National Patent
Analytical Systems, Inc.

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Following are 5 pages of comments and 2 pages of QA Description.

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Comments by Dave Radomski and John Fusco to the affidavit of Darcy Richardson in Vermont v. Dubic.

Note: Some statements in the affadavits do not pertain to National Patent, and others are so vague that it is not possible to comment on them. Generally, the first affadavit centers around 2 issues: Interferent testing detection and RFI testing and detection. Those are covered here typically without reference to specific statements except for the last several items. The second affadavit makes reference to specific statements made by Ms. Richardson.

Reference Ms. Richardson's comments on Interferent detection:

General: The Richardson affidavit demonstrates Ms. Richardson's lack of a basic understanding on the scientific concepts inherent in the design parameters regarding the use of specific wavelengths of optical filters employed in interferent detection system of the DMT instrument. Further, it is evident that this lack of understanding carried over into the implementation of the rules promulgated by the department to the point where these rules were, at times, in conflict with the manufacturers recommended operating procedures for the instrument resulting in misunderstandings and misinterpretation of what were perceived to be operational problems or instrument defects. Ms. Richardson's affidavit does not discuss specifics of what she refers to as problems and does not cite any test results other than in very general terms making it somewhat difficult to comment.

It should be noted that at no time can any of the personnel at National Patent recall that Ms. Richardson, nor anyone else in the Lab sought advice concerning, or asked to discuss the manufacturer's reccommendations concerning, interferent detection prior to development of the protocol implemented in Vermont.

Discussion of interferent parameters and design philosophy of this capability on the DMT:

The testing method developed and recommended by National Patent to be used for the DataMaster family of instruments, including the DMT, is as follows:

Note: A correct testing method must allow for system variations, within allowable limits from instrument to instrument, and depletion of the low levels of volatile organic compounds (VOCs) used as the testing agents along with variations in preparations from the preparing entity. Because of these inherent variations the following is the manufacturer's recommended testing procedure:

1. Verify that the DMT instrument has been correctly calibrated by simulating with a known vapor concentration of ethanol in water.

2. Add a small amount of the interferring substance of interest to a wet bath solution of a known concentration of ethanol in water. Mix and allow a few minutes to steep.

3. Introduce the vapor into the DMT as any other simulator vapor concentration during supervisor or breath test mode, clearing the headspace of the simulator before hand to prevent any excessive build up of the VOC. (Different VOCs have different vapor pressures and will not necessarily maintain a uniform concentration for more than a few minutes without further mixing). Note the results.

Discussion of Pass / Fail Results:

Given that the interference concentation may be close to the threshold of detection, a "passing" test would be one that either (1) flags an interfering substance, or (2) one where the reported result is within acceptable limits of the base ethanol target concentration as verified in step one above, or as verified to be the beginning known concentration prior to adding of interferent in step 2.

It is our understanding that the parameter for acceptance of interference testing developed by Ms. Richardson and used in Vermont was generally as follows:

The Laboratory prepares a solution containing an interfering substance (acetone or isopropyl alcohol or methanol) added to a base of a .100 ethanol concentration with a specific target value of interferent. The intention is that the instrument needs to detect this concentration to pass.

This "Go", "No go" philosohy is not consistent with the method outlined above for the following reasons:

A reported result of .004 with a message of "Interference Detected" would be considered passing, but a result of .002 with no "Interferent Detected" would be considered failed. Both are within the design specifications of the instrument and should be considered passing. While it may be possible under controlled laboratory conditions to achieve Go/No Go resuts, it is not practical or necessary achieve these results in field conditions. There are simply too many systemic variations caused by solutions, instrumental conditions and operator techniques to achieve precision results consistently at such low levels.

The DMT meets or exceeds all parameters for interferent detection as specified by the USDOT and, when used as recommended by the manufacturer will give consistent and uniform results.

Reference Ms. Richardson's comments on RFI detection:

General: The Richardson affidavit demonstrates Ms. Richardson's lack of a basic understanding of the design concepts inherent in the EMI (RF) detection system of the DMT instrument. Further, it is evident that this lack of understanding carried over into the implementation of the rules promulgated by the department to the point where these rules were, at times, in conflict with the manufacturer's recommended operating procedures for the instrument resulting in misunderstandings and misinterpretation of what were perceived to be operational problems or instrument defects. Ms. Richardson's affidavit does not discuss specifics of what she refers to as problems and does not cite any test results other than in very general terms.

It should be noted that at no time can any of the personnel at National Patent recall that Ms. Richardson nor anyone else in the Lab sought advice concerning, or asked to discuss the manufacturer's recommendations concerning, EMI detection prior to development of the protocol implemented in Vermont.

Discussion of EMI parameters and design philosophy of this capability on the DMT:

The RFI certification by an independent, certified testing laboratory, F Squared Laboratories, per applicable industry standards shows that when subjected to a range of frequencies during a time where the output of the DMT detector is being monitored by the system software, the instrument will abort an operation with the status message "RFI Detected" or some other error status

message depending on the operation being performed by the DMT at that point in time, or in the absence of a status message will produce an analytical result within expected tolerance is an indication of proper design and performance.

1. Ms. Richardson makes a reference to a reading of .003 in a manual (#13). This reference, taken at face value, is not a recommended value and the procedure and is not consistent with the F Squared testing standards.

2. Her statement in #15 that the "DM instrument abort" is not a correct statement and is not consistent with the manufacturers recommendation and the F Squared testing standards.

Statement #16: Ms. Richardson states: "The breath curve for Ms. Djubie demonstrates a gap between when the breath starts and the alcohol line rises. This indicates to me that the instrument may not be lining up appropriately...."

This demonstrates how little she knows about what she is looking at. The alcohol rise will always follow the breath flow curve and it cannot do anthing but follow it. The reason is that the alcohol breath sample never reaches the sample chamber until some point after the flow starts. The instument begins charting the flow curve as soon as the breath introduction starts. It does chart the alcohol curve at the same time, but since there is no alcohol in the chamber until it reaches it, the first second or so of the line will be flat, rising as detectable alcohol enters the sample chamber, typically a second or so later. It has always been this way and can be no other way.

Statement #18: It sounds like she is suggesting that RFI has a permanent impact on the ability of the instrument to operate. If she is this would be another example of her complete lack of understanding of how it works.

Statement #19: This is much too vague to comment on. She gives no indication of what she is talking about or even what symptoms she might be referring to.

Statement #21. This is an interesting comment from someone who, despite numerous invitations and urgings, steadfastly refused to come to factory training and who seemed to be generally unavailable when training was conducted at the Vermont Lab.

Regarding the Milton Affidavit (second affidavit).

General Comment: Ms. Richardson's statements lack specifics and in doing so it becomes difficult to comment precisely. However, some areas do merit pointed responses.

Statement #5: Her comments on "manufacturing defects". The initial instruments did contain detector blocks that, due to design issues, did not perform reliably over extended periods of time. The ability to adjust the flow sensor was also not acceptable. These issues were apparent soon after delivery and remedied early on with none reaching the field to be placed into service. However, we can find no references in our records to "climbing ethanol concentrations" or "contribution of RFI to reported ethanol values of the sample." These appear to be either completely fabricated or misinterpretation of symptoms caused by a lack of understanding of the instruments.

Statement #10: Her comment that the precision is worse when conducting a series of tests through a simulator in breath test mode than it is when conducting a series of tests in supervisor mode is ludicrous. The supervisor test mode utilizes a regulated flow of air from a pump through

a dedicated air path designed to give precision and repeatability to the testing procedure. The breath test mode uses the breath tube and, most importantly, a human being blowing through a simulator. This configuration adds two completely different variables to the sequence and is not expected to produce the same kind of precise and repeatable results as the former configuration. The only important issue here is wether or not the instrument met the accuracy specification as put forth by National Patent. Her claim does not dispute the accuracy of the test.

Her further comment that there was ethanol being carried over from one test to the next is lacking description but the most typical cause for this is that the operator neglected to remove or replace the mouthpiece during purge and prior to a new test. Several of the contacts between personnel at National Patent and Ms. Richardson prior to and during this period were relative to the use of the simulator during which it was discovered that she was not correctly using the device.

Statement #12: Most, if not all, of what she is calling repair instances are in fact instances of requirements that were set by the Lab that were outside the operating parameters as stated by the manufacturer. Specifically, what she is calling detector, filter and optical issues relate to the self imposed parameter that the maximum drift allowable with respect to the detector be limited to 300mv (millivolts). Ms. Richardson and the Lab were advised that detector drift over time is a typical characteristic of this type of detector and is accounted for in the ambient zeroing process. It is not and should not be considered a defect. They were further advised that this self imposed voltage range limit was going to result in needless instances of maintenance. They refused to observe the factory recommendations.

Note: While some instrument / detector combinations can and do maintain minimal drift, it is not, in any sense, necessary or advantageous that they do so.

Statement #14: The statement that "the filters responsible for interfering compounds change over time" is patently impossible and reflects her lack of understanding of the DMT in general. Filters, some as old as 20 years, have been tested here and found to have precisely the same characteristics as new filters. She presents no information or data to validate this claim and cannot do so because it does not exist.

Statement #20: This statement makes no sense.

She makes the statement that "the accuracy of the instrument decreases on the next test". This condition is so rare as to be virtually non existent and when it is found, there is always a valid hardware reason and not a systemic instrumental reason. However, she presents no information or data to substantiate this so it is not possible to say what kind of a difference she is claiming would have made the accuracy an issue. What is seen, specifically in installations such as Vermont where the simulator remains on for extended periods between tests, is that the vapor in the headspace in the simulator does not maintain a uniform concentration during idle periods. This is owing to the difference in vapor pressure between the water and the ethanol in solution. Typically this equillibrates very fast and the resulting difference in the reading is not significant (<.003) and still within instrument tolerances. Failing to understand this can result in a misinterpretation of the testing result.

General Comment:

Ms. Richardson is uniformly critical of what she terms "Software Problems". It must be kept in mind that while software development is never a simple or quick process, it is a process that typically involves a number of back and forth exchanges with acceptance testing being the burden

of the user. The Lab was advised at many points during this process that their requests were leading to an extremely complex and lengthy process of development that was going to be cumbersome to develop and test.

While there were certainly mistakes made by the engineers during this process, this is normal and must be considered part of the typical development process. There were also mistakes made by the Lab personnel and requests made that were not possible to implement or were in conflict with other areas of design specifications. Neither of these situations are abnormal but do need to be placed into the proper context.

While Ms. Richardson may not have been happy with the speed, the number of changes, and the number of re writes during this process, the choices that led to this complexity were those of the Lab and not the developer's. The final acceptance and therefore the responsibility for the accuracy and correctness of the software lies with the user. Any issues discovered later were issues not uncovered during their own acceptance testing.

Note: Many of the erroneous statements made by Ms. Richardson appear to be as a result of her lack of understanding of the theory and operation of the Instrument. This was evident to personnel at National Patent over the years. Because of this we extended numerous invitations and overtures to the Lab personnel to attend factory sponsored training. The training was always offered at no charge to the state and, at times, we offered to pay expenses to board and transport them. These offers were always refused.

DataMaster DMT Inspection, QA and Conformance Testing Procedure
Descriptive Overview

INSTRUMENT CONFIGURATION AND DESTINATION

Production instruments forwarded to the Test / Service department are paired with the instrument build document that identifies the customer sales order number, product number and other reference information for internal tracking.

INITIAL VISUAL INSPECTION

Technicians perform an inspection of external and internal components and note compliance on the checklist that accompanies internal instrument records.

SOFTWARE

Technician receives current software version for that customer and loads that software on the instrument. This includes operating software, DMT software, controller PIC software and other as required by customer configuration.

INITIAL SET-UP

Before any tests are conducted on the instrument, initial voltage adjustments are performed and relevant voltages and component identifiers are logged on the instrument build document.

BURN-IN

After initial set-up, the instrument is placed under power on the burn-in shelves for the period of time deemed necessary by NPAS to ensure no premature component failures.

CALIBRATION

After a successful burn-in period, the DMT is calibrated using manufacturer certified standards, either wet solutions or dry gas, depending on customer configuration. Calibration factors are evaluated to ensure all values fall within acceptable limits (DMT software further precludes a valid calibration if any of the factors fall outside allowable limits). A diagnostic test is performed after calibration.

ANALYTICAL TESTING

Accuracy checks are performed at minimally three alcohol concentration levels. Series' of no fewer than three separate samples per series are performed. Acceptable results are those within the larger of ± 0.002 g/210l or 2% of the target concentration (the manufacturers stated margin of error of the DMT) while taking into account the allowable tolerance of the stated control target and delivery mechanism to the DMT. In-house controls allow for greatly minimizing these external variances and results generally fall within the instrument only margin of error.

Instruments are further tested for specificity to ethanol by performing tests, either through the breath tube or the heated simulator tubes, of solutions containing separately, acetone and methanol. The acetone and methanol may or may not be added to a known base ethanol concentration. Other substances are, on occasion, tested as well but are not required.

FUNCTIONAL TESTING

Various other tests are performed to validate proper instrument performance. The specific tests performed are determined, as needed, by NPAS. They generally include, but are not limited to:

A. Verification of agreement of test results when the same standard is delivered via the breath tube and simulator ports. Results must agree within the instrument margin of error.

B. Tests conducted to verify that a sober breath test result is 0.000 g/210l when it follows an elevated ethanol concentration breath sample delivered via a wet bath simulator.

C. Consecutive breath samples delivered via a known ethanol concentration wet bath simulator to ensure sample agreement within the instrument margin of error. These individual breath samples may or may not be separated by an external standard check as part of the breath test sequence.

D. Breath tests sequences are performed using elevated wet bath ethanol concentrations to ensure proper purging down to 0.000 g/210l after sample acceptance.

E. A pulmonary syringe is used during a subject breath test to ensure sample volume reporting is accurate to within ± 10% of the delivered volume. A separate test is conducted with the syringe to ensure that a sample cannot be delivered by "sucking back".

Other checks conducted for functionality include:

Sample chamber, breath tube, and, if applicable, heated simulator tubes and simulator temperatures

Proper operation of any peripheral device to be connected to a USB port

Dry gas flow and regulator (if installed)

Quality of printouts

Data entry of customer specific information

POST POWER-DOWN CHECKS

After the analytical and functional tests are successfully completed, the instrument is powered-down for a period of time, minimally overnight. After this cool down, the instrument is powered back up and selected tests are performed to verify valid results. These include, but are not limited to, diagnostic testing, accuracy checks with a known ethanol concentration, sober breath tests and elevated ethanol concentration breath tests.

FINAL INSPECTION

Upon completion of all testing, the technician verifies that all paperwork and test reports are included with the instrument information packet and that all check-off entries are made. The instrument is visually inspected and cleaned and delivered to shipping with all documentation.

Note: This is a general overview of the test process. NPAS determines what tests are necessary to ensure proper operation along with the expected, allowable results. The process is subject to modification as seen fit by NPAS. As this process is an internal one and subject to modifications as deemed necessary, the internal documents and written procedures underlying this process are not for public disemination. NPAS will provide information regarding any specific aspect of the testing process requested if determined to be useful and/or necessary.