressure), keyboard, and printer (17T43-17T46;17T55-17T56;17T58;C-14, Seidman report at 1). Software components include firmware for the microprocessor and software to handle data retrieval, data communications, and operator input (18T54). Firmware consists of easily accessible software loaded into a processor's memory so that it can quickly execute

[52] The Alcotest 7110 uses a processor identified by Draeger as a Motorola M68HC11 (18T27-18T28;D-42).

the signal processing algorithms entered by the system's designer (16T108-16T109;17T70;C-14, Seidman report at 3). Algorithms are the buildings blocks or formula for creating the software's intended results (17T97;18T53).

To determine if firmware correctly implements the algorithms, a designer should adhere to industry standards for software development by: (1) determining the requirements based upon the customer's needs; (2) designing software architecture; (3) constructing the code; (4) testing the system containing the software; (5) obtaining the customer's acceptance; and (6) performing any necessary maintenance (16T75-16T77;17T28). The same steps should be followed for development of a system such as the Alcotest 7110 (16T75;C-14, Seidman report at 4). Seidman explained that adoption of a standardized process was the best way to assure the quality of software products (16T92;18T91).

There also are international standards for the software development (16T79). The International Standardization Organization (ISO) in Switzerland and the International Electrotechnical Commission (IEC) formed the Joint Technical Commission I (JTC I) to address standards relating to information technology (16T81). JTC I, in turn, established "Sub-committee 7" to deal with software engineering (16T80). In 1995, ISO/IEC Standard 12207 proposed a list of thirteen software development activities which roughly corresponded to the six steps identified by Seidman (16T81). Other relevant standards include ISO 9001 (general quality standard) and ISO/IEC 9003 (guidelines for applying ISO 9001 to computer software) (16T89-16T90;C-14, Seidman report at 6).

Certain organizations such as "TUV" in Germany and the American National Standards Institute (ANSI) will certify for a fee a company's software development process for conformance to a given standard (16T82-16T83;16T94). Of interest here, Draeger obtained verification of its process by obtaining a certificate of compliance with ISO 9001 (16T92-16T94;17T110;S-22). That certification led Seidman to conclude that Draeger's process for creating software met international standards of quality (16T100-16T101).

Software also may be validated and verified by an external audit team (16T101). External audits seek to (1) verify that the tests performed can be traced to the design requirements, and (2) validate that the software satisfies its intended use (16T102;C-14, Seidman report at 6). They do not require the performance of actual tests nor do they usually require a review of source codes (16T102). Seidman acknowledged that his confidence in the Alcotest 7110 would be higher if Draeger had obtained independent testing and evaluation of the Alcotest 7110's software (18T15;18T23).

Seidman, however, considered it unlikely that the Alcotest 7110's software was subject to malicious manipulation (16T110-16T112;C-13, Seidman report at 6). He explained that the presence of such "malware" required collaboration between malicious developers and users and significant resources, and found it difficult to construct a scenario containing these elements (16T117-16T118;C-14, Seidman report at 9). In contrast, Seidman used electronic voting systems as an example where someone might have an economic incentive to alter the outcome of an election by using malicious software to override election results (16T118;C-14, Seidman report at 7). In any event, he noted that source code examination would be insufficient to rule out such a possibility and that the cost of more intensive investigations was unjustified (C-14, Seidman report at 9).

Source code consists of computer language readable by a person with appropriate expertise and consists of a list of steps for implementing the algorithms (17T98). Software companies generally are reluctant to release these codes given the competitiveness of the industry (16T103-16T104). Seidman did not consider it necessary to review Draeger's source codes to reach an opinion regarding its software development process for several reasons (18T92). First, he explained that it was more important to focus on the process, not the product (18T92).

To assess the process, it was important to know if the software conformed to the expected quality standards (18T23). For example, Seidman would want to know if the software was certified in conformance with ISO 9000 and 9003 (18T92).

Second, Seidman explained that the approximately 60,000 lines of source codes for the Alcotest 7110 would be very difficult to review and that it would not benefit anyone other than a competitor or someone with experience in the domain (16T119;18T93). Third, he did not believe that examination of source codes was necessary to detect errors in the system (18T94;C-14, Seidman report at 9). Instead, Seidman said that errors could by detected by performing "black-box" testing at the system level by putting solutions of known strength into the system and checking to see if they produced the expected output (16T94;18T20).

Seidman also relied upon the results of successful tests performed in 1996, 2003, and 2006 by NHTSA to infer that the Alcotest 7110 correctly implemented the underlying algorithms and computations (17T5-17T9;17T14;C-14; Seidman report at 7, 9). Seidman acknowledged, however, that he did not review the data underlying the test results, that the two earlier tests were not conducted on the same firmware version of the Alcotest 7110 currently used in New Jersey, and that he trusted NHTSA to do good science in the same way that he trusted other federal agencies to do their jobs (17T7-17T9;17T121). He further acknowledged that he was unaware of the fact that NHTSA had discarded forty-nine incomplete AIRs printed during the third test (17T7-17T12).

If there were errors in the software, Seidman would want to know about them as they would raise questions in his mind about the instrument's accuracy (18T67). When shown several AIRs with apparent errors, Seidman said that he would want to understand the reasons for them before he gave an opinion on the accuracy of New Jersey's breath-testing program (18T77;D-59;D-60;D-61;D-62;D-63;D-64). However, he did not believe that the errors or irregularities affected the instrument's "core functionality" but rather addressed the input/output information that governed communication with the outside world (18T95-18T96). For example, he wondered why an officer would submit an AIR which showed the letter "y" in place of the specific information requested and suggested that the problem might be the result of a keyboard that was improperly connected rather than a problem with the firmware (18T96;D-64). In any event, he agreed that a municipal court judge should not rely on an alcohol test where the AIR showed an irregularity (18T96).

Based upon his training and experience and the reviews he conducted in this case, Seidman concluded that: an examination of the source code was not necessary to determine the Alcotest

7110's reliability; the software development process met industry standards; there was sufficient external testing by NHTSA, the New Jersey State laboratory, and law enforcement officials who regularly operated the instrument; and there was no reason to suspect the presence of "malware" (16T119-16T121; 17T5-17T6;17T14-17T15;17T19).

This court finds Dr. Seidman very believable and well-qualified to express the opinions he was called upon to render. He was very helpful in explaining the computer aspect of the case.

12. Summary of Testimony of Defendants' Expert, Gerald D. Simpson

After receiving his Ph.D. in physical chemistry in 1970 from the University of California, Santa Barbara, Gerald D. Simpson spent three years as a post-doctoral fellow at the Florida State University Institute of Molecular Biophysics where he did research in molecular and laser spectroscopy (62T12-62T14;D-247).[53] He then worked for Rockwell International until he retired on disability from the Rocketdyne Division in the early 1980s (62T12-62T13).

---

[53] Simpson testified by satellite video on December 14 and 15, 2006, and by telephone conference call on December 19, 2006.

Shortly after his retirement, Simpson became interested in the technology used to measure breath alcohol concentrations including infrared spectroscopy (62T14-62T15). He reviewed the literature and, in 1987, published his first article addressing the margin of error in breath test results (62T14). As his curriculum vitae indicates, he continued to publish articles on breath alcohol measurements through 1996 (D-247). He is a past member of several scientific societies, but presently does not belong to any such organizations (62T35-62T36).

Simpson has testified for the defense as an expert in breath testing about thirty to forty times, mostly in California but also in Downie (62T20;62T39-62T40;64T16). He generally did not receive a fee except in one or two cases (64T13). Defendants here in Chun offered him as an expert in breath testing and breath testing error analysis (62T20).

Simpson has designed and performed tests on the Intoxilyzer 4011-A and the Alco Sensor III fuel cell pocket breath testers, but has not performed any tests on an Alcotest 7110 (62T23-62T25). He also has not conducted any original experiments, but relied instead upon the published data of others (62T44).

Simpson essentially was of the opinion that the Alcotest 7110 worked as well as any other breath-testing instrument, but that the scientific theory behind all breath test results was flawed (62T44;64T61-64T62). He identified the following problems inherent in all instruments: (1) the margin of error approached 50%; (2) the underlying assumption that alveolar air in the lungs was in equilibrium with the blood was incorrect; (3) the standard calibration method did not ensure accuracy of breath test results; (4) there was no blind third-party proficiency testing; and (5) there was a lack of adequate validation testing (62T44-62T49;64T46-64T48;67T25-67T26).

Simpson recognized that there was uncertainty in every scientific measurement (62T53;62T55). To calculate the margin of error in breath alcohol measurements, he adopted a statistical approach based upon the use of a standard deviation from a mean for a particular sample (62T52-62T53).

According to Simpson, all evidential breath-testing instruments in the country assumed a 2100:1 blood-breath ratio (63T25). He concluded, however, that only 8% of the population fit that average and that the academic scientific community —— as opposed to the forensic science community —— would not generally accept that ratio without better testing (63T25-63T27;64T6-64T7).

Simpson relied heavily upon Dr. Dubowski's data in a 1985 article showing that the average blood-breath ratio in his population sample of healthy fully post-absorptive adult males was 2280:1 (62T62;62T69;63T42-63T43;67T5;D-235). Given one standard deviation of 242 (rounded up from 241.5), Simpson calculated that at two standard deviations, 95% confidence limits would require the test results to fall between 1796 to 2764 (62T67).

Simpson recommended using confidence limits of 99% (62T66;63T11). At 2.58 standard deviations, 99% confidence limits would be 1656 to 2904 (62T68;62T70-62T71). He then determined that the coefficient of variation was 10.6% (the standard deviation (242) divided by the mean (2280) times 100), which when multiplied by 2.58 resulted in a margin of error of 27% (62T73). Because the Alcotest 7110 assumed a blood-breath ratio of 2100:1, Simpson determined that the conversion would drop the margin of error to about 22% (62T79). In other words, if the test result fell within the margin of error, Simpson proposed correcting by 22% to account for the uncertainty (62T82).

On cross-examination, Simpson acknowledged that Dubowski testified in Downie that the standard deviation actually was 201, not 241.5 as reported in his article (67T12-67T13;67T15;D-235). Simpson further acknowledged that the change would significantly affect his own calculations (67T15). Because he was not aware of any published correction by Dubowski, Simpson felt he had properly relied upon the 1985 peer-reviewed article (67T31).

Simpson also calculated the margin of error for data from absorptive and post-absorptive populations reported in an article by Ulrich Heifer in Germany and in an article he co-authored with William Giguiere (62T52;D-243).[54] Again, Simpson determined the mean blood-breath ratio for the sample populations, the standard deviations, and the coefficients of variation (62T53). Applying the same calculations to data from the population studied by Giguiere, Simpson obtained an even wider margin of error of 46% for 2.58 standard deviations at 99% confidence limits, without taking into account the 2100:1 conversion (62T87-62T88;62T94;63T11;D-243). To account for the uncertainty, Simpson advocated adding 46% (62T94-62T96). In other words, an .08 reading must be potentially as high as .117 (by taking 46% of .08 and adding it to .08) to avoid error (62T96;63T29).

According to Simpson, Heifer studied 1150 blood and breath pairs and found that two hours after the subjects stopped drinking, their blood-breath ratio was close to 2100 (64T65). Sixty minutes after they stopped drinking, Heifer found the ratio was 1910 (64T65-64T66). It is interesting to observe that Simpson was not aware of anyone else in the breath-testing field

---

[54] The article by Heifer was not translated into English. Simpson evidently relied on Figure 1 in that article (64T64-64T65). See Ancillary Bioliography.

who cited the Heifer study (62T108). Simpson said: "They seem to have completely ignored him" (64T67).

Simpson recognized Dubowski as a leading figure in the breath-testing community, but noted that Dubowksi had never acknowledged his work (62T109). Simpson explained that the forensic science community had different standards of scientific rigor than "mainstream" scientists, probably because forensic science was applied in a way that was more consistent with law and public policy, rather than scientific method (63T35-63T36).

Simpson, however, was aware that Jones of Sweden —— acknowledged as another leading figure in the breath-testing community —— had written rebuttals to several of his articles (63T36-63T37;D-241;D-252). He rejected Jones' conclusions as well, noting that they lacked sufficient sample size or were poorly designed (64T57). Simpson also testified that other breath test studies had similar problems (67T17).

With regard to calibration, Simpson conceded that the Alcotest 7110 accurately measured the concentration of a known alcohol solution (62T91;64T5). However, he contended that the calibration method contributed only a small percentage to the total margin of error (62T91). By calculating the standard deviation or coefficient of variation, Simpson found that the expected error from the calibration method and the instrument itself contributed only about 2% to the total error (62T89-

62T91;D-241). In contrast, he estimated that about 90% of the total uncertainty came from biological factors associated with the blood-breath ratio, at least during the post-absorptive stage (62T90-62T91;64T4;D-241 at 262).

Because the largest source of error came from biological variables associated with the blood-breath ratio and not from the instrument, Simpson believed that the various safeguards in the Alcotest 7110 (such as taking the lowest of four readings and truncating the final result) and potential corrections (such as adjusting 6 or 7% for breath temperature) would only lower the total error from all sources by a small amount (63T30-63T31;63T48). Nonetheless, he said that temperature correction —— upwards and downwards —— was reasonable to avoid "false high" readings (63T49;67T29).

Simpson also believed that the use of a 9.5 wavelength on the IR spectrum reduced or eliminated all interferents (63T52). For example, he explained that one of the few interferents at 9.5 microns was dimethylsufoxide (DMSO), which he did not believe had ever been studied (63T52). Because there were many other potential interferents with low partition ratios which could affect a breath test reading, he recommended the use of a gas chromatograph to test part of the breath sample to make certain they were not present (63T54).

Simpson considered the Alcotest 7110 as a black box, which was not amenable to scientific methodology (63T56-63T57). Because a microprocessor and software controlled the operation of the instrument, he said there was no way to know whether the instrument did what it was supposed to do for each subject (63T56-63T57).

We add Simpson's comments about Downie from this "Letter to the Editor" at 14 J. of Analytical Toxicol. 263-64 n.6 (1990), where he said:

> In Downie, the court also misinterpreted testimony about the blood/breath ratio. It was concluded that "calculated blood/breath ratios are worthless for forensic purposes. They are subject to so many variables as to be unusable except for gross estimates . . . and only then at a particular moment." At this time, no model is available that permits calculation of blood/breath ratios. They have always been derived from experimental measurements of alcohol concentration of blood and air (or breath) under either in vitro or in vivo conditions. Consequently, at least for forensic purposes, there is no such thing as a calculated blood/breath ratio: there are only experimental or empirical blood/breath ratios. The Court confused calculated blood/breath ratios with the calculated BACs produced by the Breathalyzer. Based on the scientific evidence given, a correct conclusion would have been as follows: Because the value of the blood/breath ratio for any given individual is subject to so many variables, a BAC calculated from breath alcohol concentration, using an assumed value of 2100.1, is unreliable unless it can

> be proven that the individual was "fully postabsorptive" at the time of the test, in which case the uncertainty in a particular result is at least +/– 15%. . . .
>
> [D-237.]

We conclude that Simpson either misunderstood or misrepresented the Court's ruling in Downie. As did Judge McGann as the trial judge in Downie in his findings of fact, we find Simpson's thesis and testimony "simply not reliable and reject it."[55]

[55] Findings of fact by Judge McGann in Downie are on file in Judge King's chambers, as provided by the State.

13. Summary of Testimony of Defendants' Expert, Michael Hlastala

Michael Hlastala is a professor at the University of Washington where he holds appointments in the Department of Medicine (Division of Pulmonary and Critical Care) and the Department of Physiology and Biophysics (65T4-65T5). He also is an adjunct professor of bioengineering (65T5). He has a doctoral degree in physiology from the State University of New York at Buffalo (65T5;65T12).

As his extensive curriculum vitae shows, Hlastala is a member of several professional organizations and has received a number of awards including a John Simon Guggenheim Foundation Fellowship and an honorary medical degree from the University of Linkoping in Sweden (65T7). He has given lectures at universities both within and outside of the United States, and has written numerous articles on physiology including several on breath testing, as well as one book on respiratory physiology (65T7-65T9;65T14;65T17-65T18).

Hlastala's primary field of study deals with gas exchange physiology, especially the way in which highly soluble gases, such as alcohol, exchange in the lungs (65T9-65T10). In his laboratory, Hlastala has used a Breathalyzer 900A, Datamaster, and Intoxilyzer 5000, but not an Alcotest 7110 (65T12-65T13). He also has experience with pulmonary function testing as well as gas chromatography and mass spectrometry with respect to the measurement of alcohol and other substances (65T11-65T12).

Hlastala has served as an expert witness in more than 1400 cases, including Downie (65T5-65T6;65T9-65T10). Defendants offered him as an expert in physiology as it relates to breath testing (65T10). Hlastala offered testimony in three areas: (1) the exchange of alcohol in the lungs; (2) the detection of mouth alcohol; and (3) the presence of interferents (65T26-65T27). Each area is discussed below.

Alcohol Exchange

The old paradigm assumed that the breath sample tested at the end of a full exhalation was the equivalent of alveolar air in equilibrium with the blood (65T29). Hlastala disagreed, stating that the end-exhaled breath was not the same as deep lung air because of the exchange of alcohol in the airways (65T29).

Briefly, the respiratory system consists of airways which travel from the nasal cavity down the throat to the trachea, then split into two branches just above the heart, and continue to branch or split more than twenty times until they fill the chest cavity (65T31;D-172). The airways are lined with mucus, and gradually get smaller in size causing air movement to slow down (65T31-65T32). At the end of the airways, there are alveoli or air sacs surrounded by blood vessels where gas exchange takes place, meaning oxygen enters the blood and carbon dioxide leaves it (65T31-65T32;D-172).

Because alcohol is highly soluble, it adheres to the water-laden mucus on the surface of the airways (65T32). During inhalation, breath air picks up alcohol from the airway surfaces which increases the alcohol concentration to the point of saturation by the time the air reaches the alveoli (65T32-65T34;65T36).

During exhalation, however, the alcohol concentration decreases as the alcohol interacts with the airway tissue on its way to the mouth (65T34-65T38;65T43-65T46;66T5). The amount of interaction varies among individuals based upon certain physiological factors such as breathing patterns (65T34-65T35;65T44-65T45). Citing studies by A.W. Jones and others, Hlastala noted that subjects who held their breath or blew longer caused a warming of the airway tissues which resulted in less alcohol deposited there during exhalation and higher readings (65T40-65T43). Conversely, subjects who hyperventilated before their breath tests would cause additional cooling of the airway surfaces which would result in a greater loss of alcohol during exhalation and lower readings (65T41-65T43).

Another factor is temperature, both body and breath (65T43;65T56-65T57). For example, Hlastala cited a study by Dr.

Fox showing that a higher body temperature caused higher breath test values and vice versa (65T55). To compensate for the higher alcohol readings, Dr. Fox apparently found that there should be an adjustment of 8% for every degree that body temperature rose above normal (65T55-65T56).[56] Hlastala also relied upon other researchers who reported breath temperature changes could cause alcohol readings to vary by 6.5% (65T69). Hlastala, however, did not recommend correcting for breath or body temperature without more experiments (65T69-65T70).

A third factor was hematocrit, which Hlastala described as the relationship between red cells and plasma (a watery substance) in the blood (65T57). According to Hlastala, females had a slightly lower hematocrit resulting in lower breath test values as more alcohol was retained in the plasma (65T57-65T58). Hlastala, however, acknowledged that there were no studies showing hematocrit differences relating to variations in breath alcohol concentrations (66T40).

Relying upon experimental work performed by other researchers, Hlastala also found that people with smaller lung volumes had higher readings and concluded that breath testing discriminated against them (65T62-65T67;66T14-66T15;66T40;D-

---

[56] Dr. Fox's study was not marked into evidence.

256;D-261). He recommended more tests to understand the difference and correct for it (65T67).

Hlastala agreed that the 2100:1 blood-breath ratio used in the Alcotest 7110 tended to underestimate blood alcohol (66T37). While recognizing that the ratio varied among populations, he used Jones' finding that the actual ratio of blood and air in a closed container was approximately 1756:1 to conclude find that, on average, exhaled breath lost 20% of the alcohol to the mucosal surface of the airways (65T75-65T77;D-265).

To compensate for the physiological variables under the "new paradigm," Hlastala suggested using a blood-breath ratio of 1750:1 (66T6-66T9). While a 1750:1 ratio would favor more defendants, Hlastala pointed out that it would favor some (such as those with higher lung volume, lower temperature or lower hematocrit) more than others (65T83).

Hlastala also took issue with the breath-testing concept that a subject had reached alveolar air expulsion when the breath leveled off or reached a plateau (66T63-66T64). Instead, he claimed that a breath-testing instrument actually was measuring the level at which the subject stopped exhaling (66T64). He also did not see a need for truncating test results and recommended taking the average of the four readings, not the lowest (66T37-66T38).

Because end-expired breath was never the same as deep lung air, Hlastala recommended taking blood samples and if that was not practical, using an isothermal re-breathing device which required a subject to breathe in and out of a heated bag about five or six times (65T50-65T51;65T80). As he explained, the device produced more uniform breath alcohol measurements which better represented blood alcohol (65T50-65T54).[57] A single breath exhalation, however, underestimated an isothermal rebreathing sample, requiring a change in the blood-breath ratio from 2100 to about 1950:1 (66T22-66T23;66T25). To date, no state has used an isothermal rebreathing device (66T26).

Hlastala explained that he proposed the new paradigm in response to anomalies in the old one (66T16). He recognized, however, the need for more experiments to confirm the new paradigm or create another (66T16). He explained, "it's new information. It's only a decade or decade-and-a-half old and we need to do those experiments to validate it" (66T17-66T18). He also recommended further experiments on breath temperature before advocating a particular deduction (66T39)

---

[57] For a more detailed discussion, see J. Ohlson, D.D. Ralph, M.A. Mandelkorn, A.L. Babb, and M.P. Hlastala, Accurate Measurement of Blood Alcohol Concentration with Isothermal Rebreathing, 51 J. of Studies on Alcohol 6 (1990) (S-74). For that study, Hlastala and his co-authors dosed fourteen volunteers with alcohol to examine such breathing parameters as hyperventilation (66T13-66T14;66T23-66T24).

Hlastala was aware that forensic scientists, unlike the medical community, did not accept the new paradigm (66T16;66T63). Because forensic scientists failed to consider the physiological variables, Hlastala observed that all breath-testing programs had similar biases (66T16).

Mouth Alcohol

Hlastala recognized that the presence of mouth alcohol can result in false higher breath alcohol readings (65T91). Such elevations can be caused by recent drinking, regurgitation or gastroesophageal reflux disease (GERD), or by the presence of dentures or other materials that absorb alcohol (65T92).

He also recognized that the Alcotest 7110's infrared technology used a slope detector to detect mouth alcohol (65T89). In Hlastala's opinion, however, the slope detector was not "foolproof" because it did not work properly when alcohol was present both in the bloodstream and the mouth (65T85-65T88). In his report, he wrote:

> The simple explanation is that the decreasing slope for alcohol coming from the mouth offsets the rising (positive slope) on alcohol exhaled from the lungs. Since a negative slope is not detected, the slope detector will not identify mouth alcohol under this situation. While the slope detector is an important check against mouth alcohol, it does not work well when alcohol is also present in the body.
>
> [C-15, Hlastala report at 3.]

While Hlastala tested the slope detectors on the Datamaster and Intoxilyzer 5000, he never actually tested the slope detector on the Alcotest 7110 (66T46;D-257).

In Hlastala's opinion, the two-minute lockout between breath tests and the twenty-minute observation periods also did not provide complete safeguards against mouth alcohol (65T92-65T93). When asked if the combination of the slope detector, two-minute lockout, and twenty-minute observation period was sufficient, Hlastala responded that they would be helpful but it still would be difficult to detect internal regurgitation or GERD (65T94-65T95). He stated, however, that twenty minutes was a sufficient period of time to wait to stabilize the saliva concentrations if there was any vomiting (65T96).

Interferents

Relying upon the instructor training manual for the Alcotest 7110, Hlastala noted that it described ethyl alcohol and other alcohols, but did not explain how the instrument differentiated between ethanol and methanol, or any other alcohol especially when there were only trace amounts present (65T98-65T101;D-7). In particular, he expressed concern that there was no data showing the effect of small amounts of other contaminants such as isopropyl alcohol (65T102-65T103).

On cross-examination, Hlastala admitted that he did not know NHTSA had tested a generic Alcotest 7110 and firmware versions 3.8 and 3.11, that he was not familiar with NHTSA's model specifications relating to acetone, that he was unaware of OIML Recommendation 126 (which applied to evidential breath testers), and that he did not review the data from Brettell's study on interferents (66T53-66T55).

Hlastala was aware that the instrument detected interferents by comparing the tests results of the IR and EC methods of analysis (65T104). In his opinion, the real issue was how sensitive those two methods were for making the requisite measurements (65T104). He recommended Draeger perform experiments with different levels of interferents to determine the sensitive activity for minimum amounts (65T104-65T105). If contaminants existed, he recommended that the State consider subtracting .01 from the readings in every case (65T105). In the State of Washington, defense counsel argued for a similar adjustment in cases with close readings (65T105).

In his opinion and to a reasonable degree of certainty within his field, the scientific reliability of the Alcotest 7110 could not be assessed because Draeger failed to measure interferents or define the minimum value for uncertainty with regard to potential contaminants (66T10-66T11). Such information would have enhanced his understanding of the instrument (66T11).

We do not doubt Hlastala's sincerity or his integrity but he concedes that his "new paradigm" for evidential breath testing is in the developmental or experimental phase. We are not persuaded that these theories are correct or sufficiently documented at present. As in Downie, 117 N.J. at 454, Hlastala "outlined potential physical variables that could affect the blood-breath partition ratio." Ibid. We are not convinced by his testimony here to reject the conclusions of Downie and adopt his theory that evidentiary breath testing is currently unreliable.

V. FINDINGS AND CONCLUSIONS OF LAW

1. In the wake of Downie

We consider this Alcotest 7110 "scientific reliability" hearing against the background of Downie, decided by the Supreme Court in January 1990. Downie considered the scientific reliability of the now virtually extinct breathalyzer. In Downie the Court said "specifically defendants challenge the accuracy of the breathalyzer test results based on partition-ratio variability." 117 N.J. at 451. The Court accurately explained in Downie:

> The breathalyzer, the machine the State employs to ascertain blood alcohol, measures the amount of alcohol in the breath and multiplies that by 2100 to arrive at the level of alcohol in the arterial blood supplying alcohol to the brain. This 2100:1 partition ratio presumes that every 2.1 liters (2100 milliliters) of expired alveolar air (or air expired in the last 1/3 portion of a deep breath) contains approximately the same quantity of alcohol as one milliliter of blood. If a person's actual blood-breath ratio is lower than 2100:1, the breathalyzer will overestimate blood alcohol, and vice-versa.
>
> [Id.]

The Court in Downie rejected the challenge that because "people have broadly divergent ratios of breath alcohol relative to blood alcohol, the 2100:1 partition ratio is inaccurate," id., and the consequent breath test results are scientifically unreliable.

The evidence presented to us at this extensive hearing basically raised two issues:

1. Is the Alcotest 7110 reliable in measuring breath alcohol?

2. Is the adoption of the 2100:1 breath-blood ratio, used in Downie, still a valid conversion method?

The Downie Court in detail described law enforcement problems in obtaining arterial, venous or capillary blood in the field. Id. at 458-59. These practical problems created the need for breath testing, an alternative but concededly less efficacious or precise method of determining blood alcohol. In discussing the 2100:1 partition ratio, the Downie Court perceptively said:

> The 2100:1 partition ratio, in its absolute simplicity belies the fact that each subject's partition ratio is affected by a host of complex physiological variables. Henry's law, in physical chemistry, states that when a liquid that contains a volatile substance, such as alcohol, makes contact with air in a closed container and at a known temperature, a certain amount of alcohol will escape into the air space above in the form of vapor. The rate at which the alcohol vaporizes will depend on the concentration of the alcohol in the liquid and on the temperature. The higher the temperature, the more alcohol will escape to the vapor. When there is a fixed temperature and concentration of alcohol, a state of equilibrium will result in which the amounts of alcohol in air and liquid are static.
>
> The breathalyzer applies Henry's law to the blood which courses through the lungs carrying alcohol. As the arterial blood passes through the lungs, some of the alcohol will become vaporized in the alveolar air and expelled in the breath. The breathalyzer is calibrated to presume that at 34 degrees Celsius, a solution of .121 grams of alcohol per 100 milliliters of water will give off alcohol to the vapor of .10 grams per 210 liters of vapor. Thus, we arrive at the current 2100:1 partition ratio.
>
> Dr. Dubowski found that individual partition ratios vary greatly. In one experiment, Dubowski paired blood and

> breath samples from experimental subjects. He found that the partition ratio of samples from different people ranged from 1706:1 to a high of 3063:1 despite each having ingested the same amount of alcohol. A person's partition ratio may vary from time to time. Moreover, it may be that no two people have the exact same partition ratio. Thus, the 2100:1 partition ratio is merely an estimate that roughly approximates most people's ratio and that is calibrated to give the benefit of the doubt to the subject in most instances.
>
> [Id. at 459-60.]

Dr. Dubowski did not testify before us in the Chun case but this summary of his testimony in Downie fairly expresses in general terms the testimony and literature presented to us by the State on the partition-ratio issue. The State has made the record in Downie available to us.

In sum, the Court in Downie seemed confident that in only 2.3% of the cases, at the very most, "does the breathalyzer materially over estimate the blood-alcohol level potentially to the detriment of the accused." Id. at 462. And, the Court was skeptical indeed of the accuracy of this estimate of error, as too high, "subject to question," and "not established." Ibid. Various factors favor the accused in this conversion process and protect from overestimates of alcohol in blood: (1) the ratio in most people is closer to 2300:1; (2) the reading is truncated to the second decimal place, not "rounded off" to the nearest hundredth (.089 = .08); (3) a suspect may not provide a deep enough breath to register all of the alcohol present in the alveolar air, and (4) only the lowest of two tests, fifteen minutes apart, counted on the breathalyzer. Id. at 460. (The Alcotest 7110 counts only the lowest of the four IR and EC readings.) The Court in Downie found that these, among other less-significant factors, "caused the breathalyzer to render many more breath test results on the low side than on the high side." Ibid.

Dr. Borkenstein, the inventor of the breathalyzer, testified in Downie that "breathalyzer researchers and members of the National Safety Council adopted the 2100:1 partition ratio instead of the more accurate 2300:1 ratio because they wanted to err on the low side and have almost no errors on the high side." Id. at 461. We also must here remember that these possible errors would impact guilt or innocence only at or near the critical levels, i.e., .04 (commercial license), .08 (usual DWI) and .10 (enhanced sentencing of first offenders). Errors on relatively high or low readings, not tending towards the critical levels, are generally forensically irrelevant. This is the reason we recommend close attention by a fact-finder to the clinical findings and observations of the suspect at the time of apprehension, because a possible, but improbable, overestimated .08 breath reading regarding blood level may conceivably obscure and mislead a judge to an erroneous conclusion where the clinical data in the field sobriety test (FST) might otherwise strongly suggest innocence. Given the lack of absolute scientific certainty of breath-testing, we urge caution by the trial judge at the critical levels, .04, .08 or .10, when interpreting a close reading in the context of otherwise persuasive exculpatory clinical evidence.

This caution was well expressed by Judge Patrick J. McGann, Jr., the trial judge in Downie where he summarized his findings of facts on Dr. Dubowski's testimony for the Supreme Court:

> Even though Oklahoma [Dubowski's jurisdiction] does have a per se law - that is a conviction based solely on a breath alcohol or blood alcohol reading in excess of the stated standard - Dr. Dubowski believes it to be a mistake. It places over-emphasis on a single piece of evidence. He believes that the whole traditional evidential picture should be presented, i.e., evidence of inadequate driving, evidence of impairment of the driver (physical coordination tests), physical indicia of alcohol consumption and then a properly conducted breath alcohol analysis (even with a converted blood/alcohol reading). In that way neither conviction (nor exoneration) will depend on just one item of evidence, in his opinion. He believes that too much emphasis is placed on the test instead of on the person and the performance. That opinion is more strongly held as the penalties for drunk driving become increasingly harsh.[58]

---

[58] Material from the Downie record supplied by the State and

Footnote continued

We fully agree with Dr. Dubowski on this point where the reading is at the critical level, i.e., .08 or .10, in the usual DWI prosecution, because of the error margin of .004 or .005 described by Ryser and the inevitable influence of analytical and biological variation on a particular test.

Gullberg, speaking of the small percentage (5 or 6 out of 793 subjects he discussed) which clustered about the critical threshold, had a similar response.

> THE COURT: What about on the threshold there?
>
> THE WITNESS: This is the critical false/positive we want to avoid. Well, the percent that that occurs is going to be far less than 4.3 because the 4.3 percent -- these 34 individuals span the range. So maybe there's five or six that are here.
>
> MR. SACHS: Objection. Far greater, far lesser, maybe. He's been qualified as statistician. He's given us numbers on all these spots.
>
> THE COURT: That's the way they talk.
>
> MR. SACHS: I want to see numbers there.
>
> THE COURT: We'll get to that. We're concerned about the people on the margin.
>
> THE WITNESS: That's right. That's exactly right. That's the false/positive area you want to avoid. And the point is that it's

---

retained in Judge King's chambers.

less than 4.3 percent because part of these people are down here. Part are up here. And one of the interpretations of these numbers and ratios needs to consider where in the concentration range are we?

THE COURT: Is it untoward for me to inquire what Jones or you or anybody else do about those marginal subjects?

THE WITNESS: Well, no. There's nothing that can be done.

THE COURT: In the legal sense, I mean.

THE WITNESS: Right. Unless you want to define the statute differently in terms of breath alcohol concentration only so you avoid this blood/breath comparison. In my opinion that would be the ideal way to go.

MR. MENZEL: I'm going to ask that opinion be stricken. It's legislative determination.

THE COURT: It's interesting.

MR. REISIG: It is interesting, but it's a legal conclusion. He's an expert.

THE COURT: I know it is. So you think out of that population of 793 there might be four or maybe five people on -- in that threshold?

THE WITNESS: That's right.

THE COURT: And that would be some kind of societal or legal judgment. What do you do with them?

THE WITNESS: That's right. That's the risk. Certainly you want to avoid and minimize that from ever happening, but it is a small risk.

THE COURT: Now, suppose I were to suggest that the people fall in that range clustered

> around .08, that special attention be paid to the clinical picture derived from the subject at arrest and subsequent to it. What do you think of that?
>
> THE WITNESS: The only circumstances surrounding the arrest, the driving, the physical sobriety test, things of this sort could be given more weight perhaps.
>
> [Gullberg 8T10-8T12]

Against this background, we reach these conclusions of fact and law.

1. Because of the strong evidence presented by the State on the scientific accuracy of the Alcotest 7110, we find the instrument acceptable for evidentiary breath tests in New Jersey, when accompanied by the appropriate foundational proofs. Indeed, we find the Alcotest 7110 with proper foundational proofs much more scientifically reliable and independent of operator influence, intentional or inadvertent, than the breathalyzer. Of course, the multiple-step testing protocol must be meticulously followed before the test result is admitted in evidence.

2. The State's proofs on the question of the reliability of the partition or blood-breath ratio largely mirrored the State's presentation in Downie. We do not doubt the integrity and sincerity of any witness in this proceeding, presented either by the State or defense. At most, there were shades of

differences about interpretation of scientific data or understandable dispute over au courant scientific theory. We find no reason in the evidence to doubt the continuing validity of the underlying theory of a 2100:1 blood-breath ratio. The testimony of Dr. Hlastala and Dr. Simpson, on the Heifer (Bonn) and other data, presented by the defense is interesting but certainly not convincing. It perhaps may represent the next frontier in the forensic science of evidential breath testing if eventually supported by sufficient proofs —— but it is not yet vigorous enough, if it ever will be, to up-root the science explicated and found persuasive in Downie and fortified by the extensive proofs before this court. Thus we reject the defense witnesses' basic premise that the 2100:1 ratio and present breath-testing technology is fundamentally unreliable, especially when adopted, as it has been in New Jersey, with caution and appropriate leeway, so as not likely to ensnare the innocent. Of course, here the defendant has the benefit of the lowest of four independent readings (two IR and two IC) derived from two separate breath samples. This is the foremost safeguard.

2. Administrative Safeguards

In order to provide the State and defendants with necessary information regarding the instrument used in each test, the

State plans to add, in the next upgrade and modification of the firmware, additional administrative safeguards which this court finds must include:

a. The State must list the temperature probe serial number and probe value of that temperature probe on any report where such information is relevant, including the AIR, New Standard Solution Change Report, and Calibration Check documentation —— Calibration, Control Test Part I, and Linearity Part II Reports.

b. The State must publish any firmware revisions through some reasonable mechanism, including placing this information on the State Police web site.

c. In order to ensure quality control and firmware version control, the State must continue the practice of strictly limiting access to or "locking" the firmware so that changes to the firmware can be done only by the manufacturer or one of the State Police breath test coordinators authorized pursuant to N.J.A.C. 13:51-2.

d. All valid breath test results are reported on the AIR to three (3) decimal places. When a final breath test result is reported and recorded on the AIR, that value is always the lowest value of the acceptable readings within tolerance. That value is reported and recorded as a truncated number on the AIR to only two (2) decimal places. We reject the defenses' contention that the AIR should not be admitted into evidence.

e. In instances where a defendant is tested on an Alcotest 7110 and there is no reportable breath test value on the AIR for that defendant, the AIR must clearly show the source and reason why no breath test result was reported for that breath sample. This non-reportable test event in itself shall not constitute a legal determination of refusal to submit to chemical breath testing under the implied consent statutes.

f. The firmware currently in the Alcotest NJ Version 3.11, and any future modifications or upgrades of that present firmware, does not impact upon or affect the scientific reliability, accuracy or precision of the Alcotest evidential breath test instrument to detect, analyze and accurately report a breath alcohol reading. In sum, the Alcotest 7110, NJ 3.11 currently in use is scientifically reliable.

g. This court recognizes that the Alcotest 7110 is not dependent on the breath test operator to record the breath test reading or result. Operator involvement is limited to inputs of administrative information. The operator must strictly follow the test protocol and the instructions or "prompts" on the LED screen during the testing process. All analytical functions after this are performed by the Alcotest 7110, and are outside of and beyond the control or influence of the breath test operator. This is a significant advantage over the breathalyzer. If the test protocol or instructions are violated in any respect, the BAC reading must be rejected as evidence.

h. As to discovery data, the collected centralized historical data described in V(7) shall be provided for any Alcotest 7110 relevant to a particular defendant’s case in a digital format readable in Microsoft Access or similar program generally available to consumers in the open market. When such data includes tests from cases concerning defendants not part of the requesting defendant’s case, the information provided will include departmental case numbers, ages, and breath temperatures or other relevant scientific data on those other defendants' tests but not their personal identifying information, such as name, address, birth date, drivers license number, license plate number, or social security number.

i. The revised firmware shall require that the Ertco-Hart Digital Temperature Measuring System or other similar device traceable to the National Institute of Standards and Technology is in proper operating condition and that the serial number of such devices be listed on all reports where such information is relevant, including calibration, certification, and linearity reports.

j. The State shall provide regular, continuing, and meaningful training for attorneys and their experts consistent with that provided for certification of breath test operators and breath test coordinator instructors pursuant to the New Jersey Administrative Code at N.J.A.C. 13:51-1.1 to 1.14 and N.J.A.C. 13:51-2.1 to -2.2, respectively.

3. Source Codes

The discovery of the source codes by the defense pursuant to a reasonable protective order was rejected by Draeger from the outset. Conventional discovery was made difficult because Draeger was not a formal party and declined this court's invitation to intervene and defend its product in the customary manner. Eventually, Draeger offered to explain the source code aspect to this court *in camera* without a record. The defense understandably rejected such an arrangement. Draeger than suggested a very restricted review of the source codes under highly-controlled conditions, in Durango, Colorado. This offer was understandably spurned by the defense as impractical and unhelpful.

Finally, during this trial Draeger offered its source codes of some 896 pages and 53,774 lines for examination in New Jersey at the trial site by defense experts. By this time, it was too late. Such an examination would have taken weeks and considerable expense for the defense, which did not then have qualified electronic experts at hand, was ostensibly without adequate financial resources for the task, and would have delayed the trial perhaps into the summer. The parties seemed at a stand-off concerning the source code issue and this court was left to decide whether or not the so-called "black box" verification of the computer system in the Alcotest 7110 was scientifically reliable.

At this point the defense and Draeger decided to attempt negotiating a resolution to this stand-off. This court had warned Draeger that it could make a negative inference against the reliability of the Alcotest 7110 because of the withholding of relevant information. We stress here that the State was always most cooperative in discovery and never had possession of the source codes to turn over to this court or defense.

Finally, the defense and Draeger agreed to terms to insure the on-going integrity of the software/firmware codes and algorithms in a document termed ADDENDUM A. These terms were agreed to by Draeger and its counsel. Therefore, we conclude that the software and firmware, which is integral to all functions, is presumed reliable in our courts but only if the terms expressed in the attached ADDENDUM A are scrupulously followed by Draeger.

ADDENDUM A

(1) The software source code will be examined by an independent software house agreeable to Draeger and the parties in this case. This software house will examine the source code for obvious concerns within the code, and also for consistency with the algorithms as documented in the software. The source code, with the algorithms as documented in the software, will be provided to the independent software house under a confidentiality agreement acceptable to Draeger and will not be disclosed to the public, thereby preserving whatever trade secrets Draeger asserts. However, the software house will certify to the State and the public that the software properly employs the algorithms and that no errors exist in the source code.

(2) The software will be programmed so that it will be "locked" and incapable of change without such change being printed out on any alcohol influence report produced by an Alcotest 7110 MKIIIC in which it is employed. The "software lock" will be

verified by the independent software house specified in (1) and any subsequent revisions made under the process contemplated which result in subsequent software versions will be reflected by the printout of the new version numbers on the alcohol influence report.

(3) The Alcotest 7110 MKIIIC using the newly-created software version, after undergoing the source code review as specified in (1), will be tested against and measured in compliance with the O.I.M.L. specifications adopted and current at the time of such tests. This examination will be undertaken by a laboratory in the United States, and the software will be revised, if necessary, in accordance with any deficiencies in the event that the O.I.M.L. specifications are not met for anticipated version NJ 3.12. In the event the O.I.M.L specifications are not met and the software is modified, the modified software will be presented to the independent software house indicated in (1) for its review and

certification. It is expected that if the software house is satisfied the changes necessary are minor, the secondary review will be substantially modified compared to the initial review.

(4) Draeger agrees to sell to New Jersey attorneys and experts Alcotest 7110 MKIIIC units on the same terms as are in force with the State of New Jersey at the time the purchase was made with the then-current version of the New Jersey software. Draeger also agrees to offer training to the purchasers and the purchaser's employees in regard to use of the Alcotest 7110 MKIIIC on reasonable monetary terms and to warrant and service the instruments at the same rates as paid by the State of New Jersey. In the event that future software revisions take place, Draeger will facilitate upgrades of purchased Alcotest 7110 MKIIIC units to the then-currently available New Jersey software version. (Although Draeger understands that this entire agreement is subject to review and reasonable approval by the State of New

Jersey, this power is clearly within the State's purview. However, the intent of this clause is to make all current versions available to all non-governmental owners for a reasonable administrative fee.)

(5) Further, it is contemplated that in the future when the State of New Jersey requires any further software revisions, the State would give notice of such to the public and the independent software house would examine the source code changes and determine whether a complete review is necessary or whether the software house could certify that the changes made would not require an additional software review and O.I.M.L. testing. In the event of any major changes in the operational conditions of the instrument, a new and complete O.I.M.L. procedure laboratory examination, or such subset of such tests as the laboratory may determine are appropriate in light of the extent of the changes per the revision, would be required. To the extent possible, the parties envision using the same software

> house and testing lab so as to have the benefits of institutional memory; the future stability of those organizations is an important element to consider in deciding which to retain for these purposes.

This court will not indulge in any negative inference against Draeger because of its grudging attitude earlier with respect to disclosure of the source codes. The negotiated ADDENDUM A, and Ryser's forthright testimony, encourages this court to have confidence in Draeger's good faith with respect to the source codes which record and communicate the scientific findings which in turn become the Alcotest 7110's AIR. This court also finds that the "black box" testing of the computer system and source codes used to date is scientifically reliable. This court is convinced that the entire system is indeed reliable for breath testing and reporting breath alcohol measurements when the prescribed protocols are strictly followed by the operator. This conclusion is fortified by the parties' agreement to this reliability undertaking to insure fairness to the State and future defendants. The expense of the examination of the codes, and upgrades described in (1) to (5) will be on the account of Draeger. The reasonable administrative cost of making these current versions and changes generally available shall be at the cost of the persons desiring same, e.g., defendants, attorneys, Alcotest 7110 purchasers, and educational associations.

4. RFI-EMI Interference

The Alcotest 7110 used in New Jersey is well-shielded against electronic interference. The New Jersey process and procedure of administration of evidential breath tests provides adequate protection against both radio-frequency and electro magnetic interference. In addition to the carrying-case's shield, Draeger designed the instrument's five-layer motherboard to suppress RFI. During training, operators are instructed that cell phones or hand-held radio transmitters should not be used or stored in the area where the test is administered. Interference or abnormal test result signals are available to the operator visually through immediate information on the display screen (LED) and then on the AIR printout with an error message. BAC test result is reported on the AIR. The shielded Alcotest 7110 case has passed various tests for interference, including OIML, Volpe Lab, and State police testing. In order to further avoid potential interference a policy has been established and promulgated to all State and local police departments that any possible sources of RFI or EMI, such as walkie-talkies and cell phones, be banned from any area in proximity to the Alcotest instrument. The shields in the casing, the motherboard, these warnings, and the instrument's error messages provide adequate safeguards to insure scientific reliability in this regard.

5. Foundational Evidence

This court concludes that a proper foundation for the admission of an Alcotest 7110 reading shall include these elements.

a. The testimony of the operator that the customary procedures have been meticulously followed and the production of the operator's credentials.

b. These listed documents must be provided by the municipal prosecutor in discovery and may be admitted into evidence without formal proof in the discretion of the judge, if kept in the normal course of the State's business. In the event of a trial with an unrepresented defendant, these foundational documents must be placed in evidence. These documents are:

> i. Calibrating Unit, New Standard Solution Report, most recent change and the operator's credentials of the officer who performed that change;
>
> ii. Certificate of Analysis 0.10 Percent Solution used in New Solution Report;
>
> iii. Draeger Safety Certificate of Accuracy Alcotest CU34 Simulator;
>
> iv. Draeger Safety Certificate of Accuracy Alcotest 7110 Temperature Probe;
>
> v. Draeger Safety Certificate of Accuracy Alcotest 7110 Instrument unless more relevant NJ Calibration Records (including both Parts I and II) are offered;

vi. Calibration Check including both control tests and linearity tests and the credentials of the operator/coordinator who performed the tests;

vii. Certificate of Analysis 0.10 Percent Solution (used in Calibration-Control);

viii. Certificate of Analysis 0.04, 0.08, and 0.16 Percent Solution (used in Calibration-Linearity);

ix. Calibrating Unit, New Standard Solution Report, following Calibration;

x. Draeger Safety Certificate of Accuracy Alcotest CU34 Simulator for the 3 simulators used in the 0.04, 0.08, and 0.16 percent solutions when conducting the Calibration-Linearity tests;

xi. Draeger Safety Certificate of Accuracy Alcotest 7110 Temperature Probe used in the Calibration tests; and

xii. Draeger Safety, Ertco-Hart Digital Temperature Measuring System Report of Calibration, NIST traceability.

6. Breath Volume and Flow Rate

A suspect must deliver breath samples of a minimum volume of 1.5 liters. The minimum blowing time is 4.5 seconds. The minimum flow rate is 2.5 liters per minute. The breath sample when analyzed by the IR detector must reach or approach an equilibrium —— that is the infrared measure of the breath alcohol in the sample must not differ by more that 1% over .25 seconds. These are minimum criteria.

The defense argues for a minimum volume of 1.2 liters for all suspects. There is substantial credible evidence in the record that women over age sixty consistently have difficulty in reaching the 1.5 liter minimum. We agree with the defense to this extent only and so find. The minimum for women age sixty and over should be 1.2 liters. We find no credible evidence to support the theory that the minimum should be lower than 1.5 liters for the general population. The State has stressed persuasively that 1.5 liters and upwards provides a good deep breath sample for testing.

We also see no need to impose an overall maximum of 2.5 liters in volume as suggested by the defense. As we understand the evidence, the maximum volume usually tested is up to 3.0 liters. We find no evidence that a sample up to that 3.0l liters or higher is unreliable as a measure of the breath alcohol in the subject, or that the mantra, "The longer you blow the higher [BAC result] you go" is scientifically unfair to tested subjects. We are convinced that a higher volume than 1.5 liters simply presents a better sample of deep lung air for analysis by the instrument.

The State has assured us that the Alcotest 7110 can be programmed to set a minimum of 1.2 liters for women over age sixty when this information is obtained in the personal identification data from the subject and when so programmed and properly alerted, the instrument in the particular case will print out a valid BAC result.

7. Centralized Data Management

The Alcotest 7110 has the ability to communicate through the modem port with a central server by using a dedicated telephone line. This is not done presently. The State should promptly implement this improvement. This would allow daily or weekly uploads of all data from each Alcotest 7110 in the State automatically. The centralized data then can be viewed from a compatible data base program.

Breathalyzers were routinely checked in the field every six to eight weeks by State Police coordinators. Presently, the Alcotest 7110s are physically checked only once a year or sooner, if needed. This proposed transparent, easy access to State-wide digital data will help very much to assure quality control and alert the State Police to problems arising in the field. Dr. Brettell testified that this central data collection was desirable and the State should and intended to so proceed promptly.

This court strongly recommends that the State obtain and deploy a software program to create and maintain a centralized data base of digital information stored by all Alcotest 7110s throughout the State. This data should be uploaded, either daily or weekly, by a modem or internet connection to a central State location and maintained for at least ten years.

8. Non-Operator Dependent

Unlike the breathalyzer, the Alcotest 7110 is not operator dependent. With the breathalyzer, the reading and recording of BAC was based only on the observations of the operator as to where the needle indicator stopped on the dial. The operator simply wrote down his observation of the reading. No contemporaneous, machine-generated permanent record was produced by the breathalyzer.

With the Alcotest 7110 a permanent record, the AIR, is printed out and a copy given to the suspect after the test is completed. The AIR provides a complete explanation of the multiple-step test procedure as well as historic information about the arrest event and the subject, and some history about the use and testing of the Alcotest 7110 instrument. The Alcotest 7110 does not require manipulation of the physical components of the instrument by the operator to reach a BAC result, as does the breathalyzer. Once the Alcotest 7110 is activated, the entire process is automatic until the BAC result is printed out, unless the test is aborted without any BAC results. The operator has no control over the testing process itself or the result.

The objectivity of the Alcotest 7110 compared to the breathalyzer is a considerable advantage: it combines both accuracy, contemporary documentation of the result, and elimination of the ability of the operator to falsify or exaggerate the test outcome. This independence from potential operator influence and a permanent machine-printed record are decided advantage over the breathalyzer. These features are very helpful in avoiding situations like State v. Gookins, 135 N.J. 42 (1994), where the arresting officer falsified the breathalyzer results in drunken-driving cases to improperly coerce guilty pleas and obtain convictions.

9. Breath Temperature Sensor

Most breath analyzers used in the United States operate on the assumption that the temperature of an expired breath sample is 34 degrees C. Recent scientific research supports the proposition that the temperature of an expired breath sample is actually almost 35 degrees C. For each degree above 34 degrees C, breath tests will increase BAC results by 6.58%. While the relevant scientific community at this time does not generally accept breath temperature monitoring as necessary, this court finds that the technology to control this variable is accurate and readily available —— both Germany and Alabama currently use the breath temperature sensor available from Draeger.

We strongly recommend that New Jersey employ Draeger's breath temperature sensor. Unless such breath temperature sensing is implemented, all breath test results should be reduced downward by 6.58%, as done currently in Alabama. This will serve to reduce the overall margin of error from the Alcotest 7110 and increase confidence in the reported BAC as more accurate to support a finding of guilt. This court finds that until recently this technology was not used because it was either not available, too expensive or inconvenient to implement, or simply too much trouble but these reasons to abjure use of the breath temperature sensor are no longer persuasive to us. We find this is a biological variable which can and should be controlled.

10. Tolerances for the Two Breath Tests

The two breath samples when tested must be within a certain tolerance of each other for the breath test to be considered reliable. There has been considerable confusion and dispute over the appropriate allowable tolerances between the two breath samples. If the two samples are not within the tolerance range a third test is forced to determine if the tolerance can be met and the tests are reliable.

The Downie tolerance standard was .01 but this was enlarged by Dr. Brettell in the NJ 3.8 version of firmware to .01 or 10%

of the difference between the highest and lowest of the four readings (two EC and two IR), whichever is greater. NJ 3.8 was used in the Pennsauken pilot program which culminated in the Foley decision.

In his testimony before this court, Dr. Brettell confirmed that the written opinion in Foley mistakenly reported that he had testified that the NJ 3.8 software had a precision tolerance of .01 or plus or minus 10% of the mean of all four readings, whichever is greater. He testified before us that the NJ 3.8 formula was actually as described above, ".01 or 10% of the difference between highest and lowest of the four, whichever is greater."

Dr. Brettell then changed the formula for the NJ 3.11 firmware. He expanded the precision tolerance to "+/-.01 or +/— 10%" of the mean of the four readings (two EC and two IR) whichever is greater. This doubled the allowable tolerance between readings from NJ 3.8 (10%) to NJ 3.11 (20%). With a mean of 0.20, for example, the allowable tolerance in NJ 3.11 is 0.04, while with NJ 3.8 it is 0.02 and under Downie only 0.01.

In testimony before us Dr. Brettell said that he now has reconsidered the tolerance formula and concluded that it should be reduced or "tightened up." We now recommend a tolerance of plus or minus .005 or plus or minus 5% (10% overall) of the mean of the four readings (two EC and two IR) whichever is greater.

We consider this a reasonable tolerance range in all of the circumstances. Of course, only the lowest of the four readings will be admitted in evidence, if all are within this tolerance range.

We concur fully with Dr. Brettell that a tightened tolerance range is the best result to use for purposes of precision and accuracy, we hope without forcing unnecessary third tests. Use of the earlier formulas does not invalidate the test results rendered in those cases. They were not improper and inadmissible but our recent recommendation is simply a better, tighter range for precision and accuracy.

VI. THE END

This court finds that the Alcotest 7110, NJ 3.11 version is and has been scientifically reliable, under the clear and convincing evidence standard, when the test protocol is carefully followed by the operator and the instrument is functioning properly. This court is of the view that if our recommendations are followed any possible doubt on the accuracy of the instrument will be minimized.

Incorporation of the dual IR and EC technologies enhances analytical accuracy for alcohol (ethanol) and provides reassurance of a quality result. We are convinced that the Alcotest 7110 is the state-of-the-art technology available and if implemented with our suggestions will provide suspects and the general public the best possible assurance for the protection of individual rights and for public safety.

The recent motion filed on behalf of Draeger to appear as amicus is denied without prejudice, of course, to Draeger's right to make a prompt application to the Supreme Court for that relief.

*****

We attach a bibliography, part recommended and part ancillary, which may be helpful in understanding this very technical subject. We also express our gratitude for the very valuable contribution by our Appellate Division Staff Attorney Olga Chesler, Esquire, for her excellent contribution to completing this difficult task both throughout the 41-day hearing and the opinion preparation process. Many thanks, Ms. Chesler.

APPENDIX A - TRANSCRIPTS

1T - transcript of September 18, 2006 (morning)
2T - transcript of September 18, 2006 (afternoon)
3T - transcript of September 19, 2006
4T - transcript of September 20, 2006 (morning)
5T - transcript of September 20, 2006 (afternoon)
6T - transcript of September 21, 2006 (morning)
7T - transcript of September 21, 2006 (afternoon)
8T - transcript of September 25, 2006 (morning)
9T - transcript of September 25, 2006 (afternoon)
10T - transcript of September 26, 2006 (morning)
11T - transcript of September 26, 2006 (afternoon)
12T - transcript of September 27, 2006 (morning)
13T - transcript of September 27, 2006 (afternoon)
14T - transcript of September 28, 2006 (morning)
15T - transcript of September 28, 2006 (afternoon)
16T - transcript of October 3, 2006
17T - transcript of October 4, 2006 (morning)
18T - transcript of October 4, 2006 (afternoon)
19T - transcript of October 5, 2006
20T - transcript of October 10, 2006 (morning)
21T - transcript of October 10, 2006 (afternoon)
22T - transcript of October 11, 2006 (morning)
23T - transcript of October 11, 2006 (afternoon)
24T - transcript of October 12, 2006 (morning)
25T - transcript of October 12, 2006 (afternoon)
26T - transcript of October 16, 2006 (morning)
27T - transcript of October 16, 2006 (afternoon)
28T - transcript of October 17, 2006 (morning)
29T - transcript of October 17, 2006 (afternoon)
30T - transcript of October 18, 2006 (morning)
31T - transcript of October 18, 2006 (afternoon)
32T - transcript of October 19, 2006 (morning)
33T - transcript of October 23, 2006 (morning)
34T - transcript of October 23, 2006 (afternoon)
35T - transcript of October 24, 2006 (morning)
36T - transcript of October 24, 2006 (afternoon)
37T - transcript of October 25, 2006 (morning)
38T - transcript of October 30, 2006 (morning)
39T - transcript of October 30, 2006 (afternoon)
40T - transcript of October 31, 2006 (morning)
41T - transcript of November 6, 2006 (morning)
42T - transcript of November 6, 2006 (afternoon)
43T - transcript of November 8, 2006 (morning)
44T - transcript of November 8, 2006 (afternoon)

45T - transcript of November 9, 2006 (morning)
46T - transcript of November 9, 2006 (afternoon)
47T - transcript of November 13, 2006 (morning)
48T - transcript of November 13, 2006 (afternoon)
49T - transcript of November 14, 2006 (morning)
50T - transcript of November 14, 2006 (afternoon)
51T - transcript of November 15, 2006
52T - transcript of November 27, 2006 (morning)
53T - transcript of November 27, 2006 (afternoon)
54T - transcript of November 28, 2006 (morning)
55T - transcript of November 28, 2006 (afternoon)
56T - transcript of December 4, 2006 (morning)
57T - transcript of December 4, 2006 (afternoon)
58T - transcript of December 5, 2006 (morning)
59T - transcript of December 5, 2006 (afternoon)
60T - transcript of December 11, 2006
61T - transcript of December 12, 2006
62T - transcript of December 14, 2006
63T - transcript of December 15, 2006 (morning)
64T - transcript of December 15, 2006 (afternoon)
65T - transcript of December 18, 2005 (morning)
66T - transcript of December 18, 2006 (afternoon)
67T - transcript of December 19, 2006
68T - transcript of January 9, 2007 (morning)
69T - transcript of January 9, 2007 (afternoon)
70T - transcript of January 10, 2007

APPENDIX B-1

RECOMMENDED BIBLIOGRAPHY

(These are very helpful articles)

1. Kurt M. Dubowski, Absorption, Distribution and Elimination of Alcohol: Highway Safety Aspects, 10 J. of Studies on Alcohol 98 (Supp. July 1985) [D235]

   General comments on difficulties with per se drunken driver laws.

2. Allan R. Gainsford, Dinusha M. Fernando, Rodney A. Lea, & Allan R. Stowell, A Large-Scale Study of the Relationship Between Blood and Breath Alcohol Concentrations in New Zealand Drinking Drivers, 51 J. Forensic Sci. 173 (2006) [C16]

   A very recent study and article brought to our attention. Although not placed into evidence, probably by inadvertence, the article was mentioned by several witnesses and is available in Judge King's chambers. The abstract describes the sample as "21,582 drivers apprehended by New Zealand police" over a period of fifteen years. Id. at 173. This article confirms that the breath test at the 2100 ratio gives a significant advantage over the blood test:

   > It has been noted that the use of the BAC/BrAC ratio of 2100, implicit in jurisdictions expressing BrAC in terms of g/210L, gives drivers an approximately "10% advantage" over drivers who give blood samples. In NZ this advantage is even greater. The ratio of the respective legal limits for blood and breath alcohol in NZ is 2000. Our data suggest that the average BAC/BrAC ratio measured in the field is 19-25% higher than this.
   >
   > [Id. at 177.]

This 2006 article confirms our expressed view that the Alcotest 7110 as used in New Jersey provides a comfortable cushion for any margin of analytical or biological error, 10%. The conclusion fortifies our reluctance to recommend reduction of the ratio in New Jersey below 2100.

3. Rod G. Gullberg, Breath Alcohol Measurement Variability Associated with Different Instrumentation and Protocols, 131 Forensic Sci. Int'l 30, 34 (2003) [D23]

   Alcotest 7110 "yielded S.D. [standard deviation] and confidence interval estimates that were very acceptable forensically." Draeger out-performed Intoxilyzer, Datamaster and Intoximeter. See Figure 1, id. at 33; Figure 2 (using Alabama data), id. at 34.

4. R.G. Gullberg, Common Legal Challenges and Responses in Forensic Breath Alcohol Determination, 16 Forensic Sci. Rev. 92, 92 (July 2004) [D25]

   Discussion of issues arising in DWI addressed best by "prudent construction of administrative rules and employing forensically sound breath test protocol."

5. R.G. Gullberg, Determining an Appropriate Standard for Duplicate Breath Test Agreement, 39 Can. Soc'y Forensic Sci. J. 15 (2006) [AB11]

   On preference of plus or minus 5% of the mean for duplicate breath test agreement reference to probability of error detection. See Figure 4, id. at 21.

6. P. Harding, Ronald H. Laessig, & Patricia H. Field, Field Performance of the Intoxilyzer 5000: A Comparison of Blood- and Breath-Alcohol Results in Wisconsin Drivers, 35 J. of Forensic Sci. 1022, 1026 (Sept. 1990) [C1]

   Blood and breath both tested within one hour of each other for 395 pairs. Underestimated bias described:

   > Intoxilyzer 5000 results correlated well with blood alcohol concentrations, while demonstrating a low bias. The 11.5% overall systematic underestimation of BAC

found in this study is consistent with the 11% low bias found when police officers operated Breathalyzer Models 900 and 900A under similar conditions[]. This bias appears to be primarily due to physiological variables and could be substantially reduced if the instruments were calibrated using a blood/breath alcohol ratio of 2300:1 instead of the currently used 2100:1. This is an unlikely, and perhaps undesirable option from a forensic science point of view, however.

See also Figure 3. Ibid.

7. B.T. Hodgson, & M.D. Taylor, Evaluation of the Draeger Alcotest 7110 MKIII Dual C Evidential Breath Alcohol Analyzer, 34 Can. Soc'y Forensic Sci. J. 95, 101 (2001) [C2]

> Overall, the [Alcotest 7110] MKIII Dual C met the ATC [Alcohol Test Committee] standards for Approved Instruments. Both the precision and accuracy of this instrument were well within the ATC standards for acceptance throughout the range of simulator alcohol concentrations tested. The human subject testing demonstrated confidence intervals well within the ATC criteria when compared to two Approved Instruments. The MKIII Dual C is able to distinguish other potentially interfering substances from ethanol and able to detect ambient air contamination that might contribute to an apparent blood alcohol concentration.
>
> The MKIII Dual C maintained its initial calibration throughout the evaluation, a period of approximately 5 months No mechanical or electrical problems were encountered and the instrument performed without breakdown.
>
> . . . .

> The volunteer drinkers are thanked for their participation and cooperation in this study.

8. Alan Wayne Jones & Lars Andersson, Variability of the Blood/Breath Alcohol Ratio in Drinking Drivers, 41 J. Forensic Sci. 916, 920 (1996) [D19]

   Dr. Jones described the conclusion of tests on 799 individuals in Sweden, that those tested with breath alcohol methods enjoyed a 10% advantage compared to those tested with venous blood.

   > The introduction of evidential breath-alcohol analyzers in Europe has meant that prosecution for DUI can now be based on the person's BAC or BrAC depending on the sample taken. Under some circumstances, the option to provide a breath-alcohol test is not available, e.g., if a person is involved in an accident and needs treatment at a hospital, or when a breath analyzer is not available for use, or for various other reasons. This creates a dilemma for those close to a critical legal alcohol limit because of the roughly 10% advantage obtained by those who were tested on a breath-alcohol analyzer (Fig. 4) compared with analysis of venous blood. The consequences for the individual might be guilty or not guilty depending on whether a breath-alcohol or blood-alcohol test was used for forensic purposes.

9. L. Lindberg, S. Brauer, P. Wollmer, L. Goldberg, A.W. Jones, & S.G. Olsson, Breath Alcohol Concentration Determined with a New Analyzer Using Free Exhalation Predicts Almost Precisely the Arterial Blood Alcohol Concentration, Forensic Sci. Int'l (forthcoming 2006) [D18]

   Breath and blood tests in fifteen volunteers reflect very accurately the concentration of alcohol reaching the brain and supports the use of breath alcohol analysis for medical and legal purposes.

10. G. Schoknecht, G. & B. Stock, The Technical Concept for Evidential Breath Testing in Germany, Institute for Biophysics, Freie Universitat, Berlin, Germany http://www.druglibrary.org/schaffer/Misc/driving/s5p6.htm. (1995) [AB2]

German field test in 1993 using Draeger Alcotest 7110 produced this conclusion.

> Six instruments were passed to the police authorities at various locations in Germany for a field test starting in Sept. 93 and lasting for 15 months. Before the test the instruments were adjusted to 0.48mg/L at a liquid standard with an ethanol concentration of 1.21 g/L H_2O held at 34°C. Calibration checks were performed regularly every six month. The instruments were mainly operated at police stations but two of them were also tested in mobile use for several weeks. More than 700 tests have been successfully performed during the testing period where for approx. 300 tests additional blood samples were taken. The comparison between the blood alcohol concentration (BAC) and the corresponding BrAC is shown in Fig. 3. No corrections have been made for the time delay (a few minutes up to two hours) between breath and blood alcohol analysis because in general it is not known whether the subject is in the absorption or desorption phase. Despite this fact, the data show a very good agreement with a correlation coefficient of 0.98 and nearly all of the data points are within a

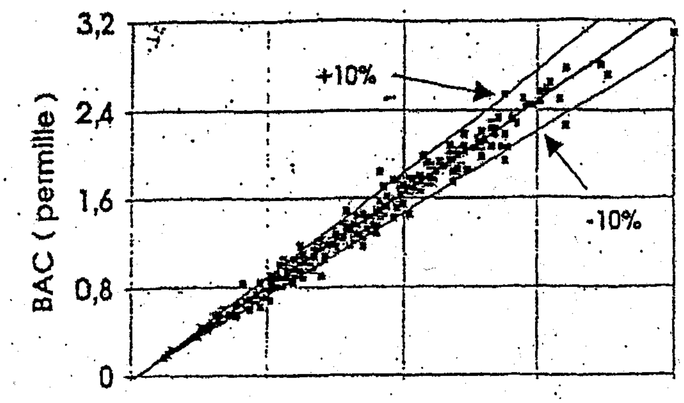

Fig.3: BrAC vs. their corresponding BAC values. The linear regression and the ± 10% range are indicated by the solid lines.

0 0.4 0.8 1.2 1.6
BrAC (mgL)

+/– 10% (rel.) distribution centered around the also plotted regression line. No outliers are observed. The regression line intercepts the BrAC axis at 0.02 mg/l which we attribute to an average time delay of 15 min. between BAC and BrAC analysis. From our data we calculate a BAC versus BrAC ratio of 2090. Where the ratio is only 1960 if breath temperature correction is not taken into account.

. . . .

In addition our data clearly point out in accordance with that breath temperature measurement improves the performance of breath alcohol analysis with respect to an equal treatment of the subjects. The data strongly support the OIML recommendation that breath temperature has to be taken into account for evidential roadside testing. But perhaps as the most important result the field trial revealed that the problem of BAC versus BrAC outliers has been overcome. Because of these outliers, which have been reported occasionally from pretest devices, breath alcohol analysis in general has been often blamed to be unreliable and not to meet the necessary requirements of evidential purposes for law enforcement in Germany.

11. M.D. Taylor & B.T. Hodgson, Blood/Breath correlations: Intoxilyzer 5000C, Alcotest 7110, and Breathalyzer 900A Breath Alcohol Analyzers, 28 Can. Soc'y Forensic Sci. J. 153, 153 (1995) [AB12]

In this recent study the Alcotest was compared to the Intoxilyzer and the Breathalyzer with these conclusions in the abstract:

> Two infrared (IR) breath alcohol analyzers, the Alcotest 7110 and the Intoxilyzer 5000C, were evaluated against blood results and against the Breathalyzer 900A currently used by Canadian police agencies. A total of 18 healthy human subjects were used for the breath to breath comparisons while 15 of those subjects each provided two blood samples approximately one hour apart for blood/breath correlations. The IR analyzers and the Breathalyzer showed a high degree of correlation with blood samples (n = 15: r = 0.974 for the Breathalyzer, r = 0.971 for the Intoxilyzer, and r = 0.989 for the Alcotest). All three instruments underestimated the blood results (mean differences, blood minus breath: 12 mg% for the Breathalyzer, 18 mg% for the Intoxilyzer, and 9 mg% for the Alcotest). In breath to breath comparisons the Intoxilyzer underestimated the Breathalyzer (n = 18, mean difference Breathalyzer minus Intoxilyzer = 4 mg%) while the Alcotest overestimated the Breathalyzer (n = 17, mean difference Breathalyzer minus Alcotest = -3 mg%).

See Figure 6, id. at 626. The linear regression analysis for the Alcotest 7110 was most impressive.

APPENDIX B-2

ANCILLARY BIBLIOGRAPHY

1. Joseph C. Anderson & Michael P. Hlastala, Breath Tests and Airway Gas Exchange, 20 Pulmonary Pharmac. & Therapeutics 112, 117 (2005) [D255]

> 6. Conclusions
>
> Airway gas exchange significantly impacts the interpretation of breath tests, particularly for gases with a blood-air partition coefficient greater than 100. The absorption-desorption kinetics of airway gas exchange cause the end-exhaled gas concentration to be less than the blood value by up to 30%. Additionally, factors such as airway perfusion and diffusion that govern airway gas exchange are intrinsic to the lung and affected by lung disease. Other factors like inspired air temperature and breathing maneuver should be carefully controlled to ensure accurate and repeatable breath measurements.

2. William Giguiere & G. Simpson, Medicolegal Alcohol Determination: In Vivo Blood/Breath as a Function of Time, 27 Int'l Assoc. Forensic Toxicol., Chemistry Centre, 494 (V.J. McLinden & D.J. Honey eds., 1992) [D243]

No summary is attempted.

3. Ulrich Heifer, Breathalcohol-Concentration/Bloodalcohol-Concentration: Utopia of a Forensically Usable Means of Evidence, 23 Alcohol, Drugs and Behavior 229, 238 (July 1986) [D244]

This article is in German and is untranslated. In the English summary the author states:

> Summary

> With the help of the results of 133 drinking tests with 1150 pairs of measurable values as well as with the help of experiments with animals we must answer in the negative to the question, asking for the physiological definite answer and the legal usefulness of the alcoholic concentration in blood indirectly found out by way of breathing. The area of the alveoli is an instable compartment for the distribution of ethanol, at least until an equilibrium is reached after reaching the maximum area of venous alcohol in blood.
>
> The handling of "Alcotest 7310" by the police causes a tendency "to filter" so-called unnecessary blood-tests of low concentrations. The lack of coordinating an alcoholic concentration in blood indirectly found out by way of breathing is demonstrated by the insufficient conformity of 1,000 pairs of measurable values (BAC [AT] and BAC [blood]), taken from the experiences gained by the police.

The author seems to conclude that breath testing is not reliable.

4. Michael P. Hlastala, <u>The Alcohol Breath Test –– A Review</u>, 84 <u>J. Applied Physiology</u> 401, 406-07 (1998) [D254]

Authors reject the theory of the alcohol breath test (ABT) and call for a new wave of research to improve the accuracy of BrAC measurement.

> Implications for the ABT
>
> For years, forensic scientists have struggled to explain the variability in BrAC. The problem followed directly from the tenaciously held belief that the last part of the exhaled BrAC was equal to the alveolar alcohol concentration. Recent experimental and theoretical studies dealing with the gas exchange of highly soluble

> gases have led to a new model for pulmonary alcohol exchange. This new model is based on the airway exchange of alcohol and can be used to explain the large observed variability in BrAC.
>
> The theory of the ABT is old and outdated. In principle, the ABT, as currently used, is based on the respiratory physiology of the 1940s and 1950s. The physiological understanding of pulmonary alcohol exchange has gone through a tremendous evolution in the past 50 years, revealing that physiological variability has a great impact on the ABT. It is now clear that most of the variability is due to physiological parameters that may change from one ABT to the next. Recognition that alcohol exchanges in the airways, rather than the alveoli, opens up the ABT for a new wave of research to improve the accuracy of BrAC measurement.

5. Michael P. Hlastala, Invited Editorial on "The Alcohol Breath Test", 93 J. Applied Physiology 405 (2002) [D261]

   No summary is attempted.

6. Michael P. Hlastala, Wayne Je Lamm, & James Nesci, DWI, NACDL 57 (2006) [D257]

   No summary is attempted.

7. Michael P. Hlastala, The Impact of Breathing Pattern and Lung Size on the Alcohol Breath Test, 35 Annals of Biomed. Eng'g 264, 272 (2006) [D256]

> In conclusion, alcohol exchanges between the respired air and the airway tissue during both inspiration and expiration. This airway gas exchange causes the exhaled alcohol concentration to always be less that the ACC [alveolar air concentration]. A consequence of this

> airway exchange is that BrAC depends on lung size and the amount of effort provided by the subject.

8. Dominick Labianca & G. Simpson, Statistical Analysis of Blood- to Breath-Alcohol Ratio Data in the Logarithm-Transformed and Non-Transformed Modes, 34 Eur. J. Clinical Chem. Clinical Biochem. 112 (1996) [D245]

   Authors assert results are consistent with a blood breath ratio of 2300:1.

9. Dominick A. Labianca, The Flawed Nature of the Calibration Factor in Breath-Alcohol Analysis, 79 J. of Chem. Educ. 1237 (2002) [D249]

   The author is very skeptical of current methods of breath testing as flawed.

10. G. Simpson, Accuracy and Precision of Breath Alcohol Measurements for Subjects in the Absorptive State, 33 Clinical Chem. 753, 756 (1987) [D252]

    The author is very skeptical of current methods and says:

    > But more importantly, if it is not known whether a subject is in the absorptive or postabsorptive state, then it is not possible to know how reliable the AAC [the BAC result from a quantitative evidential breath alcohol analyzer (AAC = BrAC x 2100)] result is. Overestimates of actual BAC can be anywhere from 15% to more than 100%. Errors of this magnitude raise questions about satisfying legal criteria for due process.
    >
    > . . . .
    >
    > Too few data are available to establish statistical limits for the accuracy and precision of breath testing results in the absorptive state. However, results from

data in the literature indicate that breath testing is not a reliable means of estimating a subject's BAC during absorption. The results also indicate that there is a significant likelihood that a given subject will be in the absorptive state when tested under field conditions. Because of large differences in arterial BAC and venous BAC during absorption, breath test results consistently overestimate the result that would be obtained from a blood test —— by as much as 100% or more. In order to have some idea of the reliability of a given breath test result, it is essential to determine by some objective means whether the subject is in the absorptive or postabsorptive state. In the absence of such information, an appropriate value for the uncertainty associated with the absorptive state should be applied to all breath test results.

11. G. Simpson, Accuracy and Precision of Breath-Alcohol Measurements for a Random Subject in the Postabsorptive State, 33 Clinical Chem. 261 (1987) [D241]

    See #10 above.

12. G. Simpson, Medicolegal Alcohol Determination: Widmark Revisited, Clinical Chem. (1988) [D250]

    See #10 above.

13. G. Simpson, Do Breath Tests Really Underestimate Blood Alcohol Concentration?, 13 J. of Analytical Toxicol. 120 (1989) [D248]

    See #10 above.

14. G. Simpson, Medicolegal Alcohol Determination: Comparison and Consequences of Breath and Blood Analysis, 13 J. of Analytical Toxicol. 361 (1989) [D250]

See #10 above.