COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS.

BOSTON MUNICIPAL AND
DISTRICT COURT DEPARTMENTS

DOCKET NOS. 1248 CR 1075,
1201 CR 3898, and others

COMMONWEALTH

v.

EVANDO ANANIAS, CHRISTIAN FIGUEROA, AND OTHERS

MEMORANDUM OF DECISION ON CONSOLIDATED DEFENDANTS' MOTION TO EXCLUDE BREATH ALCOHOL CONTENT PERCENTAGE RESULTS USING THE ALCOTEST 9510 AND ANY OPINION TESTIMONY

In a consolidated litigation, defendants of the Boston Municipal Court and District Court Departments charged with Operating a Motor Vehicle while Under the Influence of Intoxicating Liquor (G.L. c. 90, § 24) seek, in limine, to exclude breath test results produced by the Alcotest 9510, a breathalyzer instrument developed by Draeger Safety Diagnostics, Inc. (Draeger). For the reasons set forth below, this motion is **DENIED in part** and **ALLOWED in part**.

I. Procedural Background

On August 3, 2015, the Chief Justice of the District Court issued an order of special assignment consolidating 531 cases in which defendants charged with Operating a Motor Vehicle while Under the Influence of Liquor challenged the scientific reliability of the Alcotest 9510, the breathalyzer device currently used throughout the Commonwealth. A hearing pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and Commonwealth v.

Lanigan, 419 Mass. 15 (1994) was scheduled to commence on January 25, 2016 as part of a scheduling order issued October 5, 2015. After a series of discovery motions, the Court determined that the hearing on this issue as it related to the Alcotest 9510 source code would be confined to a static analysis.[1] On November 9, 2015, the Chief Justice of the Boston Municipal Court likewise consolidated 64 cases raising the same issue. The Court (McManus, J.) in that litigation permitted a defense request for dynamic as well as static analysis of the Alcotest 9510 source code.[2] As a result of these and various other rulings, both the Commonwealth and the defendants in these parallel litigations sought appellate review before a Single Justice of the Supreme Judicial Court. On June 6, 2016, the Single Justice (Botsford, J.) issued an order joining both sets of cases into a single consolidation and permitting the defendants to perform dynamic testing on the Alcotest 9510. The order required that the Massachusetts State Police Office of Alcohol Testing ("OAT") make two Alcotest 9510 breathalyzers and ancillary components available to the defendants. On June 13, 2016, the Chief Justice of the Trial Court assigned these further consolidated matters to this Court. After a series of additional delays due to discovery conflicts, issues concerning a protective order for the confidential Alcotest 9510 source code, and appeals to the Single Justice regarding the schedule set by the Court, the Daubert-Lanigan hearing commenced on January 18, 2017, in the Concord District Court. The Court heard testimony over ten days. Although there are 535 cases formally consolidated, it is estimated that an additional two to three thousand cases are stayed pending the outcome of this litigation.

[1] "Static analysis" involves analyzing the efficacy of software by a review of the source code. Generally, a static analysis involves the use of software tools to review source code in much the same manner that spellcheck or grammar check analyzes ordinary prose. Proper static analysis must be accompanied by a manual review of the code itself.

[2] "Dynamic analysis" is testing that involves running a program on a device to observe its functionality.

II. Legal Standard

The defendants move to exclude the results of their breath tests pursuant to Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993) and Commonwealth v. Lanigan, 419 Mass. 15 (1994). When a party challenges the admissibility of scientific or technical evidence, a trial "judge . . . has a gatekeeper role," Lanigan, 419 Mass. 15, 26 (1994), "to protect fact finders from exposure to expert testimony 'that is not based on reliable methodology.'" Peterson v. Bd. of Assessors of Boston, 62 Mass. App. Ct. 428, 433 (2004) (quoting Canavan's Case, 432 Mass. 304, 315 (2000)). More broadly, this "gatekeeper role" extends to situations in which any "'evidence produced by a scientific theory or process' is at issue." Commonwealth v. Camblin, 471 Mass. 639, 648 (2015) (quoting Commonwealth v. Curnin, 409 Mass. 218, 222 (1991)).

The burden of persuasion as to the reliability of a particular scientific theory or process rests with its proponent. See Palandjian v. Foster, 446 Mass. 100, 112 n.17 (2006). This burden is satisfied "either by establishing general acceptance in the scientific community or by showing that the evidence is reliable or valid through an alternate means." Canavan's Case, 432 Mass. at 310. Factors a court may consider in determining reliability include: "whether the scientific theory or process (1) has been generally accepted in the relevant scientific community; (2) has been, or can be, subjected to testing; (3) has been subjected to peer review and publication; (4) has an unacceptably high known or potential rate of error; and (5) is governed by recognized standards." Commonwealth v. Powell, 450 Mass. 229, 238 (2007) (citing Daubert, 509 U.S. at 593-94). However, because "[a]pplication of the Lanigan test requires flexibility" and "[d]iffering types of methodology may require judges to apply differing evaluative criteria to determine whether scientific methodology is reliable," Canavan's Case, 432 Mass. at 314 n.5,

"[n]ot all of the factors identified in Daubert will be applicable in every case." Palandjian, 446 Mass. at 111.

The test of reliability is a flexible one, and "a trial judge has broad discretion in determining which factors to apply to assess the reliability of proffered expert testimony." Palandjian, 446 Mass. at 107. A trial judge's decision in this regard will be reviewed only for an abuse of discretion. Commonwealth v. Shanley, 455 Mass. 752, 762 (2010). It is also within the trial judge's discretion to determine whether to hold an evidentiary hearing at all. Palandjian, 446 Mass. at 111; Commonwealth v.Addy, 79 Mass. App. Ct. 835, 838 (2011) (judge may, but is not required to hold an evidentiary hearing on a Daubert challenge).

III. Scope of Hearing

It is well established in Massachusetts that breath test evidence is admissible in criminal prosecutions. See Commonwealth v. Barbeau, 411 Mass. 782 (1992). However, in Commonwealth v. Camblin, 471 Mass. 639 (2015), the Supreme Judicial Court held that the scientific reliability of a particular breathalyzer instrument, there the Alcotest 7110,[3] may be tested by defendants as to whether "the source code and other challenged features of the Alcotest functioned in a manner that reliably produced accurate breath test results." Id. at 650. The Supreme Judicial Court rejected the Camblin motion judge's conclusion that our Legislature's specific provision for the admissibility of breath test results in OUIL cases combined with the New Jersey Supreme Court's full vetting of issues relating to the reliability of the Alcotest 7110, see State v. Chun, 194 N.J. 54 (2008), established reliability and obviated the need for a hearing.

[3] The Alcotest 7110 is the immediate predecessor to the Alcotest 9510. According to expert testimony from Draeger representatives, which the Court credits, the analytical systems employed by the two machines with respect to measuring alcohol are virtually identical. The calibration system, on the other hand, is substantially different, as the Alcotest 9510 uses a more reliable dry gas standard.

In the current consolidation, the defendants sought to expand the scope of the reliability challenge permitted in Camblin, arguing that the Alcotest 9510 presents different analytical issues than the Alcotest 7110. Although the defendants' motion is divided into sixteen individual challenges, these can be reduced to four categories: (1) whether the source code, as developed and implemented in the Alcotest 9510, reliably produces accurate results; (2) whether the Alcotest 9510 relies on flawed scientific theories regarding blood-to-breath ratio; (3) whether Office of Alcohol Testing ("OAT") methodology relating to the Alcotest 9510 produces unreliable results; and (4) whether the Alcotest 9510 source code contains security vulnerabilities that make it susceptible to intentional manipulation that could produce unreliable results.

The Commonwealth countered that this hearing should have been limited to source code issues. It argued that the Alcotest 9510 and 7110 are practically identical analytically, and that the other issues regarding the device are not "novel," because they were addressed in the Camblin litigation. The Commonwealth objected to extending the scope of this hearing to include the validity of theory of blood-to-breath ratio used by the Alcotest 9510, based on the Supreme Judicial Court's longstanding recognition of "the reliability of the scientific principles underlying the use of breathalyzer evidence." Commonwealth v. Durning, 406 Mass. 485, 490 (1990). The Commonwealth further suggested that OAT practices and purported source code security weaknesses are issues of evidentiary weight rather than of admissibility based upon scientific reliability. More generally, the Commonwealth objected to this Court hearing any issues that overlapped with Camblin, reasoning that it would be an unwarranted duplication of effort.

Upon consideration of arguments by the parties, the Court agreed to extend the scope of the hearing beyond source code issues to include the defendants' challenge to the blood-to-breath ratio as derived from "Henry's Law"[4] and applied in the Alcotest 9510, as well as to OAT's methods and protocols for preparing the breathalyzer instruments prior to their deployment. As to the underlying scientific principles utilized by the Alcotest 9510, the defendants' claim, supported by expert affidavits, that the evolving understanding of chemical engineering of the human lung renders the long accepted formula obsolete sufficiently raised the issue for the purpose of this hearing. Regarding OAT protocols and methodology, after hearing from the parties, it became clear that the Alcotest 9510 is sent to the various police departments in a different condition than as received by OAT from Draeger. Additionally, the calibration of an instrument performed by OAT prior to its initial deployment and during its annual certification raises scientific methodology concerns that fall under the umbrella of Daubert-Lanigan. To the extent that there is an overlap in issues addressed by the Camblin litigation, this Court fundamentally disagrees with the Commonwealth's position. Although the decision rendered on remand in the Camblin case is clearly exceptionally thorough and well-reasoned, see Court's Ruling on Defendant's Motion *in limine* to Exclude Alcotest Results as Scientifically Unreliable Following Remand by the Supreme Judicial Court, dated May 11, 2016 (Sullivan, J.), the fact remains that the issues as resolved there have not been considered by a Massachusetts appellate court. Moreover, however analytically similar the Alcotest 9510 and Alcotest 7110 may be, the individual defendants in this consolidation are different from those in Camblin, with different attorneys, different witnesses, and individual due process and witness confrontation rights. In

[4] Henry's Law states that, at a constant temperature, the amount of a given gas dissolved in a given type and volume of liquid is directly proportional to the partial pressure of that gas in equilibrium with that liquid. A different ratio applies to each type of gas and liquid. As such, Henry's Law governs the solubility of gasses in water. It is the theoretical basis for describing the behavior of liquid solutions in wet simulators, and describes the effect of blood alcohol on human breath.

considering whether to expand the scope of the hearing, the Court recognized that claims based upon alleged human error or those pertaining to an individual breathalyzer machine as used in a particular police department are issues of evidentiary weight rather than admissibility based on the reliability of scientific principles or methodology. The Court was also mindful of the extraordinary public resources expended in this litigation and the concomitant obligation to resolve any issues that appear to be common to all potential defendants who submit to an Alcotest 9510 breathalyzer test so that they need not be repeated in individual cases.[5] Yet, even with this broad view, this Court declined to consider the defendants' fourth category of challenges given the hypothetical nature of potential intentional manipulation of the code by some mythical, third-party malfeasant. To the extent there is evidence that any particular Alcotest 9510 instrument was hacked, the defendants may advance those claims in a particular case. The mere theoretical possibility that an Alcotest 9510 device, like any technology, may be hacked is insufficient to require its global exclusion.

IV. Discussion

The Alcotest 9510 breathalyzer instrument uses "dual sensor" technology to determine the quantity of alcohol in a breath sample. One sensor uses infrared (IR) spectography to analyze the sample, while the other sensor employs electric chemical (EC) fuel cell oxidation. IR spectography measures the degree to which a substance absorbs infrared light at various wavelength frequencies. Both technologies have been used in evidential breath testing since the 1970s. The Alcotest 9510 begins its infrared detection of alcohol when a subject blows air into a tube; the expelled breath passes through a heated cuvette into an infrared chamber, where an

[5] The parties in this consolidated litigation are represented by fourteen lead attorneys, six for the Commonwealth and eight for the consolidated defendants. To date, the Court has approved public funds upon motions for the consolidated defense totaling $351,597.47. During the hearing, counsel indicated that one of the Commonwealth's experts was paid $125,000. Witnesses called to testify have traveled from as far as Germany and Sweden.

infrared detector examines the absorption of infrared light at 9.5 microns. Measurement at the 9.5 micron wavelength range is designed to avoid other chemical substances, in particular acetone, accidentally being read and calculated. The EC fuel cell sits on top of the IR chamber, and part of the breath sample is funneled into it as the subject blows into the tube. The fuel cell passes electricity through the sample, causing a chemical reaction that releases energy in the form of an electrical current. The fuel cell then measures the level of electrical current, or signal, produced by this chemical reaction, which is proportional to the sample's alcohol content. A single breath blown into the Alcotest 9510 results in 128 IR and EC calculations per second. Although the IR and EC measure a sample simultaneously, they are not interdependent. Rather, the device compares the infrared reading against the fuel cell reading. In Massachusetts, only the IR reading is reported to the operator; the EC reading is intended to verify the IR result and to detect any interfering substances in the breath sample. The results must agree within specified limits, which are preset in the instrument before delivery by Draeger according to local specifications. A result falling outside the locally prescribed threshold of agreement causes an error or "status" reading, which should terminate the test.[6] The Alcotest records and stores all

[6] During the hearing, the defendants offered examples of fifteen cases in which the value of the IR and EC readings exceeded the prescribed threshold of agreement, yet the instrument still reported a BAC result. This prompted an investigation by OAT and Draeger and the calling of an additional witness by the Commonwealth. According to this witness, Brian Shaffer, a member of the Draeger management team, the parameter setting for the acceptable difference between IR and EC sensor readings is set by Draeger. OAT has no ability to alter this setting. The correct value of this setting is 38 micrograms/liter, which after certain algorithmic calculations equates to .008 (or a 10% difference at .08% BAC). The fifteen cases identified by the defense were produced by six different devices. Of the six, investigators had inspected two by the time of Mr. Shaffer's testimony, both of which were set incorrectly at 60 micrograms/liter. This wider tolerance range does not directly impact the subject BAC result, but it does permit results to be reported when the tolerance level for detecting interferents is outside the acceptable range. In other words, it makes the device less sensitive to interferents. The BAC results in these instances should not have been reported, since the instrument should have reported an error and, if set correctly, shut down. All Massachusetts Alcotest 9510 machines were called into OAT for similar inspection. At the time of Mr. Shaffer's testimony, ninety of the approximately 350 Massachusetts Alcotest 9510 devices had been inspected, and not one was set correctly according to Draeger specifications. Some of the devices were set so that they would be less sensitive to interferents, while others were set to lower than 38 micrograms/liter, making them more sensitive than prescribed. Draeger's explanation for this mystifying and disturbing situation is human error on the part of the Draeger programmers setting parameters. The Commonwealth points out that the fifteen "problem" cases identified by the defense were among 93,000 on the database provided to the consolidated defendants. It is not clear to the Court

results, both IR and EC, internally, and in Massachusetts the data is transmitted to a central server from which the information can be extracted.

It is important to note, at the outset, that all scientific measuring devices have generally accepted levels of uncertainty. No scientific measuring device could ever return exactly the same result twice; indeed, lack of variations would be suspect. Breathalyzer devices generally are to be expected to be within the greater of .005 or 5% of the "true" value. Known solutions obtained from laboratories are certified to be within .002 of the "true" value. Accordingly, an accurate and precise measurement, within the scientific meaning of that term, will still vary a small amount from the "true" value.

A. Black Box Testing of the Alcotest 9510

In determining whether the Alcotest 9510 produces reliable breath test results, one factor the Court may consider is the extent to which the instrument has been subjected to testing and the results of any such tests. "Black Box" testing is a method that involves examining the functionality of an instrument by running it and subjecting it to tests without accessing its internal components or operating system. In the United States, all evidential breath testing devices must meet certain specifications and be approved by the National Highway Traffic Safety Administration (NHTSA). This testing is performed in the Alcohol Countermeasure Laboratory at the Volpe Center, a Massachusetts-based government "think-tank." Edward Conde, a chemical engineer with thirty years of experience at the Volpe Center, has tested approximately 800 breathalyzer machines over his career, including the Alcotest 9510 on three occasions. He has never worked for Draeger nor for any other company that manufactures

whether the fifteen cases are the product of an exhaustive search of the materials provided to the defense. In any event, the Court allowed the defendants' oral motion to be provided with any reports and notes from the investigation. Although the Court finds that this issue does not impact the *scientific reliability* of the Alcotest 9510 or the *science underlying it*, the situation certainly requires swift remediation.

evidential breath testing devices. He has no incentive to approve devices, and to the contrary looks for reasons to fail them. Most breathalyzers he tests, in fact, do fail, at least initially. Regardless of the results, once he completes his testing, Mr. Conde submits a report to NHTSA. If a breathalyzer machine passes muster, it may be listed on NHTSA's conforming products list and used by law enforcement agencies.

Mr. Conde's prime directive in his work is to answer the question "does the machine reliably measure alcohol?" In order to reach this conclusion, he tests for the following: (1) precision (whether the device hits the same spot every time) and accuracy (whether it hits the spot for which it is aiming every time) using solutions with a known alcohol percentage; (2) acetone interference (whether acetone injected into the simulator is appropriately detected); (3) alcohol free simulation (whether the device ever registers alcohol when measuring an alcohol free solution); (4) breath sample (whether results remain the same regardless of the length or intensity of a blow); (5) input power (whether results vary depending on the voltage used to operate the device); (6) ambient air (whether the temperature of the air outside the device impacts results); (7) vibration stability (whether shaking of the instrument in three dimensions at various amplitudes and frequencies impacts results); and (8) electrical safety (whether the device has any electrical connections that might endanger its user). As reported by Mr. Conde, the Alcotest 9510 passed all eight tests, and accordingly is included on the NHTSA conforming products list. Mr. Conde opined that the Alcotest 9510 consistently operates in a manner that reliably measures alcohol.[7] Based upon his extensive experience testing breathalyzer machines,

[7] In Camblin, the Supreme Judicial Court noted that the reliability of a breathalyzer is not established simply by virtue of the fact that it appears on the NHTSA list of conforming products. 471 Mass. At 650 n. 24. Here, however, the Court heard live testimony regarding the particulars of the instrument being subjected to actual testing, which is one of the factors a court may consider in a Daubert-Lanigan analysis. As with Camblin, Mr. Conde tested a generic Alcotest 9510, not one loaded with Massachusetts-specific software.

his relative objectivity, and the exhaustive tests he performed, the Court credits Mr. Conde's conclusion.[8]

B. The Alcotest 9510 Source Code

Although it is evident that the Alcotest 9510 consistently operates as designed in producing verifiable breath test results in a laboratory setting, this does not end the discussion. The Alcotest 9510 is dependent on its computer to control and report its measurements. Its functions are directed by two microprocessors that work in tandem: one operates the system itself, performing such tasks as clicking on the screen or printing hard copies of results; the other causes the device to measure alcohol concentration based on certain algorithms. The instrument's capabilities are defined and directed by binary code in the microprocessors rather than by ordinary prose. For example, using the phrase "now measure alcohol" does not work; instead, the programmer must use programming words, i.e., source code, that are then converted into binary language by a compiler, and thus direct the device to perform a specific operation. The Commonwealth maintains that the Alcotest 9510 source code was developed and implemented in a manner that produces accurate and reliable results. The consolidated defendants contend that the source code utilized in the Alcotest 9510 fails to meet industry standards in several ways and that it contains a variety of flaws that result in its overall unreliability.

The Commonwealth presented testimony regarding the Alcotest 9510 source code from three Draeger representatives: (1) Dr. Burkhardt Stock, who holds a Ph.D in physics and who developed procedures underpinning both the Alcotest 9510 and the Alcotest 7110; (2) Soenke

[8] In addition to passing NHTSA standards in the United States, the Alcotest 9510 was approved by the International Organization of Legal Metrology (OIML), and has satisfied rigorous testing standards in Australia, France, Germany, and the Netherlands. It is currently used for evidential breath testing in twenty countries.

Fischer, a software programmer who worked on the Alcotest 9510 source code; and (3) Hansueli Ryser, Draeger's Vice President of Government Affairs, who has extensive technical experience in evidential breath testing machines and currently oversees Draeger's contracts, compliance verifications, and approvals. Andrew McKenna, a source code analyst employed by Security Innovations, Inc., reviewed the Alcotest 9510 source code on behalf of the Commonwealth. The consolidated defendants proffered the testimony of Evan Kovanis, a computer hardware and software research engineer employed by Zeidman Consulting, a California based company that specializes in high-tech consulting and litigation support. The Court received and considered reports and/or affidavits from each of these expert witnesses.[9] All of these witnesses demonstrated a breadth of knowledge, a depth of understanding, and an ability to translate complex engineering and computer coding concepts into relatively digestible descriptions for their largely lay audience. Remarkably, there were many areas in which the Commonwealth and defense experts agreed regarding the source code. Ultimately, however, they disagreed as to whether it was written in a manner that causes the Alcotest 9510 to produces reliable breath test results.

Experts for both parties agree that perfect source code does not exist. Nor is perfection the standard under Daubert-Lanigan. Many of the flaws in the code identified by Mr. Kovanis were seen by Mr. McKenna as well. In general, the Court found Mr. Kovanis to be an informative and credible witness. He performed a relatively thorough analysis of the source code and identified numerous areas of concern. Ultimately, however, the Court agrees with Mr. McKenna's assessment that Mr. Kovanis' concerns are misplaced, at least so far as the overall reliability of the instrument is concerned. In some instances, Mr. Kovanis pinpointed code errors

[9] The Court approved a request for public funds for dynamic testing and the defendants retained an expert in dynamic analysis of source code; however, the defendants elected not to call the witness nor was his report entered as an exhibit.

that exist, but do not impact the operation of the device. In others, he identified apparent coding "problems" that, in context, were simply alternative paths to the same end. A couple of the issues raised by Mr. Kovanis were the product of his not fully reading the code, and thereby missing programming language that appeared a line or two before or after the apparent "error" he detected. Although Mr. McKenna also noted ways in which the Alcotest 9510 source code "misbehaves," his overall conclusion was that it will produce accurate and reliable results. The Court credits this opinion. After weighing the testimony of each witness and considering the nature and context of the particular issues raised by the consolidated defendants, the Court is satisfied that the Alcotest 9510 source code is written and executed in such a manner that the device produces accurate and reliable results. The Court discusses the defendants' specific concerns with respect to the source code below.[10]

1. Industry Standards and Programming Best Practices

The defendants contend that Draeger did not meet generally accepted industry standards in its development and production of the Alcotest 9510 source code. Dr. Burkhardt Stock, a Draeger employee for over thirty years, was a pivotal player in creating procedures for the company's breath testing machines. Over his career, Dr. Stock has authored a number of papers in the field, the principles of which he incorporated into the development of both the Alcotest 9510 and the Alcotest 7110. As explained by Draeger's Soenke Fischer, the Alcotest 9510 source code was written as a component of the five phase "waterfall" model of software design and development. He describes this process as follows: (1) "Definition" (Phase1) – the development team gathers requirements from the customer; (2) "System Design" (Phase 2) – the

[10] Although the consolidated defendants' pleading enumerates challenges to the results of the Alcotest 9510 in sixteen numbered paragraphs, several of these challenges became merged during the hearing and others not pressed sufficiently to require a specific ruling by the Court.

software team determines how to accomplish the defined goals; (3) "Programming" (Phase 3) – the computer code is written by software programmers; (4) "Integration/Validation" (Phase 4) – different aspects of the software (in the Alcotest 9510, for example, the system microprocessor and the alcohol measuring microprocessor) are integrated and programmers test to insure that the instrument operates according to the customer's specifications; and (5) "Maintenance" (Phase 5) – the device is modified, as necessary, based upon customer change requests. In his critique of the Draeger operating model, Evan Kovanis suggests that an additional step that he called an "implementation period" should be inserted between the Programming and the Integration/Validation phases. In considering Mr. Kovanis' testimony, the Court finds that the distinction he draws is really one of semantics, and cannot discern a meaningful difference between his approach and Draeger's. The Court credits Mr. Fischer's testimony that Draeger's approach is consistent with the operating standard in the software industry.

The defendants also argue that the Alcotest 9510 source code does not adhere to "programming best practices." During his testimony, Mr. Kovanis characterized Draeger's efforts as "sloppy programming that makes the code hard to understand." Yet, he based his opinion largely on his own education and experience, rather than on any established written industry guidelines set forth by a governing body or association of software developers. Thus, despite his extensive credentials, the discussion does not end with Mr. Kovanis' opinion. According to Andrew McKenna, no such universal standard of "programming best practices" exists. He asserts that, contrary to such disciplines as engineering or medicine, the software development community is a "meritocracy," in which general acceptance is based upon use and functionality of the particular source code. Mr. McKenna recognized many of the same programming idiosyncrasies identified by Mr. Kovanis, and indicated that he too might have

written the source code differently in various places. Yet, he likens these differences to architectural design variations, rather than a departure from established programming practices. After weighing all of the testimony on this issue, the Court is persuaded that computer source code programming, while at its core a scientific endeavor, in practice has an inherent element of artistic expression; different programmers will write code differently to achieve the same result. The choices of the Draeger programmers in writing the Alcotest 9510 source code do not offend an established set of "best practices."

More importantly, despite the defendants' criticisms, they do not identify specific adverse manifestations of Draeger programming choices for Alcotest 9510 source code. The role of the Court in this litigation is to determine whether the source code produces reliable blood alcohol results, not whether the software is efficient, elegant, or easy to understand and debug. Accordingly, the Court finds that this argument does not raise concerns regarding the reliability of the Alcotest 9510 breath test results.

2. Unchecked Return Values

The defendants assert that the source code "returns values" from functions that are "unchecked," rendering the software unreliable. As explained by Mr. Kovanis, when the source code "calls a function," it tells the instrument to perform a task. The code should check to confirm that the function has actually occurred or if there were errors, and then react, or "return a value," accordingly. For example, if a program calls a function that adds two numbers, it should verify that the function actually returns a number and report an error if the function fails. The Alcotest 9510 does not do so in certain places, such as in the function that coordinates the alcohol measurement taken by the IR and EC sensors. At first glance, this appears to be a critical shortcoming. Yet, as explained by Soenke Fischer, it merely represents a different software

design choice. Instead of relying on return values, the Alcotest 9510 source code contains a "Global Error Variable" as an alternative means of checking for errors. The Global Error Variable is a program that runs continuously in the background of the software to check for function errors. It is set to make the software aware of when an error occurs, and to stop the device from working when such an error message appears. Mr. McKenna initially shared Mr. Kovanis' concerns, because he too was unaware of the source code's Global Error Variable. When informed of this programming device, Mr. McKenna concluded that it renders the absence of checks on certain return values in the Alcotest 9510 source code immaterial to the reliability of its results; he characterized it as just a different way of doing the same thing. The Court credits this explanation, and finds that unchecked return values do not impact the reliability of the Alcotest 9510.

3. Electrochemical Sensor Bit Location in Hardware Configuration

The defendants next cite the setting of the "bit"[11] in the EC sensor to the "off" position as undermining the system accuracy of the Alcotest 9510. In short, the source code sets a particular bit to 0, which tells the program that no EC sensor is available. Once again, Mr. McKenna was concerned with this portion of the source code as well until he heard Soenke Fischer's explanation. Mr. Fischer testified that, before the Alcotest 9510 source code can be run by the user, it must be loaded with a configuration file, which varies from jurisdiction to jurisdiction. Mr. Kovanis acknowledged that he was unaware that the sensor bit setting is modified by the loading of a configuration file. The Massachusetts configuration file, as explained by Mr. Fischer, turns the setting of the EC fuel cell sensor bit to "on" and thereby permits the device to utilize the EC sensor. The Court credits Mr. Fischer's testimony that designing source code in a

[11] A "bit" is the smallest unit of computer information, registering a single 1 ("yes") or 0 ("no"). A "byte" consists of eight bits, and thus can express exponentially larger values. A megabyte refers to 1,048,576 bytes.

manner that requires subsequent configuration is a very common practice, and is satisfied that the EC sensor bit location in the source code does not present a problem. In the Massachusetts version of the configuration file added to the Alcotest 9510, the bit for the EC sensor is set to "yes," meaning that it is in the "on" position.

4. Uninitialized Variables

In the context of computer programming, a "variable" is a space in the memory of the software used to store data. A variable is "initialized" in the source code when the programmer assigns it a value prior to its first use. For example, if a program wanted to count the number of times an operator pressed a key, it would assign a variable (here "K") and add 1 to K every time the operator pressed the key. The defendants assert, and Mr. Kovanis testified, that a variable must be initialized to a specific value in order to guarantee accurate operation of the software. He likened it to setting an odometer to zero before starting a trip so that miles traveled can accurately be calculated. The defendants argue that the Alcotest 9510's use of uninitialized variables causes unreliable breath tests. Their contention fails for several reasons. First, as Mr. McKenna noted, contrary to Mr. Kovanis' analogy, an odometer need not be set at zero to provide accurate information; as long as there is a starting point noted, the distance to the end point can be calculated using simple math. Second, the Court credits Mr. Fischer's testimony that uninitialized variables are not used in any mathematical equations or decisional logic performed by the Alcotest 9510; the defendants offered nothing to counter that assertion. Third, the uninitialized variables discovered by the defendants were known to Draeger, because they used a static analysis tool to identify such issues when first developing the Alcotest 9510 source code. Draeger declined to take corrective action in the form of writing new code lines because they determined that the variables lacking initialization bore no consequences with respect to the

function of the device. Fourth, Mr. McKenna located several of the same uninitialized variables as Mr. Kovanis, but also pointed to several variables identified by Mr. Kovanis as uninitialized that, in fact, were initialized.[12] To the extent variables were uninitialized, Mr. McKenna categorized the findings as "low severity." He pointed to the context, and opined that they did not impact the Alcotest 9510's ability to produce reliable results. The Court credits this opinion, in large part because uninitialized variables in the Alcotest 9510 source code are overwritten with known, initialized variables after approximately eight milliseconds, or less than a ½ second. Since the breath test itself may not be administered for at least fifteen minutes, and administrative tasks performed by the breath test operator could not humanly be executed in less than a ½ second, there is no practical ramification to this initialization delay. Finally, as it relates to the specific concerns cited by the defendants, the absence of initialized variables actually would result in the earlier recognition of potential errors in the running of the program. The Court is satisfied that if such an error were to occur, it would be detected by the global error safeguard built into the Alcotest 9510 source code.

5. Data Integrity and Management

Many of the concerns expressed by the defendants regarding data integrity and management stem from the issues surrounding uninitialized variables. For the same reasons as discussed above, the Court rejects these concerns. The defendants also suggest that the Global Error Variable "may" get overwritten when program flow is interrupted in certain routines; however, Mr. Kovanis cites no specific example of how this possibility would result in erroneous

[12] Mr. Kovanis acknowledged during cross-examination that several places in the source code where he believed variables were uninitialized actually were initialized. The initialization occurred a few lines above those on the code he checked, and he simply missed them.

breath sample results. The Court credits Mr. Fischer's testimony that Global Error Variables in the Alcotest 9510 source code are not overwritten.

6. Clipping of Sensor Measurements

The defendants' motion asserts that the source code directs that negative values from the IR and EC sensor measurements be rounded up to zero. The assertion, however, is accompanied by no evidence from an expert with sufficient background to support it. The Court declined to permit the defendants to raise this issue through the testimony of Mr. Kovanis, whose academic background and experience are in computer engineering. While the defendants present this claim as a source code issue, it actually relates to the underlying physics and chemistry that the source code is implementing, not the design of the code itself. Mr. Kovanis is neither a physicist nor a chemist, and thus was not qualified to opine on this issue. To the extent the issue was raised during the testimony of Dr. Stock, who as a physicist has the requisite expertise, the Court is satisfied with his opinion that such rounding, or "clipping," does not impact the reliability of Alcotest 9510 breath test results.

7. Hardware Error Check Programming

This argument is based upon the findings in Mr. Kovanis' report that the portion of the source code that checks for hardware errors in the Alcotest 9510 uses uninitialized variables. During his testimony, Mr. Kovanis acknowledged that if such an error occurred it would stop the instrument from executing the code and report an error; it would not produce an actual result that is unreliable. He also conceded that he did not review an area of code one line above the location he believed was uninitialized at which the function actually was set. Accordingly, the Court rejects this challenge.

C. Interfering Substances

The defendants argue that the Alcotest 9510 fails to detect and accurately report substances other than ethanol that may interfere with a breath sample, thereby producing unreliable test results. In support of this contention, the defendants offered the testimony of two witnesses. Dr. Andreas Stolz is a professor at the National Superconductivity Laboratory at Michigan State University. He holds Ph.D and Master's degrees in Physics. Dr. Stolz specializes in infrared spectrometry and evidential breath testing, and has testified on these subjects in numerous cases in several jurisdictions. Dr. Joseph Anderson, is a biomedical consultant and professor of bioengineering at University of Washington. He holds Ph.D and Master's degrees in Chemical Engineering. Dr. Anderson has testified approximately 175 times as an expert in eight states as well as in federal court. The defendants do not press the issue of interferents as it relates to acetone, since the IR detector's ability to eliminate acetone interference by taking measurements at a micron level different from acetone's wavelength is well established.

Using Massachusetts Alcotest 9510 breathalyzers, Dr. Stolz experimented with several chemicals to determine whether they could be measured and reported by the device without triggering its alcohol interferent detection system. While most of the chemicals failed to register at all on the Alcotest 9510, there were a couple of substances that raised questions. Dr. Stolz first ran a series of tests with these chemicals added to water to create solutions of varying concentrations in order to see whether the machine would register a blood alcohol content (BAC) result. In one instance, the machine showed a sample without ethanol measuring as high as .02% BAC with no interference detected. Dr. Stolz then repeated the tests, this time combining the chemicals with a .076% ethanol solution in an attempt to artificially raise the BAC reading. His

results included one combination that raised the BAC result to .08% without reporting interference. Although all of these tests were conducted in-vitro, Dr. Anderson testified that all of the chemicals, at least theoretically, could enter the human body by swallowing, breathing, or through the skin. He further explained that most of the chemicals used by Dr. Stolz are found in products with which humans frequently come into contact. The defendants argue that such failures to detect interferents by the Alcotest 9510 critically undermine its reliablility.

The Commonwealth counters this argument by identifying a number of flaws in Dr. Stolz's experiments and conclusions, as well as in Dr. Anderson's reasoning. In support of its position, the Commonwealth offered the testimony of Dr. Alan Wayne Jones. Dr. Jones earned a Ph.D in Chemistry and Pharmacology in 1974. He was the head of the National Laboratory of Forensic Toxicology for Sweden from 1985 to 2013. He currently lectures at the University Hospital in Stolkholm, Sweden. Dr. Jones has engaged in extensive research and written over 400 papers in more than 100 different scientific journals on the effects of alcohol on the human body. He has peer-reviewed other scientists' research for over forty years, appraising the merits of various articles in over fifty different scientific journals. Dr. Jones has lectured on subjects relating to forensic toxicology and testified in courts in many countries hundreds of times over his career. He is recognized by those in the community, including Dr. Anderson, as the world's foremost expert on forensic toxicology, particularly as it relates to blood and breath alcohol. In addition, Dr. Jones has specific expertise in breath testing devices. He has published over ten papers on the issue of interferents and breathalyzers. Based upon this extraordinary resume, as well as the manner in which the training and experience it reflects was manifest in his courtroom presentation in both form and content, the Court fully credits Dr. Jones' testimony.

Although generally respectful of Dr. Stolz's scientific process, at least in the abstract, Dr. Jones cast serious doubt on the applicability of his experiments to human subjects. Dr. Jones reminded the Court that all of Dr. Stolz's results were the product of tests performed using inanimate containers. He testified, in essence, that none of the chemicals used would have practical applications to human interaction with the Alcotest 9510. In support of this conclusion, Dr. Jones explained that potential exposure through contact with chemicals found in ordinary household items as posited by the defense experts cannot possibly present practical problems for the use of evidential breath testing, since massive dilution with total body water would make these chemicals undetectable. This is consistent with Dr. Stolz's results showing the majority of such chemicals not registering on the Alcotest 9510 at all. Dr. Jones also described how, once inside the human body, one of the chemicals would metabolize into acetone, while another would dissipate too rapidly to be absorbed into the blood. Dr. Stolz and Dr. Anderson agree that the Alcotest 9510 reliably detects acetone interference. Dr. Jones testified that if consumed by a human in the quantity and concentration necessary to produce a response in the Alcotest 9510 as reported in Dr. Stolz's tests, several of the chemicals used in the experiments would cause physical reactions requiring emergency medical care, if not incapacity or fatality. [13] Ultimately, Dr. Jones opined that Alcotest 9510 reliably detects interferents, and that none of the chemicals cited by Dr. Stolz and Dr. Anderson present issues that undermine its ability to generate ethanol-specific blood alcohol content (BAC) results.[14]

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[13] Although Dr. Anderson did cite a few examples of studies in which subjects actually had ingested chemicals at concentration levels within the range used by Dr. Stolz, the Court finds that these represent outliers on the extreme margins. One of the studies was authored by Dr. Jones, who testified that Dr. Anderson had taken the data out of context.

[14] The Commonwealth also submitted into evidence a number of articles and studies that discuss the extreme unlikelihood of interfering substances causing issues for evidential breathalyzers. Although none specifically address the Alcotest 9510, the Court finds the principles underlying the articles persuasive.

Based upon all of the evidence presented on this issue, the Court is satisfied that the Alcotest 9510 distinguishes ethanol from other substances potentially found in human breath, and therefore returns reliable BAC results based solely on ethanol measurements. To the extent a defendant breath test comes from an extreme outlier who ingests another chemical intoxicant in an amount sufficient to register a BAC without being detected and without severe medical consequences that render the subject unable to provide a test sample, the potential failure of the Alcotest 9510 to detect the contributing substance while marginally raising the BAC result is an issue of evidentiary weight or affirmative defense as opposed to admissibility based upon scientific reliability of the instrument.

D. Blood-to-Breath Ratio Theory

The scientific principles underlying evidential breath testing have long been accepted in Massachusetts and throughout the country. See Camblin, 471 Mass. at 651-55; Chun, 194 N.J. at 95-96; Fisher v. City of Europa, 587 So. 2d 878, 887 (Miss. 1991); People v. Nieves, 143 Misc. 2d 734, 738 (N.Y. City Crim. Ct. 1989); State v. Johnson, 717 S.W.2d 298, 304 (Tenn. Crim. App. 1986); Pruitt v. State, 216 Tenn. 686, 691-92 (1965). Nevertheless, the consolidated defendants in this litigation claim that science is evolving with respect to the physiology of breathing, and consequently argue that all breath test results, including those produced by the Alcotest 9510, are fundamentally flawed and scientifically unreliable.

In support of this position, the defendants presented further testimony from Dr. Joseph Anderson. Dr. Anderson is a colleague and protégé of Michael Hlastala, who first posited this "new paradigm" of breathing many years ago. During a fascinating presentation, Dr. Anderson testified about the chemical engineering processes of the lung as they relate to the expulsion of alcohol in the breath. He elaborated on the Hlastala theory that ethanol delivered in a breath test

sample originates from the lining of the bronchi and not the alveolar space. This "airway exchange model" fundamentally alters the analysis of breath alcohol. As relevant here, all evidential breathalyzer devices, and indeed the Code of Massachusetts Regulations (CMR) that pertain to breath testing, rely on the understanding that alcohol is best measured in "deep lung" or "end-expired" aveolar air. Dr. Anderson contends that no such air exists. He testified that the physiological model on which the Alcotest 9510 is based is not in step with current research in the field regarding alcohol exhalation. Ultimately, Dr. Anderson opined that the proper understanding of human breathing patterns using the Airway Exchange Model translates into a blood-to-breath ratio of 1800:1, as opposed to the 2100:1 that has been followed since the 1950s.[15] This, he claims, leads to incorrect and unreliable BAC results being produced by the Alcotest 9510.

Although intrigued by Dr. Anderson's presentation, the Court is not convinced that he is correct. His theory still appears to lack sufficient documentation. See Chun, Special Master's Report at 222 (September 2005); Chun, 194 N.J. at 50-52. Dr. Jones, whose credentials were discussed in detail in the previous section, strongly disagrees with the Hlastala/Anderson paradigm. So, apparently, do the vast majority of forensic toxicologists.[16] In Dr. Jones' opinion,

[15] The blood-breath ratio, based on Henry's Law, is the ratio between the amount of alcohol in the blood and the amount of alcohol in the breath. The amount of alcohol detected in the breath must be multiplied by the blood-breath ratio to obtain the amount of alcohol in the blood.

[16] The Commonmwealth's argument on this point is compelling: "It is also worth noting that far from being accepted in the scientific community, many of his peers have disputed Mr. Hlastala's claims. For example, Theodore J. Siek, a forensic toxicologist, strongly disagreed with Mr. Hlastala's "new paradigm" in a commentary published in the Journal of Forensic Sciences after the publication of Mr. Hlastala's article, cited to by the defense. See Siek, Theodore J., Commentary on Hlastala MP. Paradigm Shift for the Alcohol Breath Test, J. Forensic Sci.,Vol. 55, No. 6 (2010), attached as Exhibit . . .. Dr. Siek believes that the paper should have been published as an opinion piece, not an experimental paper because it was not supported by any studies done by the author, and pointed out that "no toxicologist in recent years has advocated a change in the standard ratio, because the ratio used today, 2100:1, matches up with reality." Id. . . . James G. Wigmore, widely known and respected expert in the field of breath testing, also submitted commentary refuting Mr. Hlastala's claims, referring to his "paradigm" as "myopic" and criticizing the selective and misleading citations to the literature in this area employed by Mr. Hlastala. See Wigmore, James G., Commentary on MP. Paradigm Shift for the Alcohol Breath Test, J. Forensic Sci., Vol. 56, No.

the 2100:1 ratio may actually result in a breath testing device underestimating a subject's blood alcohol content. All breath testing machines in the United States and Canada use the 2100:1 ratio, as do several in Europe. Some countries in Europe use a 2400:1 ratio (which would result in higher blood-alcohol content results) in their evidential breathalyzers.

Given the weight of the evidence and the near universality of opinion, the Court is convinced that the blood-to-breath ratio theory on which the Alcotest 9510 relies is generally accepted in the relevant scientific community and remains sound science.

E. OAT Methodology and Procedures

The Massachusetts State Police Office of Alcohol Testing is a calibration laboratory. Among its functions are the configuration, deployment, annual calibration, and maintenance of all Alcotest 9510 breathalyzer devices currently in use throughout the Commonwealth of Massachusetts. OAT oversees the certification and training of the Massachusetts breath alcohol testing program. It does not perform any repairs or maintenance on the internal operations of the Alcotest 9510.

Melissa O'Meara, the Technical Leader of OAT, is responsible for the day to day operation of the laboratory, as well as for establishing policies and procedures for breath test

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1 (2011) . . . Further undermining the defendants' claims regarding the underlying physiology of breath testing are several large scale, peer reviewed studies in which researchers in the United States and abroad have compared breath test results against blood test results obtained from the same individuals, demonstrating that breath testing accurately measures blood alcohol levels. See Stowell, A.R. et al., New Zealand's Breath and Blood Alcohol Testing Programs: Further data analysis and forensic implications, 178 Forensic Science International 83 (2008); Taylor, M.D. and Hodgson, B.T., Blood/Breath Correlations: Intoxilyzer 5000C, Alcotest 7110, and Breathalyzer 900A Breath Alcohol Analyzers, Can. Soc. Forens. Sci. J., Vol. 28, No. 2 (1995); Harding, Patrick M. et al., Field Performance of the Intoxilyzer 5000: A Comparison of Blood and Breath Alcohol Results in Wisconsin Drivers, 35 J. Forensic Sciences1022 (1990), attached collectively as Exhibit . . .. These studies show that for approximately 95 percent of people, breath tests will measure blood alcohol as lower than or equal to the actual amount of alcohol in the blood. See Harding et al. at 1024; Alan Wayne Jones & Lars Andersson, Variability of the Blood/Breath Alcohol Ratio in Drinking Drivers, 41 J. Forensic Sciences 916, 916 (1996); Stowell et al. at 83, all attached as Exhibit . . .."

administration and training. She supervises the scientific process and the scientists who are tasked with ensuring that all Alcotest 9510 breathalyzers used by Massachusetts law enforcement agencies are functioning properly and set within parameters as required by Massachusetts regulations. Her educational background includes a Bachelor of Science degree in Chemistry, with a minor in Biology from the University of Massachusetts at Lowell. She has been a scientist in the Massachusetts State Police Crime Laboratory for over twenty-four years, serving in a variety of capacities before becoming the supervising scientist at OAT in June of 2011 and its Technical Director in December of 2013. Ms. O'Meara currently works with three other scientists at OAT.

The consolidated defendants raise an array of issues pertaining to OAT's practices, ultimately arguing that the laboratory's deficiencies impact the reliability of Massachusetts Alcotest 9510 test results to the point that they should be deemed inadmissible. Janine Arvizu, a certified laboratory quality auditor, testified on behalf of the defendants. Ms. Arvizu received her Bachelor of Science degree in Chemistry from California Polytechnical Institute at San Luis Obispo and worked at the U.S. Department of Energy for ten years before starting her own Quality Assurance firm. Although she never visited OAT, Ms. Arvizu fully reviewed all written protocols and other documents relating to OAT's compliance with scientific standards. Upon consideration of her testimony, the Court credits Ms. Arvizu's opinions in certain areas, but finds that her standards of scientific review might be so high as to be unattainable. In keeping with her role, Ms. Arvizu looked for problems anywhere she could find them at OAT; the Court certainly takes no issue with that approach. Yet, the Court must consider her assessment of OAT in light of her own tacit acknowledgement that she has never audited a laboratory that she found fully satisfactory. Ms. Arvizu also conceded that her testimony in over 150 cases, all for criminal

defendants challenging the reliability of breath test results, has sounded the same themes in criticizing laboratory procedures.

Although numerous sub-issues were discussed, Ms. Arvizu's chief criticisms of OAT can be reduced to four main areas: accreditation, measurement uncertainty, lack of traceability, and absence of protocols. The Commonwealth contends that these challenges pertain to the weight of the evidence rather than its admissibility. As to the first three, the Commonwealth may be correct; however, since they apply to laboratory practices that potentially impact all Massachusetts Alcotest 9510 devices, the Court felt it was prudent to address them in this litigation, as previously discussed. On the question of OAT protocols, the Court is convinced firmly that the existence, sufficiency, and standardization of laboratory procedures reflect scientific methodology, which squarely raises gatekeeper issues of reliability under a Daubert-Lanigan analysis.

The OAT laboratory's lack of accreditation is not disputed by the Commonwealth. It is the significance of this fact upon which the parties disagree. Ms. Arvizu indicated in her testimony that adhering to a standard generated by an authoritative scientific body as reflected in accreditation is a minimum requirement for reliable laboratory work. She pointed out that accreditation does exist for laboratories that perform breath alcohol calibrations. Ms. O'Meara certainly recognizes the importance of laboratory accreditation as well. Since assuming stewardship of OAT, she has steadily made improvements to its operating procedures in an effort to obtain accreditation from the American Society of Crime Lab Directors (ASCLD). Currently, according to Ms. O'Meara, only twenty-two calibration labs in the United States are accredited; only a few of those are state laboratories. Although accreditation is a laudable goal, the Court is not convinced that its absence inherently undermines the reliability of OAT's work.

The concerns regarding "measurement uncertainty" and "traceability" are largely interwoven. Measurement uncertainty relates to the margin of error created by the measurement process, whereas traceability refers to the ability to relate a measurement to an original reference point through an unbroken chain of calibrations. Each of these concerns was addressed to the Court's satisfaction by Ms. O'Meara. Regarding measurement uncertainty, the Court accepts the Commonwealth's argument that the concept has only recently been applied to breathalyzer testing. Still, according to Ms. O'Meara, OAT actually does calculate a measurement uncertainty regarding its calibrations of 7% by drawing on historical OAT data regarding system error (5%) and adding it to the dry gas manufacturer's margin of error as reported on its certificates of analysis (2%).[17] She also credibly testified that "traceability" has different meanings depending on the scientific application, and that OAT traces such materials as the dry gas it uses through manufacturer information on the cylinder. The manufacturer maintains further records that make the substance traceable to its origins. Neither of these issues causes the Court particular concern with respect to OAT's procedures and any impact they may have on the reliability of Alcotest 9510 results.

The Court is not as sanguine with respect to OAT protocols. The defendants contend that OAT protocols, to the extent they exist, do not comport with scientific standards. Ms. Arvizu credibly testified as to the reasons why scientific results generated in a setting that has no

[17] Experts on both sides agreed that all scientific test results are subject to a standard deviation or margin of error. So, although this 7% measurement uncertainty does not raise concerns with respect to the scientific reliability of the Alcotest 9510, and the defendants do not claim otherwise, it certainly raises concerns regarding accuracy of certain results as reported. This is particularly troubling as it relates to criminal defendants charged under the per se portion of G.L. c. 90, § 24. For example, as Ms. O'Meara testified, the measurement uncertainty on a .080% BAC reading means that the true value could be from .076% to .086%. Because the Alcotest 9510 result as reported is truncated, the BAC would be reported as a .08%. Even if the true BAC of the sample value factoring in the OAT margin of error is .076%, the defendant would be criminally liable based upon the reported result. This problem could be remedied in a variety of ways, including by allowing defendants to elicit the margin of error at trial or by stipulations between the parties.

documented, validated, standardized procedures cannot be considered reliable. Ms. O'Meara agreed in substance, testifying that "reliability of lab results depends on policies and procedures."

When Ms. O'Meara became the supervising scientist at OAT, there were no formal, written policies in place covering the duties and responsibilities of OAT scientists or the management of the equipment and materials under OAT care. Nor were there written protocols formally standardizing testing and calibration procedures to be followed by the lab's scientists. Under her leadership, the laboratory began to establish written policies to formally direct and document operational procedures. From September 12, 2012 to May 18, 2016, the following protocols were promulgated: Simulator Testing Protocol, Version 1.0 (September 12, 2012), Solution Protocol, Version 1.0 (September 12, 2012), Protocol for testing Dry Gas Standards Version 1.0 (September 12, 2012), Initial Set-Up Procedures for the Draeger Alcotest 9510, Version 1.0 (November 12, 2012), Solution Protocol, Version 2.0 (November 4, 2013), Dry Gas Standards Verification, Version 2.0 (November 4, 2013), Certificate of Calibration Procedure for the Alcotest 9510, Version 1.0 (September 15, 2014), Office of Alcohol Testing Administrative Manual, Version 1.0 (May 25, 2014), Certificate of Calibration Procedure for the Alcotest 9510, Version 2.0 (May 18, 2016). Each of these protocols sets forth, with varying degrees of specificity, a standardized, step-by-step approach to the topic it covers.

According to Ms. O'Meara, prior to these written guidelines, OAT protocols consisted of worksheets with checkboxes used by scientists for particular tasks. The worksheets typically had additional data reflecting a scientist's work stapled or paper clipped to it. An example of such a worksheet is part of the record evidence (a silhouette of a paper clip is visible on the copy marked as an Exhibit 88). Absent from these forms, however, is a variety of important items,

such as the permissible tolerance range of the IR and EC sensors for the annual calibration check. Ms. O'Meara testified that this type of information was made known through "word of mouth around the lab." She testified that procedures with respect to preparing breathalyzer devices for deployment into the field, testing of solutions and dry gases, verification of standards received from outside suppliers, annual certification, administrative procedures, and quality control were all informally shared in undocumented meetings of scientists assigned to the laboratory. The Court credits Ms. Arvizu's testimony that, during the relevant time period, the scientific community required written protocols for accepting the presumptive reliability of calibration laboratories. This standard clearly was not met. Despite Ms. O'Meara's attempt to impute some sense of orderliness and consistency to the manner in which the worksheets were created and catalogued, the Court does not accept the proposition that they functionally equated to written protocols. In the absence of written protocols, it cannot be assumed that any particular calibrator understood or routinely applied the proper standards in calibrating a device. Based upon the evidence presented, the Court finds that, although the necessary pieces were gradually falling into place as protocols steadily were developed, the Commonwealth has not shown that OAT had a scientifically reliable methodology for calibrating the Alcotest 9510 prior to the promulgation of the Certificate of Calibration Procedures for the Alcotest 9510 on September 14, 2014.

The deployment of the Alcotest 9510 breathalyzer to Massachusetts law enforcement agencies began in June, 2012. OAT completed roll-out of the device in August, 2012. Currently, there are approximately 350 Alcotest 9510 breathalyzer machines in the field. Each of these devices was calibrated by OAT according to Massachusetts specifications before its delivery to a local police department and requires calibration certification annually. According

to Draeger representative Burkhard Stock's testimony, "if an instrument is not calibrated correctly annually, it will not work in the field." Without demonstrating a scientifically sound methodology, the Commonwealth cannot convince the Court that Alcotest 9510 devices deployed or last certified by OAT prior to September 14, 2014 were calibrated routinely in a manner that would produce scientifically reliable results. Accordingly, any Alcotest 9510 BAC result from a device calibrated and last certified by OAT between June, 2012 and September 14, 2014 presumptively is excluded from use by the Commonwealth in any criminal prosecution. That is not to say that the Commonwealth is precluded from presenting witnesses, presumably calibrating scientists from OAT, on a case-by-case basis, to demonstrate to a trial judge that the BAC result in a particular case is the product of a properly calibrated instrument. As to any Alcotest 9510 calibrated and certified after September 14, 2014, the Court finds that OAT's protocols, while remaining a work in progress, were sufficiently documented, validated, and standardized such that any results produced by those devices were the product of scientifically reliable methodology.

V. Conclusion

After weighing all of the credible evidence presented during the Daubert-Lanigan hearing and considering the applicable law, the Court finds as follows:

1. the Alcotest 9510 breathalyzer device operates in a manner that produces scientifically reliable BAC results;

2. the source code underlying the Alcotest 9510 breathalyzer device was developed and implemented in a manner that produces scientifically reliable BAC results;

3. the theory of blood-to-breath ratio underlying the algorithmic functions used by the Alcotest 9510 to produce BAC results remains sound science;

4. the methodology employed by OAT from September 14, 2014 to the present produces scientifically reliable BAC results;

5. the annual certification methodology employed by OAT from June, 2012 to September 14, 2014, based upon the evidence presented, did not produce scientifically reliable BAC results; however, the Commonwealth may demonstrate to the trial judge, on a case-by-case basis, that a particular Alcotest 9510 was calibrated and certified using scientifically reliable methodology, and thus that a particular BAC result is scientifically reliable.

Accordingly, the Court **DENIES** the consolidated defendants' Motion to Exclude Breath Alcohol Content Percentage Results Using the Alcotest 9510 and Any Opinion Testimony for any breathalyzer results from a machine calibrated and certified after September 14, 2014, but **ALLOWS** the motion as to any results produced by a device calibrated and certified between June of 2012 and September 14, 2014, subject to the possibility of a case-by-case demonstration of the reliability of OAT's calibration of a particular device to a trial judge in the court in which the Commonwealth seeks to offer the result as evidence.

February 16, 2017

So Ordered,

Robert A. Brennan
Justice of the District Court