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## INTEROFFICE MEMORANDUM

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**TO:** DATAMASTER CENTRAL FILE  
**FROM:** AMANDA BOLDUC  
**SUBJECT:** 100151 VSP-ROYALTON DATAMASTER TOLERANCE CHECK  
**DATE:** 7/13/2011  
**CC:** STUART SCHURR, STATE'S ATTORNEY OFFICES, ED LUCE

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### TOLERANCE CHECK STATUS OF VERMONT DATAMASTER DMT INSTRUMENTS

On April 22, 2011, I was forwarded a message by Stuart Schurr from David Sleight which said the following:

*VSP Royalton instrument: The certification reviewed in May shows that the tolerance check was turned off at that time. That's not uncommon after the initial testing which is why the options must be reset before the instrument is installed at a location. With the info the simulator vapor was an 0.096 when 0.097 was the cutoff lends further support that the tolerance was never turned back on. This means that since it was installed in May the instrument has not been checking for interfering compounds or checking to see that concentrations and temperatures were within acceptable range. Without being able to detect interfering compounds, this instrument does not meet the Rules and Regulations on this test or any test that has been taken on it since it was put in the field in May of 2010. If the Health Department has fixed this then there will be a TSI indicating that the tolerance was turned back on and the information that the tests are invalid relayed to the State's Attorney's Office. If they have not, then the instrument in Royalton is not in accordance with the Rules and Regulations and the tests should not be considered for evidential purposes.*

Upon learning this information, I immediately reviewed this instrument's maintenance file to confirm the tolerance check status. Instrument 100151 was certified by me and reviewed by former VDHL employee Darcy Richardson on 5/25/10. I reviewed the Certification report and found that it showed that the tolerance check was off. I then contacted VSP-Royalton and had an on-duty officer post the instrument "Out of Service". Next I called Stuart Schurr to confirm that the instrument was now out of service. Finally, I contacted Windsor County Deputy State's Attorney David Cahill to apprise him of the situation.

At the time, it was the understanding of the VDH Laboratory breath alcohol program staff that the Tolerance Check status referred to the instrument's setting to report an error if the simulator result was not within range, if the heated zones were not to temperature, or if a chemical other than ethanol was present in a sample. It has now been explained by NPAS that this is not the case (see attached NPAS correspondence). On April 25, I retrieved the unit and printed out every test performed on the instrument with the filter readings displayed. I then manually inspected each ticket for compliance with the standards below. (See subject test reports attached).

- The simulator test result(s) must be within +/- 5% to target.
- The simulator temperature result must be 34 degrees C +/- 0.5.

- Filter 2 and filter 3 results for all samples (simulator and subject) must be  $<0.0050$  or a combination of the two  $<0.0070$  for samples where  $X [1] < 0.1$ . For samples  $X [1] > 0.10$  see attached: Table of Interferent Thresholds (VDHL DMT Tech Manual Section 2, page 4).

I created a chart detailing my results (See attached). In this chart, I list each subject sample taken by this instrument, the date of the test, subject name, case number, incident location, the target value of the simulator solution, the simulator vapor reading, the subject sample result, and the simulator temperature. I then made note as to whether those tests were passing (P) or failing (FAIL). For the simulator results, I found a significant number of tests that should have been failing due to “Standard Out of Range”. This is reported when the simulator result is not within  $\pm 5\%$  to the target value.

I did not find a single simulator result where an interferent should have been flagged. Based on the filter readings, none of the subject samples reported a result that would have been flagged as “Interferent” either. On each sample, the reported simulator temperature was within specification. Furthermore, the attached letter from Mr. Markefka, the Director of Engineering explains that even though the tolerance check was off the instrument would still have appropriately documented an interferent if one was detected and would have appropriately reported temperature errors should one have occurred.

Instrument number 100151 will have its controller board replaced as part of a routine upgrade and will then be recalibrated and certified per VDHL protocol (See TSI, attached).

There was one other time that I found that the tolerance function check was off on two DMT instrument s that were deployed. While reviewing the Installation record from 8/31/10, I discovered that the Manchester PD (100142) DMT did not have its simulator temperature monitoring settings activated properly. On 9/2/10, I went to this agency to activate the temperature and discovered that the tolerance check was also not activated. I then contacted Winhall PD (100148) and had them check their tolerance settings as this instrument was also installed on 8/31/10. They confirmed that their tolerance check was off. I then went to Winhall PD and activated the tolerance. (See Meeting Minutes 9/10/10 and 9/20/10 attached). The settings were corrected on 9/2/10 prior to any subjects being processed on either instrument. On September 14<sup>th</sup>, 2010 I sent an email to Ed Luce, the VDH Quality Systems Specialist asking if someone should review all of the records in-house to ensure that no other instruments were in the field with their tolerance set to off. He responded that he thought that was a good idea; however that was not done.

The tolerance check was turned off on all these three instruments when they were being used for officer training. The tolerance check function was not turned back on after the training. It is not standard practice nor is it in our policy and procedures to turn off the tolerance check during the calibration or certification of the instrument.

As a precautionary measure, on April 26, 2011 Steve Merrill and I both reviewed every certification report on every instrument in the VDHL fleet of DataMaster DMTs. We checked to ensure that the tolerance check was set to ON. The only certification reports found to have the tolerance check set to OFF were the three noted in this memo: Winhall PD, Manchester PD and Royalton VSP. The most recent date of certification for each instrument was documented (See attached: Certification Review for Tolerance Check Status Check-list). The VDHL is also

requesting each and every agency to print out their current Options settings and send them to the lab to reconfirm that the options settings are correct.

The Corrective Action taken due to this mistake is as follows. A change will be built into the next revision of software that will force the options to reset to default as the first step of an Installation procedure. Until the software revision is implemented, subsequent to each instruments Certification, VDH laboratory staff will reset the options to default and will print out the Options report. This report will be included with the Certification packet for review, which will also include a final review and sign-off by the Organic Chemistry Program Chief.