

Intoximeters

Manufacturer And Distributor Of Alcohol Testing Equipment

January 25, 1995

SENT VIA FACSIMILE

Mr. Kenneth C. Edgell
U.S. Department of Transportation
Office of the Secretary of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590

Dear Ken,

There are two sections of the DOT rules that I feel need your interpretation to better clarify both their intent and what is permissible under the rule.

The first is an issue regarding the number of attempts allowed when providing a breath sample before the test is considered a refusal and the subject must be referred to a physician for further evaluation. The rule states (FR, Rules and Regulations, 2/15/94, pages 7359 & 7360.):

" 40.69 Inability to provide an adequate amount of breath.

- (a) This section sets forth procedures to be followed in any case in which an employee is unable, or alleges that he or she is unable, to provide an amount of breath sufficient to permit a valid breath test because of a medical condition.
- (b) The BAT shall again instruct the employee to attempt to provide an adequate amount of breath. If the employee refuses to make the attempt, the BAT shall immediately inform the employer.
- (c) If the employee attempts and fails to provide an adequate amount of breath, the BAT shall note in the "Remarks" section of the breath alcohol testing form and immediately inform the employer.
- (d) If the employee attempts and fails to provide an adequate amount of breath, the employer shall proceed as follows:
 - (1) Reserved
 - (2) The employer shall direct the employee to obtain, as soon as practical after the attempted provision of the breath, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide an adequate amount of breath."

It is my understanding that the object of this section of the rule is to get an adequate sample of breath from a subject given that the subject is attempting to provide the sample. It also appears that this section of the rule is written to define the minimum number of tests that a BAT is required to offer to a subject who is not making a sincere effort of providing a breath sample.

A subject that is tested on a variety of instruments will find that some EBT's are more difficult to provide a breath sample than others. Given the different designs of sample assemblies and the different sensors analyzing the breath as it passes through the instrument, it becomes fairly clear as to the reason for the variations in the breath flow requirements for instrumentation that offers automatic sampling .

As a result, limiting a subject to just two attempts to give a proper sample may not be adequate for someone who has never encountered a breath test instrument before. This is because a subject may blow too hard or too soft on the first attempt not meeting the requirements of the instruments automated system. On the second attempt the subject is often embarrassed and in some instances is nervous about being able to give an adequate sample which can make providing the sample even more difficult.

With an individual who has a small vital capacity, the problem will be more frequent as the subject may be borderline on meeting the instruments requirements even under the most ideal situation.

As seen in law enforcement testing and already noticed in testing under the DOT rules, there is a percentage of subjects that will have trouble triggering the automatic sampling requirements of an EBT. Using a literal interpretation of the rule the employee must be removed from their jobs until they have seen a physician if they are not able to get the instrument to accept their breath sample on either the first or second attempt. Removal of these employees from their

Mr. Kenneth C. Edgell
January 25, 1995
Page Two

job can be disruptive to the workplace, especially in industries like the airlines, or trucking where an airplane or a truck cannot move until the physician reviews the subject or a person to replace the employee is available.

The number of employees having this problem would be reduced if more than two attempts at providing a sample were allowed.

Several approved EBTs do not have automatic sampling and depend wholly on the operators ability to depress the sample activating button at the proper time. If the automatic sampling device had an option to take a manual sample after the subject had unsuccessfully attempted to provide an adequate sample on the first and second attempt, and the rules permitted a third attempt which could be taken manually, the numbers of employees unable to provide a sample would be reduced to a minimum.

In regards to this part of the rule, my specific questions are: (1) Is it acceptable for an instrument to offer more than two attempts at collecting the sample in a given test sequence? (2) Given the instrument can take both an automatic sample and a manual sample is it permissible for the BAT to take a manual sample if the subject appears to be making an effort to blow but is unable to meet the minimum requirements of the instrument's automatic sampling?

The second issue is in regards to section "40.55 Quality assurance plans for EBTs" within which the requirements for performing a calibration and a calibration check on an EBT is addressed. The rule states,

- (3) The employer shall ensure that inspection, maintenance, and calibration of each EBT are performed by the manufacturer or a maintenance representative certified by the device's manufacturer or a state health agency or other appropriate state agency. The employer shall also ensure that each BAT or other individual who performs an external calibration check of an EBT used for alcohol testing subject to this part has demonstrated proficiency in conducting such a check of the model of EBT in question.

We as a manufacturer, have taken a literal interpretation of this part of the rule. We have trained BAT's under the model guidelines and as well we have incorporated calibration technician training into our instrument training. In fact, students successfully completing an Intoximeter's training class will be qualified to run calibrations under this part of the rule.

The strictest interpretation of this section would require that the manufacturer or a qualified state agent, would have to train everyone who might need to calibrate an EBT. In order to accommodate the demand for this training, Intoximeters has offered a trainer orientation class where the students have the ability to become factory authorized calibration technician trainers. This allows others to train calibration technicians on our instrumentation, but still the certificate generated must come from the manufacturer and there is both a cost and a fee associated with this process (not to mention the back up paper trail necessary to justify the issuance of the certificate). The appearance from the outside is that the manufacturer has a monopoly on training, when in reality, most manufacturers had designed instruments to be field calibrated with a simple, straight forward calibration and verification routines.

This section of the rule needs interpretation, I have heard from several users that have claimed to have communicated with your office and are of the opinion that once they have gone through a class where they have been trained to proficiency on the EBT and its calibration then they themselves can train others to calibrate the EBT and they can, under their own name certify those that they train as both a BAT and a Calibration Technician. If this is in fact the proper interpretation, we need to know so that we do not misinform those that request information about the minimum requirements for training.

Your response to these questions would be both helpful and appreciated.

Sincerely,


M. Rankine Forrester
Executive Vice President



**U.S. Department of
Transportation**

Office of the Secretary
of Transportation

400 Seventh St., S.W.
Washington, D.C. 20590

January 26, 1995

Rankine Forrester
Intoximeters, Inc.
1901 Locust St.
St. Louis, MO 63103

Dear Mr. Forrester:

Your recent letter to this office seeks clarification in two areas covered under 49 CFR Part 40, "Procedures for Transportation Drug and Alcohol Testing Programs." The first area concerns whether or not a BAT may exercise any procedural options in order to complete a test where the employee is exhibiting the inability to provide an adequate breath sample. Section 40.69(b) assures that the employee will have at least two attempts to provide an adequate breath sample, on either a screening or confirmation test, by stating:

"The BAT shall *again* instruct the employee to attempt to provide an adequate amount of breath. If the employee refuses to make the attempt, the BAT shall immediately inform the employer."

In the situation where the BAT, in his or her best judgment, feels that the employee is making a true effort to comply with the breath testing process but is unable to blow hard enough or long enough to get an adequate sample in the EBT's "automatic mode," the BAT does have the option (under Part 40) to attempt to accomplish the test using the EBT's "manual mode." This "option" would fall under the provisions of section 40.67(b), where the BAT believes that it would be practicable to complete the process by beginning a new screening or confirmation test. Naturally, the BAT must be trained to proficiency in operating the EBT in the "manual mode."

In a situation in which the BAT did not believe that the employee was making a true effort to blow hard enough or long enough to obtain an adequate sample, then it would not be *practical* for the BAT to use the provisions of 40.67(b). This situation may constitute a refusal to test, and the BAT would immediately inform the employer.

As added information, DOT rules do not mandate that the employer remove an individual who is unable to provide an adequate breath sample from safety-sensitive functions until the medical evaluation is complete. However, the rules do not interfere with employers who, acting under their own authority, choose to "stand down" an employee pending the result of the medical evaluation.

The second area in which you seek clarification concerns section 40.55(b)(3), which states:

"The employer shall ensure that inspection, maintenance, and calibration of each EBT are performed by the manufacturer or a maintenance representative certified by the device's manufacturer or a state health agency or other appropriate state agency. The employer shall also ensure that each BAT or other individual who performs an external calibration check of an EBT used for alcohol testing subject to this part has demonstrated proficiency in conducting such a check of the model of EBT in question."

Specifically, you want to know whether those trained to calibrate a specific EBT may, in turn, train all others (e.g., BATs) to calibrate a similar EBT. Calibration needs to be done according to specific criteria—which is set forth in the manufacturer's QAP. Calibration also needs to be performed by specific entities—namely the manufacturer of the EBT, a representative certified by the manufacturer of the EBT, a state health agency, or another appropriate state agency (e.g., law enforcement), either of whom have also been certified to calibrate the EBT. (Note: It would be reasonable to assume that the state agencies would have received their calibration training from the manufacturer of the EBT.)

The DOT has purposely limited inspection, maintenance, and calibration functions in an attempt to increase the overall reliability of industry test results. We feel that anyone who has purchased an EBT should have the opportunity to be trained (in accordance with Part 40) to perform any or all these functions on that EBT, if such is permitted under the guidelines of the QAP. However, anyone performing these functions must be qualified as one of the entities listed in section 40.55(b)(3).

If I can be of further assistance, please contact me at (202) 366-3784.

Sincerely,



Kenneth C. Edgell
Senior Program Analyst
Office of Drug Enforcement and
Program Compliance