

provide a known alcohol vapor concentration to test the accuracy and proper working order of the instrument.” WAC 448-16-030(8) (Emphasis added). A simulator is a device which when filled with a **certified** simulator solution, maintained at a known temperature, provides a vapor sample of known alcohol concentration. WAC 448-16-030(11) (Emphasis added).

The Washington State Toxicology Lab (WSTL) is responsible for the preparation, testing, and validation of solutions. Simulator solutions are reference materials used to calibrate, test, and ensure the accuracy and precision of DataMaster and individual breath tests. Accordingly, the Breath Testing section depends on the work product of the WSTL as the base for calibration of instruments and for the verification checks performed in the field with each test.

State Toxicologist Dr. Barry Logan (Logan) promulgated protocols and procedures contained in the Policies and Procedures Manuals that governs the preparation and testing of solutions. There are separate protocols that govern the preparation of external standard solutions (field solutions) and quality assurance solutions (QA solutions). In general, a toxicologist mixes the solutions according to the protocols, and then each of the 16 toxicologist tests the solutions by preparing vials of the mixture and submitting them to headspace gas chromatography along with control vials and blank vials. The results are recorded for each toxicologist into the “solution certification database,” which is then used to calculate a “certified” value assigned to the solution. This solution is then used by the Breath Test section for calibrations, validations, etc. with respect to the instruments. The toxicologists then “certify” that they have performed

the tests and that the results as published are correct. These certifications are intended to be used in court in lieu of live testimony by the toxicologists.

There were many irregularities present during the preparation, testing, and validation of these solutions. Because of these irregularities, this court cannot consider the breath test results to be reliable, scientific evidence that is helpful to a trier of fact under ER 702.

The irregularities are described below:

Inaccurate Certifications

1. Anne Marie Gordon (Gordon) was promoted to Lab Manager sometime in 2003.
2. Gordon informed Logan that her predecessor had other analysts test solutions for him, but he certified that he had prepared and tested the solutions. Logan informed Gordon that this was not an acceptable practice.
3. Sometime in 2003, Gordon engaged in the same practice by signing CrRLJ 6.13 certifications that she had tested and prepared the solutions and that the tests were accurate and correct. However, it was Lab supervisor Ed Formosa (Formosa) who had prepared and tested solutions for Gordon from 2003 to 2007.
4. The Washington State Patrol (WSP) received two anonymous tips that exposed the unacceptable practice. The initial tip was received on March 15, 2007, and it stated that "simulator solutions are being falsified as far as the certification."
5. Logan assigned Gordon and Formosa to investigate.
6. On April 11, 2007, after looking into the complaint, Gordon and Formosa presented a memorandum to Logan. They reported that there was not a problem with the

6. The court found that “[n]o solutions have ever left this laboratory with an incorrect concentration.”

7. This court adopts the decision of the South Division, Snohomish County District Court, entered on November 30, 2007.

Software Deficiencies

8. The WSTL does not have any protocols or procedures that require software be validated or checked for accuracy or fitness of purpose, or to determine that the data generated was correct.

9. The software did not account for and include the data from the fourth toxicologist in the calculation of the standard deviation in determining precision.

10. The software was changed in August 2005. By this time, WSTL had hired four additional toxicologists. The data from these four additional toxicologists were not included in the calculations.

11. The third software error involved the software miscalculating the vapor alcohol concentration by five ten-thousands, a significant miscalculation.

12. The software that placed the results on the spreadsheet was not checked for capability and updated to allow for the additional analysts who were hired. These results were used to calculate average solution concentration, standard deviation, range, precision CV and equivalent vapor concentration. These calculations were integral to the certification of solutions.

13. The WSTL protocols require that data from “all” analysts be included in the calculations.

Human Error and Negligence

14. During the testing of simulator solutions, the results for each analyst are entered into a database and recorded on a worksheet. The worksheets are prepared by support personnel. The analysts then sign on the worksheets to acknowledge that the numbers on the worksheet are correct. The analysts do not check to make sure that the data entry on the worksheet is the same as the values on the chromatograms, which is a printout that contains the raw data results generated during testing.
15. There have been cases where the numbers on the worksheets differ than the values on the chromatograms.
16. The worksheets are posted on the website and relied upon by the public in determining the accuracy and precision of the breath testing machines in the field.
17. This Court adopts Finding of Fact 27 in the King County District Court Order, and similarly finds that there were at least 150 instances of non-software related errors committed by analysts, which includes the following:
- a. Incorrect data entered into certification spreadsheets.
 - b. Incorrect test values for controls.
 - c. Incorrect or non-labeling of solutions.
 - d. Incorrect testing dates of solutions on the declarations, where it *pre-dates* solution preparation dates.
 - e. Using a chromatograph machine (Machine #1) that has different operational characteristics than the other machines used in the Lab. Machine #1, during re-testing of a sample, loses some of the vapor concentration. Vapor concentration is an important component to an accurate measurement of a sample and during the certification of a

solution. The record is unclear as to how long Machine #1 remained in use to conduct testing. It was later fixed.

Major deficiencies revealed in audits

18. Prior to October 2007, the process for testing the simulator solution had never been audited.
19. The breath testing process had never been subjected to an internal audit.
20. Logan admitted that the "process had gone on basically unchanged for 20 years and had not been challenged. It was not perceived as a high-risk process, and its shortcomings were not identified." Logan further admitted that everyone involved in the process became "complacent" and that "a lot of assumptions [were] made about the robustness of the procedure and reliability of the results."
21. In 2004, the Washington State Patrol conducted an internal audit of the WSTL. The Findings and Conclusions from the audit reveal the following:
 - a. The simulator solution books were not properly maintained.
 - b. Gordon herself stated that she did not have time to follow WSP policies and procedures.
 - c. WSP policies and required procedures appear to be of secondary concern to Lab personnel.
22. In 2007, the Washington State Patrol conducted an internal audit of the WSTL. The Findings and Conclusions from the audit reveal the following:
 - a. The department is unnecessarily exposed to litigation due to insufficient documentation and disregard for evidence handling policies and procedures.

- b. The WSTL failed to complete mandatory, quarterly self-audits which jeopardizes operational performance as well as accreditation.
- c. Evidence handling procedures were inadequate and there was insufficient documentation.

23. In October 2007, outside consultants from the American Society of Crime Laboratory Directors (ASCLD) Consulting conducted an audit into the "operational and management practices" of the WSTL as it relates to the Breath Testing Program. The following findings and conclusions were highlighted:

- a. The WSTL has not applied the same operational and quality assurance standards to the functions of the Breath Test Section laboratory, as compared to other testing performed in the laboratory.
- b. There are no policies or procedures that detail the requirements for documentation, technical review, data transfer, or verification of database calculations for the breath test functions.
- c. The database that contains the data from toxicologists testing the solutions was not validated or reviewed prior to it being used and relied upon by the Breath Testing section to test the accuracy of the instrument.

Inadequate Training; Deviations from Protocols and Scientific Standards

24. Logan admitted that the absence of procedures to review the data collected from gas chromatography is one of the "major deficiencies" within the Lab.

25. Compliance with protocols for preparing, testing, and certifying the simulator solutions is important to ensure the accuracy of the breath test results.

26. Any deviations from the protocols must be documented in writing and approved by the Lab Manager or Toxicologist.
27. Up until December 2007, the WSTL had no protocols on how to treat data that fall outside of the acceptable range for the mean value of the solution. The mean is used to calculate the standard deviation (CV). The CV has to be within +/-5% to be precise.
28. The +/-5% error rate serves as a "quality check of the overall process of having prepared and tested the simulator solution." The +/-5% error rate assumes variability such as how each analyst pipettes the solution, how tightly the vials are sealed when it is inserted in the chromatographs, etc.
29. The +/-5% error rate does not factor in the variability of negligent, known, or intentional errors that can be identified. According to Logan, if there is an identifiable error that someone has made, that error needs to be corrected in order to have a better result.
30. In instances where errors were due to negligence, software deficiencies, discarding of data, and other identifiable reasons described herein, there is insufficient evidence in the record to find that a 1.3% rate for "forensically indefensible" errors applies.
31. There were instances where analysts rejected data and did not record a reason, which appears to be arbitrary conduct.
32. The variations in data (i.e. values that lie outside of acceptable range) allow an accurate determination of the mean of the analysts' results. The mean is then used to calculate the standard deviation and the bias of the instrument.

33. Calculation of the standard deviation is for the purpose of the measurement of precision of the instrument during the QA process.

34. Discarding data without any scientific reasons can affect these calculations.

Logan admits that arbitrarily discarding data undermines the accuracy process of solution testing. In instances where analysts rejected data without identifying reasons, the court is unable to determine whether there is a scientific or statistical basis for the discard of data.

35. Although rejecting data based on a scientific reason is acceptable, there is no protocol that requires a toxicologist to record reasons why data was discarded.

36. WSTL did not have a protocol that governs the use of outliers (a reading that is unexpectedly outside of the normal range of variability) and discarding data until it was promulgated in December 2007. Logan stated that it is "good scientific practice" to have a policy and criteria as to how to treat "outliers," which is a value that comes from the population other than what is being measured—i.e. the population in question is the values measuring the solution concentration.

37. Protocols for the WSTL governing preparation and testing of solutions conflicted with the protocols applied to the Breath Testing section. Consequently, analysts in the Breath Testing section used field solutions on the instruments during the QA process. Field solutions and QA solutions have different acceptable range. QAP solutions are used to verify the accuracy and precision of the instruments. Logan states that when he promulgated the protocols, he intended that **only** QAP solutions are used on the instruments during the QA process.

38. WSTL protocols require that a control sample be injected after every tenth injection in the instrument as a control, followed by a blank sample. Protocols also

require that the analyst record the external control value during testing of the field solution and during the quality assurance process. There were instances where analysts enter incorrect external control values.

39. The court adopts the Findings regarding the impact of tests conducted in the field that were referenced in the King County District Court Order.

40. All measuring machines have bias. Bias in the DataMaster is identified during the QAP process. Bias is determined by using mathematical formulas and calculations. Bias is lack of accuracy in a breath test instrument. The breath test program is not design to account for any potential bias in the instrument.

ANALYSIS

Substitute House Bill 3055 and ER 702 after Jensen

When the Legislature passed Substitute House Bill (SHB) 3055, it amended RCW 46.61.506, specifically subsection (4), which addresses a *prima facie* case with eight foundational elements and the “admissibility” of the test if such *prima facie* case has been shown.

Interestingly, however, the Legislature left intact subsection (3) of the statute, which defines a “valid” breath test to be an “analysis” of the person’s breath “performed according to the methods approved by the state toxicologist. . . .” At the same time, WAC 448-13-060 was repealed, which was the regulation that defined a “valid” test and its foundational requirements.

In so doing, the Legislature defined what can be considered admissible evidence by listing the eight foundational requirements, with the intention of curtailing pre-trial motions seeking suppression of breath tests in DUI cases. Then, the Legislature gave

Logan the authority to promulgate “techniques or methods” to define a valid test by leaving subsection (3) intact. The Legislature recognized the importance of methods in obtaining the breath test results and deferred to Logan’s expertise to implement such methods. Accordingly, Logan promulgated WAC Chapter 448-16 to replace the repealed WAC Chapter 448-13, citing RCW 46.61.506(3) as his authority.

Therefore, individuals may attack the reliability of the breath test results if the test is not performed according to methods established by the state toxicologist. The examination of the process and methods of how the breath test results are obtained requires the trial court to scrutinize the science and determine admissibility. A discussion of the case law that led up to the Supreme Court’s decision of City of Fircrest v. Jensen, 158 Wn.2d 348 (2006) is helpful to understand the trial court’s authority to assess the reliability of the breath test and to suppress.

In Jensen, the court referred to DNA testing and placed BAC breath test results on the same level as other scientific tests such as DNA test results. By doing so, the Frye standard is fitted into ER 702 by placing the reliability of the method or technique within the framework of the threshold requirement that the testimony is helpful to the trier of fact. Consequently, evidence that is unreliable has little or no probative value and is not helpful to the trier of fact. Like DNA evidence, if the breath test evidence shows that a given testing procedure was so flawed as to be unreliable, then the results may be excluded because they are not helpful to the trier of fact. State v. Kalakosky, 121 Wn.2d 525 (1993) (cites omitted).

Significantly, the Court in Jensen determined that the statute could be harmonized with the rules of evidence so that the trial court is able to carry out its “gate keeping”

function, even in light of the statute's admissibility requirement. The Court reasoned that the "gate keeping" function is preserved because "[t]he act does not state such tests must be admitted if a prima facie burden is met; it states such tests are *admissible*."

The Court in Jensen applied the same analysis in State v. Zwicker, 105 Wn.2d 228 (1986) and State v. Long, 113 Wn.2d 266 (1987)). In Long, the Court addressed a statutory amendment that governs admissibility of refusal evidence. RCW 46.61.517, as amended, read as follows: The refusal of a person to submit to a test of the alcohol content of his blood under RCW 46.20.308 is *admissible* into evidence at a subsequent criminal trial. There, the Court recognized the Legislature's authority to require refusal evidence to be admissible at a trial, while at the same time, recognizing that the trial court can still exclude refusal evidence under ER 403.

Thus, consistent with case law, the statutory amendment at issue in this case is subjected to the same analysis that was applied in Zwicker, and Long, i.e., that trial courts can engage in a review of admissibility of breath test evidence under evidence rules. Under ER 702, the trial court engages in a two-part inquiry: (1) whether the witness qualifies as an expert; and (2) whether the expert testimony would be helpful to the trier of fact.

"Related portions of statutes are to be interpreted and construed so that all the language used is given effect, with no portion rendered meaningless or superfluous." State v. J.P., 149 Wn.2d 444, 450, 69 P.3d 318 (2003) (quoting Davis v. Dep't of Licensing, 137 Wn.2d 957, 963, 977 P.2d 554 (1999)). A review of the admissibility of the breath test evidence under ER 702 results in a harmonized reading of subsections (3)

and (4) by giving each its intended effect, and is not inconsistent with Jensen, contrary to the State's contention.

The State also argues that trial courts cannot suppress breath test results because strict compliance of protocols is neither required nor implied in subsection (3), citing State v. Mee Hui Kim, 134 Wn. App. 27 (2006). Kim does not stand for the proposition that a trial court cannot suppress evidence based on non-compliance of protocols. Rather, the Court's decision in Kim is limited to its record established below, and does not stand for the sweeping rule that the State urges this court to apply. In Kim, the defendant argued that the information from the Logbook showed that State failed to comply with the Head Space GC Protocol. At the pretrial hearing, Ann Marie Gordon testified that the blood alcohol test results complied with the WAC requirements and that the Logbook was available at the lab for review. Importantly, the trial court allowed the defendant to provide additional evidence to renew her objection to the admissibility of the test result. The Court specifically noted that the trial record did not show that additional evidence was presented. Accordingly, the Court in Kim decided the case based on the record below. Therefore, trial courts are still able to weigh evidence that WSTL failed to comply with its protocols in a motion to suppress under ER 702.

Systematic Errors, Negligence, and Deviations from Protocols and Scientific Standards

The State urges this court to admit the breath test results and allow the trier of fact weigh the evidence. However, to do so in light of the irregularities that have come to light and described herein would render ER 702 meaningless.

Expert testimony from the record of proceedings held in other jurisdictions indicates that any scientific process or any measurement from a machine has some

variability or error in the result. For the DataMaster, the breath test results have a margin of error of accuracy to +/-5%, with the precision reading at +/-3%. The margins of errors do not account for errors arising out of failing to follow proper procedures, or negligent accidental mistakes, or errors that can be identified. Although the record is unclear as to whether these identified errors amount to a "scientifically indefensible" error rate, it is enough that the identified problems herein compromised the final work product and undercut the reliability of the breath tests.

The reliability of the breath test results is suspect because the WSTL did not have proper procedures and policies in place to identify, catch, and prevent human, software, and machine errors. Software errors resulted in the omission of data from one toxicologist, and then later, data from four toxicologists, in violation of protocols. Software was not validated nor reviewed for fitness of purpose in violation of scientific standards. Transferring scientific data was left to support staff person. After the data was transferred, no scientist reviewed and checked against the raw data before he/she signs off to indicate that the numbers were accurate, in violation of scientific standards. Finally, one chromatograph machine malfunctioned, but its status was ignored, and it remained to be in use for a period of time.

There were conflicting and confusing protocols that governed the use of solutions. Field solutions were used on the machines during the QAP process, which was not intended by Logan when he implemented the protocols. Although the record does not indicate that this occurred in Snohomish County, it did happen in other jurisdictions. This is but another example of the lack of training and clear protocols governing simulator solutions. In addition, analysts discarded data without identifying reasons, and

would re-test until data came within range. In these instances, it tends to create a system where only those data that were within the acceptable range were included in the calculations of accuracy. Regardless whether data was discarded for physical reasons, for no identified reasons, or because the data had values considered to be outliers, the lack of protocols resulted an inconsistent application of how to deal with this data.

The Legislature deferred to Dr. Logan to promulgate protocols and methods to operate the WSTL and to conduct breath testing. The public is entitled to expect that WSTL follow its own policies and procedures. This is especially important when trial is effectively based upon measurement by a machine, and guilt or innocence is determined by a machine. See City of Seattle v. Allison, 148 Wn.2d 75 (2002) (J. Chambers, dissent)).

Audits conducted after the exposure of the irregularities confirm the operational deficiencies of the WSTL as it relates to the breath testing. The simulator solution process had never been audited. Mandatory self-audited were not completed. Due to complacency, everyone involved in the process overestimated the robustness of the breath testing process. Business was conducted as usual for twenty years.

Business as usual meant running afoul of scientific standards that are commonly accepted in the scientific community and making mistakes that compromised the reliability of the breath testing process. Dr. Nayak Polissar, an expert called by the State in the King County District Court hearing, testified that only superior methods will ensure accuracy, and that the accuracy and precision necessary for a particular laboratory task is dependent upon the particular use intended for the final product. As stated by the National Institute of Standards and Technology (NIST), “[a]ccuracy . . . is judged with

respect to the use to be made of the data.” NIST Special Publication 260-100, 2 (1993).

The litany of problems discussed herein and the past problems of the WSTL are a reflection of a “culture of compromise” that exists in the WSTL. Accuracy was sacrificed for expediency. As the State Toxicologist, Dr. Logan admittedly bears responsibility for the WSTL’s shortcomings. Management conduct by Gordon and Formosa set the ethical tone for other toxicologists and analysts. It should be noted, however, that this court does not find that other toxicologists and analysts participated in testing solutions for Gordon. Rather, it should come as no surprise that the questionable conduct by management infects the Lab as a whole and provides a fertile ground for systemic carelessness and negligence.

In determining the reliability of the breath test results, *how* the results are obtained is of equal importance to the end result itself. While the State argues that no specific prejudice to each of these defendants has been shown due to the irregularities, it cannot be ignored that the “ethical lapses, systematic inaccuracy, negligence, and violations of scientific principles” have cast a black shadow over the integrity of the entire breath testing process.

Presently, the WSTL is undergoing accreditation, and the process is expected to be completed sometime in July 2008, or perhaps later. This court acknowledges that steps have been taken to address some of the errors and irregularities that have been revealed. Undoubtedly, this will be an ongoing process toward a scientifically, reliable work product. When the State believes that the “process” has reached that point, the State is free to argue that the breath test evidence can meet the reliability requirements of ER 702.

CONCLUSION

For the foregoing reasons, this court concludes that the work product from the preparation, testing, and validation of the simulator solutions is tainted by the errors, inaccuracies, violations of protocols and scientific standards, which renders breath test results unreliable, and therefore, not helpful to a trier of fact under ER 702.

IT IS HEREBY ORDERED that all breath test results are suppressed. Since the breath test results are suppressed under ER702, this court need not address other arguments for suppression made by counsel.

DATED this 15th day of May, 2008.



Judge Tam T. Bui