DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket 48513]

RIN 2105-AB95

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: Under the Omnibus Transportation Employee Testing Act of 1991, the Department of Transportation is required to implement alcohol testing programs in various transportation industries. This rule establishes uniform testing procedures that would be used by all Department of Transportation operating administrations conducting alcohol testing programs under the Act or conducting alcohol testing programs modeled on those required by the Act. This rule also implements changes required by the statute in the Department's drug testing procedures.

DATES: Effective Dates: This rule is effective March 17, 1994, except § 40.25(f)(10)(i)(B), which is effective August 15, 1994. Compliance Date: Compliance with § 40.25(f)(10)(i)(B) is authorized beginning March 17, 1994.

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SUPPLEMENTARY INFORMATION:

Background

The Omnibus Transportation Employee Testing Act of 1991, enacted October 28, 1991, directed significant changes in the Department of Transportation's substance abuse-related programs for most transportation industries that the Department regulates. These changes are discussed in detail in the Common Preamble published in today's **Federal Register.** With respect to drug testing procedures, the Act added a requirement for using the "split sample" approach to testing, which Congress believed would provide an additional safeguard for employees. The Act also imposes a variety of requirements for alcohol testing procedures, which this regulation also implements. The Coast Guard is not amending its existing alcohol testing regulations (33 CFR part 95 and 46 CFR part 4), and will continue to use separate procedures for that testing.

The Department's drug testing procedures, 49 CFR part 40, have governed drug testing under all six operating administration drug testing rules since 1988. Likewise, this rule governs alcohol testing procedures for the five modes affected (the Coast Guard is not covered by the alcohol testing procedures of this part). Under the rule, the existing drug testing procedures become a separate subpart of the regulation, and we are adding new subpart containing the alcohol testing procedures.

Having all the Department's uniform drug and alcohol testing procedures in a single regulation will simplify compliance for covered parties and avoid confusion by permitting all parties to look to one source for information on these issues. This should be particularly helpful to those employers who have employees covered by more than one DOT operating administration. However, employers regulated solely by the Coast Guard should continue to refer to 33 CFR part 95 and 46 CFR part 4 for alcohol testing requirements and procedures.

The Department published the Notice of Proposed Rulemaking (NPRM) for this rule on December 15, 1992, at the same time as the operating administrations (OAs) published their proposed alcohol and, in some cases, drug testing rules. We received over 250 comments to the part 40 docket. In addition, the OAs' dockets received some comments on the testing procedure issues raised by the part 40 NPRM. The Department considered all these comments.

Comments and Responses

Split Sample Procedures for Drug Testing

This discussion concerns how we will carry out a statutory requirement to use the "split sample" method for collecting and analyzing urine samples for purposes of the Department's drug testing program. The Act requires split samples to be used for testing under the Federal Highway Administration (FHWA), Federal Aviation Administration (FAA), Federal Transit Administration (FTA), and Federal Railroad Administration (FRA) rules.

Mandatory Use of Split Sample Method

The NPRM proposed to implement the statutory requirement for split samples in drug testing by making mandatory the optional split sample procedure in the existing part 40. The procedure would remain optional under the Research and Special Programs Administration (RSPA) and Coast Guard drug testing rules, which are not affected by the Act. Several commenters wanted the split sample procedure to remain optional in all modes. Because the statute requires the use of split samples in the four OAs mentioned above, the Department cannot adopt this comment. In order to give employers time to prepare to use the split sample collection method, the rule does not require affected employers to begin using this method until 6 months from the date of this rule's publication. Employers, who under the existing rule have the option of using this approach, may begin using the split sample method at any time.

Sample Volume

The NPRM proposed that the total amount of urine collected be 45 ml (30 ml for the primary specimen and 15 ml for the split specimen). The existing rule calls for a 60 ml collection; the Department believed that this was a greater quantity than is needed. Eighteen comments supported the NPRM proposal; two commenters opposed the proposal, one of whom supported collecting 60 ml each for the primary and split specimens. Based on information about laboratory testing needs gained over the course of four years of implementing a drug testing program, the Department is persuaded that 45 ml (30 ml for the primary specimen and 15 ml for the split specimen) is sufficient. This reduction from the current 60 ml minimum should also reduce "shy bladder" situations in which a test is canceled for lack of sufficient specimen volume.

Time Period for Requesting Test of Split Specimen

Another subject of interest to commenters was the time frame in which employees could request a test of a split specimen. The NPRM proposed a 72-hour period, following the employee's being informed of a verified positive test, during which he or she could request a test of the split specimen. Twenty commenters favored this approach, saying that this period was sufficient to allow an employee to make a choice about whether to request the test of the split specimen. Some of these commenters also asserted that allowing the much longer times permitted under some OA regulations (e.g., 60 days) could lead to tests of deteriorated samples and unreasonably postpone employer disciplinary actions. Seven commenters suggested a longer

time frame (e.g., a week, 20 days, 30 days, or 60 days). One of these comments asserted that employees needed a longer time to become aware of their rights, study their options, and seek representation. Three commenters favored a uniform time frame applicable to all OA rules, while one favored allowing each OA to set its own time frame. One commenter asked whether medical review officers (MROs) were required to inform employees of the time period available to request a test of a split specimen.

The Department will adopt, on a uniform basis, the 72-hour time period. The Act requires the Department's procedures to provide for a test of the split specimen "if the individual requests the independent test within 3 days of being advised of the results of the confirmation test." To comply with the statute, the Department is not required to provide a time period longer than 72 hours.

Moreover, the Department has not seen a persuasive rationale for permitting a longer time period. Nothing prevents an employee who is told of a verified positive test from deciding in a very short time to seek a test of the split specimen. For example, some employees testing positive admit that they used drugs. Such employees may well not believe that testing the split specimen is necessary. If the employee concedes that the test was accurate, but contends that the MRO should have verified the test negative based on information concerning legitimate use of a drug, the employee is likely to seek redress other than a test of the split specimen. If, on the other hand, the employee is adamant that he or she never used a prohibited substance, or believes that the laboratory erred, the employee may well seek a test of the split specimen. None of these decisions on the employee's part need take more than 72 hours. Decisions concerning legal options, representation etc. can be made in the time frames appropriate to the processes involved: the decision on whether to seek a test of a split specimen need not wait on a decision about whether or how to make use of a grievance procedure, for example.

By saying that the 72-hour time period for requesting a test of the split specimen is a uniform requirement, we mean that any time an employee makes a request for a split specimen test within 72 hours of being informed of a verified positive test, the split specimen must be tested. Except in the limited circumstances discussed below, employers or MROs are not required by part 40 to provide for a test of a split specimen if the employee makes the request more than 72 hours after being informed of a verified positive test. There is no information in the rulemaking record to support the need of employees in any particular industry for a longer time period. Nothing in this provision prohibits an employer from voluntarily (e.g., as part of a labor-management agreement) honoring a request for a test of a split specimen made after 72 hours.

The suggestion that MROs inform employees of this time period is a good one. To make the 72-hour period for making a choice on testing a split specimen meaningful, it is necessary to ensure that the employee knows about the timeframe. For this reason, we have added to the final rule a requirement that the MRO notify each employee about this choice. We have inserted parallel language concerning requests for the reanalysis of the primary specimen in situations (i.e., under the Coast Guard and RSPA drug rules) where the split sample collection method is not used.

Under the final rule, when the MRO tells the employee that he or she has a confirmed positive test, the MRO must also tell the employee that he or she will have 72 hours following notice of a verified positive test in which to request a test of the split specimen. This notification is required in all cases of confirmed positive laboratory results, except in those situations in which an employee has effectively waived the opportunity to talk to the MRO. The 72-hour clock does not start to run until the time when the employee is notified, whether by the MRO or the employer, that the test result is a verified positive.

The employee is not required to wait until after a verified positive test in order to request an analysis of the split specimen. An employee could, if he or she chose, ask the MRO at the time of the notification of a confirmed positive test to initiate the test of the split specimen. The MRO would satisfy this request. The verification process would continue, and the MRO would notify the employer of the verified result in the usual way. The verification and notification processes would not be on hold pending the result of the analysis of the split specimen. Such a delay in removing from performance of a safety-sensitive function an individual with a verified positive test could not be justified on safety grounds. Once a test is verified as positive, the employee must be removed from safety-sensitive functions. The employee may not again perform safety-sensitive duties until he or she has met the conditions of the applicable operating administration rule for return to duty, pending the result of the test of the split specimen.

In any situation in which the MRO does not personally notify the employee of a verified positive test, we advise the MRO, upon receipt of a request from an employee to test the split specimen, to contact the employer or other party for verification of the time the employee was notified of the verified positive test. This should help to avoid potential questions about whether the employee has made a timely request.

In addition, to ensure that employees are not unfairly deprived of the opportunity to request a test of the split specimen, the Department is adding a provision to allow an employee who fails to request this test within 72 hours to present information to the MRO that the failure to make a timely request was caused by circumstances beyond the employee's control. This provision is similar to one in the existing rule concerning an employee's opportunity to convince the MRO that there was a good reason for the employee's failure to contact the MRO for verification purposes (see § 40.33(c)(6)). If the employee persuades the MRO, the MRO would initiate a test of split specimen, even though the employee's request had been made after the 72-hour period ended.

Number of Collection Containers

With respect to the collection itself, the NPRM proposed that the employee provide the specimen into a collection container, which would, in most cases, be subdivided and poured into two separate specimen bottles. One commenter favored the proposed approach; six others said that a two-container, rather than three-container approach, made more sense. That is, in all situations—not just unusual situations, as the NPRM proposed—the employee should urinate into a specimen bottle, which would become one specimen. The collection site person would then pour an amount of the urine from that bottle into a second bottle, which would become the other specimen. Commenters said this approach would save time and money.

The Department believes that these comments have merit, and the final rule permits either approach. The employer could use a collection container with the specimen subdivided and poured into two specimen bottles. Alternatively, the employer could use a specimen bottle capable of holding at least 60 ml, into which the employer would urinate. The specimen would then be subdivided, with 30 ml being poured into a second specimen bottle, which becomes the primary specimen

for testing purposes. The original specimen bottle, into which the employee had urinated, would become the split specimen.

This latter point may seem counter-intuitive, but there is a reason for it. We want to make sure that there is a 30 ml primary specimen. Pouring 30 ml of the void into the second specimen bottle insures that this will be the case. If the instructions were to pour 15 ml of the void into the second bottle, to be used for the split specimen, the primary specimen might wind up with less than 30 ml of urine if the collection site person overpoured. Laboratories have informed the Department that they intend to provide only 60 ml bottles to collection sites, because of the economies of mass producing a single size container and to avoid confusion by collection site personnel. For this reason, the final rule's procedure should not result in extra costs.

Storage of Split Specimens

Three commenters recommended that employers be authorized to store split specimens at the collection site rather than send them to the laboratory, in order to reduce shipping costs. The Department is not adopting this suggestion. Generally, laboratories have better, more secure storage facilities than many collection sites. The chances of loss, deterioration, tampering, etc. of a specimen are likely to increase in non-laboratory locations. A uniform procedure for storage and re-shipment of split specimens is likely to reduce opportunities for error in the system. The rule also addresses the issue of how long the split specimen should remain in storage. As noted above, the employee must notify the MRO within 72 hours of being informed of a verified positive test to trigger a requirement for a test of the split specimen. Consequently, it is not necessary for the laboratory to retain the split specimen for a prolonged period. In the Department's view, it is sufficient to require the split specimen to be stored 60 days from the date it arrives at the laboratory, if a request for testing it has not been received. (The primary specimen would remain in storage for one year, as under the existing rule.)

Choice of Alcohol Testing Methods and Devices

NPRM Proposal

The NPRM for alcohol testing procedures proposed that both the initial and confirmation tests would be done on an evidential breath testing device (EBT). An EBT is a breath testing device that is on the National Highway Traffic Safety Administration's (NHTSA) Conforming Products List (CPL), a list of breath testing devices that NHTSA has approved for use by law enforcement agencies in drunk driving cases. In addition, the EBTs would have to print out results and assign a sequential number to tests, to ensure that test results were preserved in a way that minimized the chances for human error or collusion (e.g., the disregarding of an initial positive test by an employer who did not want to lose an employee's services).

The NPRM also proposed training requirements for breath alcohol technicians (BATs), who would administer the tests, and maintenance and calibration requirements for EBTs. In requiring EBTs for all testing, DOT proposed that other testing methods—blood, saliva, urine, non-evidential breath, performance testing—could not be used for either screening or confirmation tests. In summary, the Department made this proposal because EBTs are a well-established, reliable, and accurate testing method; EBTs are minimally intrusive; EBTs can provide an on-the-spot result that allows employers to take action that prevents potential safety risks; and EBTs can produce a printed record of the test result that will prevent disputes about the accuracy and integrity of the testing process.

Comments

Overview

This proposal generated more comments than any other feature of the NPRM. Approximately 190 of the comments to part 40 addressed some aspect of testing methodology. These comments came from a variety of sources, including employers in all the industries covered by the proposed regulations, unions, laboratories, manufacturers of testing equipment and products, and consortia and third-party testing service providers. The most consistent theme among comments on this subject was a desire for greater flexibility in the choice of testing methodology than the NPRM proposed.

Support for NPRM Proposal

Twenty-six comments, representing employers in several industries, unions, third-party testing services, manufacturers of breath testing equipment, state police agencies, and the National Transportation Safety Board, supported the NPRM proposal. They cited as reasons for their support the non-invasiveness of breath testing, its long acceptance by courts and employees, its provision of a quantitative readout, simplicity compared to blood or urine testing, and the relatively low operating costs involved. Some of these commenters qualified their support of the NPRM proposal by saying that breath testing, while a good method, should be one of an array of options available to employers, or required only for certain types of testing (e.g., pre-employment and random) where the employer has control over the time and place of testing.

Concerns About Cost of NPRM Proposal

Eighty commenters, representing principally employers in all the regulated industries, third-party testing service providers, and manufacturers of other testing devices that compete with EBTs, said using EBTs for both screening and confirmation tests was too expensive. They quoted capital costs per EBT between $2–10 thousand (some EBT manufacturers who commented agreed with the lower end of this range). This cost would be multiplied, they believe, by a need to obtain EBTs for all the locations in which employers operate. For example, a trucking association cited a motor carrier that would have to buy an EBT for each of its 600 locations, at an estimated cost of $1.2 million. In addition, there would be BAT training, maintenance, and calibration costs. Commenters who talked in cost per test terms cited estimates of between $20–100 per test, which they said was much higher than for competing methods. Railroad industry employers (who now use breath testing for alcohol) said that, to reduce capital costs, EBTs should not be required to have the sequential numbering and printout capabilities proposed in the NPRM (which they said would add $1500 to the cost of an EBT).

Concerns About Difficulty in Implementing NPRM Proposal

Some commenters feared that there would be insufficient numbers of EBTs, BATs, and testing sites available to implement the proposal. There would be a rapid expansion of the need for EBTs (one commenter estimated a 3000-4000 percent increase in the market) that manufacturers may be unable to fulfill, as well as a rapid training need for thousands of BATs that would take substantial time to meet. Seventeen commenters (including a number of third-party service providers and employers) said that the cost of obtaining EBTs and training BATs, the unfamiliarity of many third-party testing sites with breath testing, and liability concerns would deter many potential third-party service providers from

participating. This would particularly be a problem in small towns and rural areas, where the low volume of testing would make the needed investment too costly.

Concern About Confrontations

Twenty-eight commenters (principally third-party service providers and employers) expressed concern about the possibility of confrontations between BATs and employees. These confrontations would occur, commenters said, because the BAT—not an employer representative with supervisory authority over the employee—would be the messenger of bad news about a test result. Several commenters cited the image of a 90-pound female BAT having to deal with an angry (and perhaps intoxicated) 300-pound truck driver who had just been told he had failed an alcohol test.

Other Comments About NPRM Proposal

Commenters expressed other concerns about the EBT–EBT approach. Some found the process too time-consuming. Others pointed out that the collection site is commonly recognized as the weak point of the drug testing process, and that conducting the alcohol testing process there increased the chance of error. Other comments said that there were too many opportunities for human and mechanical error in the breath testing process, which, together with what they regarded as the unreliability of EBTs at low alcohol concentrations, created numerous opportunities for litigation. Some commenters also said that, if all screening and confirmation testing were done on EBTs, the two tests should be run on different machines.

Legal Issues

Several commenters raised legal challenges to the proposal. Nine commenters (primarily manufacturers of competing devices and unions) said that the statute requires split samples (i.e., the subdivision and retention of a portion of a sample for an additional test at a laboratory as a safeguard for the accuracy of the process) in all cases. Generally, EBTs do not retain breath samples. Therefore, these comments said, methods that permitted split samples (e.g., blood, urine, saliva) must be used. Thirty-one comments said that the statute contemplated the use of different methods for the screening and confirmation test, respectively. Eleven comments said that, since the results of EBT tests would be used to refer persons for rehabilitation or treatment, they would be considered medical devices subject to Department of Health and Human Services (DHHS) regulation. Since DHHS had not approved EBTs as medical devices, their use could be blocked.

Desire for More Flexibility

Seventy-five commenters (representing a wide variety of equipment manufacturers, employers, and third-party service providers) favored allowing employers to choose the best testing method for them. In addition to the virtue of flexibility, this approach would permit each employer to choose the most cost-effective method of compliance in its own circumstances.

Most of these commenters appeared to favor testing methods that would use two different testing methods (e.g., non-evidential breath or saliva screening test, blood test for confirmation). Ten commenters disagreed on this point, saying that non-evidential screening tests should never be permitted. Their primary concern was about the accuracy of these testing methods. Several commenters who favored using non-evidential screening tests conceded that it would probably be necessary to suspend an employee's performance of safety sensitive functions pending a confirmation test of a positive non-evidential screening test. Most commenters who addressed confirmation procedures in a two-method system said that confirmation tests (of whatever body fluid) should be done on GC (gas chromatography, the same highly accurate method used for confirmation tests under the drug testing program).

Specific Comments on Other Testing Methods

Non-Evidential Breath Testing Devices

(e.g., tubes filled with materials that turn a certain color when alcohol-laden breath is blown into them or small, hand-held electronic devices that register the presence or absence of alcohol concentration in breath)

Twenty-nine commenters, including a variety of employers and manufacturers of the devices, supported using non-evidential breath testing devices. Most commenters cited cost (estimated at between $90–550 for various models of non-evidential breath testing machines, and about $2–4 each for disposable devices) and convenience as reasons. A few opponents of non-evidential breath testing devices said their accuracy was questionable, both with respect to false positives and false negatives.

Saliva Testing

(i.e., a device which registers a particular alcohol concentration when a swab with saliva from the employee's mouth is inserted into it)

Forty-five commenters favored the use of saliva testing. These commenters included a variety of employers, third-party service providers, equipment manufacturers, and others. Commenters claimed several advantages for use of screening saliva tests: modest cost (estimated at between $5–20 per test); simplicity of use, little need for training; existing "approvals" from NHTSA and Food and Drug Administration (FDA) for some devices (though in contexts other than a workplace testing program); non-invasive nature of the devices; sufficient accuracy for screening tests. Two commenters also said that, while it was most typical to use blood testing for confirmation after a saliva screen, saliva specimens could also be used for confirmation, as laboratories could run a gas chromatography analysis on saliva.

A few commenters expressed concerns about saliva testing devices. A union provided data that it said showed that saliva devices had a mixed record for accuracy. Other commenters said saliva remained an unproven method, that saliva devices were not ethanol-specific, and that saliva alcohol and blood alcohol results may differ. Proponents of saliva testing devices conceded that chain of custody forms would be needed and that there was no method of automatically generating permanent records of test results that positively identified a particular employee with a particular result. They said that keeping paper records was adequate for this purpose, however.

Blood Testing

Forty-eight commenters (again representing a variety of employers, plus third-party providers, laboratories and others) favored allowing the use of blood testing as a confirmation test method. The advantages cited for this method included well-established scientific and legal acceptance for accuracy, the availability almost anywhere of technicians trained in drawing blood, and utility for post-accident testing on employees who are unconscious. Some of these commenters said that, while blood testing is admittedly more invasive than other methods, employees accept it because of its reputation for accuracy. Also, they said, the low expected positive rates on screening tests will mean that few blood confirmation tests would have to be performed. Commenters estimated costs to be in the $20–60 range per test.

Seven commenters opposed the use of blood testing, primarily on the ground that it is too invasive. In addition, a few commenters said that DHHS or DOT

would have to develop laboratory certification standards for blood testing. Some comments said that employees might have to be required to "stand down" during the interval between the blood collection and the return of the test result from the laboratory.

Urine Testing

Eight commenters favored allowing the use of urine testing, including some employers who now use this approach to their satisfaction and laboratories that do urine testing. One advantage cited for this approach is that alcohol could simply be added to the list of substances for which urine samples taken for drug testing are tested, at a low incremental cost. Commenters said that DOT or DHHS should develop laboratory certification procedures and cutoff levels. Some commenters also noted that detailed collection procedures would have to be developed, since urine testing for alcohol is more complicated than urine testing for drugs (e.g., two voids, twenty minutes apart, are recommended to measure alcohol concentration in urine).

Performance Testing

Five commenters, most of whom were manufacturers of the devices, supported the use of performance tests for the screening or screening test. (A performance test does not measure alcohol concentration; it measures deviations from a personal norm of reaction time, motor coordination, etc.) One commenter opposed performance testing devices as inappropriate for this program.

Responses to Comments on Testing Methods

Legal Issues

The Act provides, with respect to confirmation testing, that all tests * * * shall be confirmed by a scientifically recognized method of testing capable of providing quantitative data regarding alcohol * * *

Some comments asserted that this provision requires that a different testing method be used for the screen and confirmation tests, respectively. The statute says no such thing, stating only that the confirmation test must use a "scientifically recognized" method that can provide "quantitative data" regarding alcohol. As long as the method of confirmation meets these criteria, the statutory requirement is satisfied. Breath testing is scientifically and legally recognized as a method for accurately testing alcohol concentration, and devices meeting the Department's requirements provide quantitative data. (Blood testing, of course, also meets the statutory criteria.)

The ability of a method of confirmation testing to pass these statutory tests is not dependent on the choice of a method of screening testing. Testing of breath for confirmation, as provided in this rule, is equally valid under the statute whether evidential breath testing, non-evidential breath testing, or saliva is used for the screening test. Testing of blood for confirmation is equally valid under the statute whether blood, breath, saliva or urine is used for the screening test. All that matters is that the confirmation testing method meet the statutory criteria in its own right.

With respect to split samples, the Act requires the Department's regulations to provide that each specimen sample be subdivided * * * and that a portion thereof be retained in a secure manner to prevent the possibility of tampering, so that in the event the individual's confirmation tests results are positive the individual has an opportunity to have the retained portion assayed by a confirmation test done independently at a second certified laboratory if the individual requests the independent test within 3 days after being advised of the result of the confirmation test * * *

Some commenters asserted that this language should be read to require that split samples be used in all alcohol testing, with the implication that a method that did not permit the use of split samples could not be used. Since most EBTs—including those proposed by the Department in the NPRM—do not retain a sample that could theoretically be subdivided and preserved for testing of a split specimen, some of these commenters asserted not only that blood or other liquid-based testing methods were required, but that breath testing was prohibited.

This interpretation is flatly contrary to the statute, which specifically contemplates the use of breath testing (*see, e.g.*, sec. 3(a) of the Act, adding section 614(d)(6) to the Federal Aviation Act). Breath testing is a well-recognized form of alcohol testing, and there is no evidence that Congress had any intention of prohibiting its use, either indirectly by requiring split samples or otherwise. The legislative history makes clear that the Senate sponsors of the legislation intended that breath testing be used and that split samples were not mandated for breath testing. In the floor debate, during a colloquy between Senators Danforth and Hollings, Senator Hollings stated

> [t]here are also requirements for split samples, primarily included in the legislation to allow urine samples to be retested. DOT would have the authority to determine that blood samples should be similarly handled. This specific requirement is not relevant in the case of breath testing for alcohol, but DOT is directed by this legislation to provide necessary safeguards in this area to ensure the validity of test results.
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> 137 Cong. Rec S 14764, 14770.

There is also internal evidence in the wording of the statutory provision that supports the reasonable interpretation that the split sample requirement is intended to apply to liquid body fluids like urine and blood, but not to breath. The statute uses the word "samples" in ways that refer primarily to samples of liquid body fluids. For example, section 614(d)((1) of the amended Federal Aviation Act refers to the need for "privacy in the collection of specimen samples." Privacy is very important with respect to collection of urine samples for drug testing. Because elimination functions are not involved, privacy is not as important in breath collections. In paragraph (d)(6) of the same section, the statute refers to detecting and quantifying "alcohol in breath and body fluid samples, including urine and blood." In this language, the phrase "including urine and blood" is best understood as modifying "body fluid samples," as opposed to "breath." Given the way that the term "sample" is used in these portions of the statute, the use in paragraph (d)(5) of "sample" should also be used to refer to liquid body fluid samples (i.e., urine and blood). When this paragraph speaks of the "specimen sample be[ing] subdivided," then, it is imposing a split sample requirement on blood and urine, not on breath.

Some commenters argued that the language mentioned above from paragraph (d)(6), requiring the Department to "ensure appropriate safeguards for testing to detect and quantify alcohol in breath and body fluid samples, including urine and blood * * *," creates a right for employees to have a screening test confirmed by blood testing. This language, on its face, does not create such a requirement, since it does not specify any particular sort of test for either screening or confirmation purposes. There is ambiguous legislative history on the point, with the Senate report on the Act saying both that "an employee testing positive for alcohol using a specimen other than blood shall be entitled, at that employees [sic] option, to a blood test" and that "the Committee has not specified the type of test to be used in either the screening or confirmation test." Given that the statute does not explicitly require blood

testing for confirmation, and that the portion of the statute that mandates confirmation testing requires only a "scientifically recognized" confirmation test that can produce "quantitative data" (criteria that breath testing clearly meets), the Department does not believe it would be reasonable to view this ambiguous legislative history as a mandate for the availability of blood confirmation testing in all cases.

The Department does not believe that regulations of the Food and Drug Administration (FDA) would interfere with the implementation of breath testing under this rule. FDA does regulate the safety, labeling, etc. of medical devices. It is our understanding that FDA may be considering initiatives to regulate EBTs used as medical devices in medical settings. FDA does not, however, regulate or certify the precision or accuracy of EBTs that are currently used for law enforcement purposes or that would be used under the DOT alcohol testing program. (These would not be viewed as medical devices used in medical settings.) We believe that current FDA rules are, and future FDA rules would be, consistent with NHTSA certification of EBTs.

Flexibility and Cost

Many commenters made flexibility in testing methods a high priority. The Department agrees that flexibility is desirable. However, the Department also believes that any testing system should meet a series of criteria, each of which is necessary to execute the statute faithfully and to ensure that the safety and accuracy goals of the program are met. The Department cannot emphasize too strongly the importance of ensuring accuracy and reliability of testing devices and methods, at both the screening and confirmation test stages. This is needed, among other reasons, to protect employees from even temporarily being identified as misusers of alcohol. In the context of drug testing litigation, the courts, in upholding the Department's program, relied to a substantial extent on the reliability and accuracy safeguards in that program.

Within these constraints, our objective is to provide maximum flexibility and minimum cost. The Department's criteria for carrying out its objectives in this area are the following:

- As required by the statute, the method used for confirmation should be scientifically recognized and able to produce a quantitative result. The method should meet NHTSA Conforming Products List (CPL) standards at 0.02 and higher alcohol concentrations.
- The confirmation method should be alcohol-specific (i.e., does not produce a reading for acetone).
- The confirmation method should generally provide documentation of quality control/calibration and be admissible as forensic evidence in administrative proceedings.
- The testing method used for confirmation should provide a result at the time and place of the test, so that an employee whose continued performance of a safety sensitive function may present a safety risk can be removed from performing that function.
- The testing method used for the screening test should minimize the occurrence of false positives and false negatives and should meet stringent standards for precision and accuracy (e.g., +/− .005 at 0.02 alcohol concentration).
- The testing method used for screening tests should provide a result at the time and place of the test and be specific for measuring alcohol concentration.
- The testing methods used for confirmation tests should provide a printed, permanent record of the test number and test result, in order to avoid uncertainty about whether this employee took this test with this result. The testing methods used for screening tests should provide either this kind of record or be used in conjunction with procedures that provide a record of the test result linked to the individual tested through some form of permanent documentation. The purpose of this criterion is to prevent collusion and cheating.
- The testing methods used for screening and confirmation tests should, as a policy matter, be as non-invasive as possible.

At the present time, only evidential breath testing methods meet all these criteria for screening and confirmation tests. Applying these criteria strictly would result in a final rule that, like the NPRM, permitted only evidential breath testing for both tests. The points made by commenters favoring the NPRM approach further support using evidential breath testing for both tests.

The Department, to achieve a reasonable balance between the legal and policy goals on which the criteria are based and commenters' desire for greater flexibility, is modifying the approach proposed in the NPRM. First, the final rule will permit EBTs that are on the NHTSA CPL, but that do not meet the additional requirements for confirmation EBTs (e.g., sequential numbering and print-out capability), to be used for any screening test. While these EBTs may be used for screening tests at this time, because NHTSA has determined them to meet appropriate accuracy and precision standards, non-evidential breath screening devices (e.g., "breath tubes") may not be used at this time.

Second, in an NPRM published in today's **Federal Register**, the Department will propose to permit blood testing to be used in limited circumstances. In the case of a reasonable suspicion test or a post-accident test, where an EBT meeting the requirements of part 40 is not readily available, the employer could use blood testing for the confirmation test. Blood alcohol testing would also be available as an option in "shy lung" situations. This NPRM also proposes blood testing procedures to be used in these circumstances. The rationale for allowing this limited use of blood testing is discussed in the preamble to the NPRM.

Third, the Department is also publishing in today's **Federal Register** a notice proposing to adopt criteria and procedures that would permit additional alcohol screening devices to be used for screening tests in the program. This proposal would be intended to result in the adoption of model specifications for a conforming products list for alcohol screening devices. Under this proposal, manufacturers of devices could submit their products to DOT for evaluation and, if their devices met the model specifications, the Department would authorize their use as screening devices in DOT-mandated alcohol testing. This approach will permit greater flexibility in the use of screening devices that are not now appropriate for use, including those supported by their manufacturers and others in comments to the part 40 docket, if they are able to meet DOT model specifications.

With respect to costs, commenters had three basic concerns. First, commenters believed that EBTs meeting all the NPRM's requirements would be too expensive. Some commenters believed that adding features such as a sequential numbering and printout capability would add considerably to the cost of the devices. The Department's information, included in our regulatory evaluations, and based on data obtained from manufacturers, suggests that the list price per unit of an EBT meeting all the NPRM criteria for use in confirmation tests is about $2000. (There are some indications that prices may be lower for purchases in quantity.) There are other EBTs on the CPL, available under the final rule to be used for screening tests, that list for about

$1000, again with the possibility of lower prices for purchases in quantity.

Because the Department is proposing to permit blood testing in post-accident and reasonable suspicion situations where a breath testing unit is not readily available, the numbers of EBTs that any employer would have to obtain may be reduced significantly from earlier estimates, lowering many commenters' estimated capital costs of the program. This is because employers would not have to provide an EBT at all its work sites against the contingency of a reasonable suspicion or post-accident test happening there, as a number of employers' estimates assumed. Commenters identified having to pre-position EBTs at all work sites, even the small and remote ones, as a major cost of compliance with the NPRM (even though the NPRM would not have imposed this requirement). In addition making blood testing available means that the time workers would be held out of service pending a test would be reduced significantly, resulting in further savings. We refer commenters to today's NPRM on blood alcohol testing for further information.

Second, commenters expressed concern about the costs of training personnel and maintaining and calibrating the instruments. While training can be expensive, we believe that these costs are difficult to avoid if the accuracy and integrity of the testing program are to be protected. As other devices are approved under the Department's forthcoming procedures, employers will have the opportunity to determine if use of other methods will reduce their overall costs.

Third, some commenters (especially from the railroad industry) who already use EBTs expressed concern about the costs of the additional features that the NPRM would have required (e.g., sequential numbering capacity, print-out capability). The final rule responds to these concerns by allowing EBTs without these features to be used for screening purposes. A railroad could use its existing EBTs (assuming they are on the NHTSA CPL) for screening tests, while obtaining only as many of the machines with the additional features as it needed for confirmation testing. This would reduce the additional costs that these employers would have to incur.

When the Department issues a broad mandate for employee testing, the overall effect is likely to be the creation of additional opportunities for professionals, manufacturers, and other businesses to serve the markets created by the DOT requirements. These opportunities can fairly be expected to lead to an influx of participants into the market. There is ample evidence that this has been the case in the Department's drug testing program, and it is reasonable to expect that similar economic opportunities will draw businesses and professionals into the alcohol testing market. The Department believes that this factor is likely to outweigh, by a substantial margin, any deterrent effects on participation in the program related to equipment or training costs, the newness of the procedures, liability, or the willingness of businesses and professionals to participate.

Comments that potential participants would be deterred for these reasons were, for the most part, speculative. Given the market's response to the drug testing rules since 1988, it is fairer to assume that the market's response to the even larger-scale alcohol testing program will not be timid. With respect to the issue of sufficient EBTs being available, the Department has contacted EBT manufacturers, and we do not anticipate any serious shortage of devices as the program begins operation. If, at any time, the Department learns that there are inadequate supplies, the Department could postpone or otherwise modify its rules.

While the image of a large, angry, intoxicated employee confronting a 90-pound female BAT over a positive result is a graphic one, the speculation and spotty anecdotal evidence provided by commenters to back up their concern on this matter is not sufficient to cause the Department to retreat from its position that immediate results are needed. (This concern goes to any testing method that provides an immediate result, not just to breath testing. It might appear even more strongly in a situation in which an individual is told, as the result of a non-evidential screen, that he is to "stand down" and not work for three days while a laboratory test result is obtained.)

The point of getting an immediate result is safety: if an employee, of whatever size, has a higher alcohol concentration than the Department's rules permit, the individual should not be performing a safety-sensitive function. In the interest of safety, we need to stop the individual's performance of that function now, not two or three days later when a laboratory test result becomes available. We also want to prevent the unnecessary cost of holding an employee out of service for two or three days pending laboratory results following a non-evidential screen. BATs are not given the responsibility of taking a driver's keys away. The DOT alcohol testing form includes a statement, to be signed by the employee, that persons who test positive should not drive or perform other safety-sensitive functions. Employers have a responsibility, as part of their alcohol education for employees, to emphasize that employees must cease performing safety sensitive functions if they test positive.

The Department does not believe that it is necessary to use two separate EBTs in order to have a valid, defensible result. EBTs on the NHTSA CPL are designed for accuracy, and the internal and external calibration checks built into the Department's procedures are sufficient insurance against error. (Where employers choose to use an EBT without the additional features for screening tests, of course, the employer will necessarily use a different machine for the confirmation test.) The Department is convinced that EBTs meeting its requirements are sufficiently accurate and reliable, at the alcohol concentrations that will be tested for, and that excessive invalidations of tests or successful lawsuits or grievances will not occur. Similarly, the likelihood of extensive errors by testing personnel should be diminished by the BAT training requirements.

Manufacturers of alternative testing devices, and some other commenters as well, advocated various other methods of testing, particularly for screening tests. As noted above, the Department intends to take action that could result in decisions to authorize use of other screening devices and to authorize the use of blood testing in some circumstances. The Department has decided not to permit the use of these alternative methods until they can meet the criteria we believe are necessary for accurate testing meeting the requirements of the statute. The following paragraphs summarize the Department's reasons for not permitting the use, at this time, of other testing methods:

Blood Testing

- This is the most invasive form of testing.
- Employees may fear needles or fear infection from improper medical procedures.
- Additional collection procedures, chain of custody procedures, and equipment requirements would be needed, making regulatory requirements more complex.
- Laboratory certification standards and testing protocols would need to be established. As noted in the accompanying NPRM, this poses potentially significant problems even in the limited context in which the Department is proposing to permit the use of blood testing.
- Results would not be available for at least 24 hours, and could take 3–4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was

affected by alcohol, which would reduce the safety benefits of the program.

Urine Testing

• Present laboratory certification standards and testing protocols do not cover urine testing for alcohol. There would have to be additional laboratory certification procedures and testing protocols developed for urine testing.

• Urine testing for alcohol (as distinct from drugs) requires a complex collection process, involving two separate voids with an interval between them. Addition of a preservative to prevent the creation of alcohol by microbial fermentation is also recommended. We would need to add new collection procedures to accommodate these requirements, as well as new training requirements for collection site personnel. These additional procedures would make the collection process more complex and multiply the chances for errors.

• Urine testing is regarded as the least accurate method currently available for determining the amount of alcohol in the body.

• A blood to urine ratio has not been definitively established, making it difficult to equate a urine test result for alcohol to a particular blood or breath alcohol level.

• There are greater costs of employee "downtime," for transporting the employee to a collection site for testing and for the longer collection procedure.

• Testing of urine specimens would have to take place in a laboratory. Results would not be available for at least 24 hours, and could take 3–4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program.

Saliva Testing

• Especially at low alcohol levels, saliva devices are likely to have a higher rate of false positives and negatives than EBTs on the CPL.

• Some saliva devices do not provide quantitative results.

• Because saliva screening testing devices are disposable, and do not generate a record of the test, ascertaining whether a particular employee took a particular test and had a particular result, or that the test took place at all, would be difficult. (The use of a log book, which helps to address this concern where EBTs without sequential numbering or printout capabilities are used, would be difficult in the case of disposable devices. The log book would accompany the EBT wherever it went, which would not be possible with disposable devices.)

• There are different saliva-based technologies, each requiring the establishment of criteria for accuracy, reliability, etc. Until NHTSA criteria are established for these technologies, it is premature to permit their use in the DOT program.

• If laboratory confirmation methods (e.g., blood) are used in combination with saliva screens, confirmation results would not be available for at least 24 hours, and could take 3–4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program. If breath testing confirmation is used, cost savings claimed for the use of disposable devices over the use of breath testing for both screening and confirmation testing would be reduced substantially.

• The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for saliva testing, adding further complexity to the program.

Non-evidential Breath Testing

• Non-evidential breath devices (i.e., disposable devices and others not on the CPL) have a higher rate of false positives and negatives than evidential EBTs.

• Non-evidential breath screening testing devices do not generate a record of the test, so that ascertaining whether a particular employee took a particular test and had a particular result, or that the test took place at all, would be difficult. (The use of a log book, which helps to address this concern where EBTs without sequential numbering or printout capabilities are used, would be difficult in the case of disposable devices. The log book would accompany the EBT wherever it went, which would not be possible with disposable devices.)

• If laboratory confirmation methods (e.g., blood) are used in combination with non-evidential breath screens, confirmation results would not be available for at least 24 hours, and could take 3–4 days to arrive. Confirmed results would, therefore, not be available at the time the employee was affected by alcohol, which would reduce the safety benefits of the program. If breath testing confirmation is used, cost savings claimed for the use of non-evidential devices over the use of evidential breath testing for both screening and confirmation testing would be reduced substantially.

• Non-evidential EBTs on the market appear to vary greatly in type of technology used, quality, and accuracy. Until NHTSA criteria are established for these devices, it is premature to permit their use in the DOT program.

• The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for non-evidential breath testing, adding further complexity to the program.

Performance Testing

• The statute requires testing for alcohol concentration, not diminished performance. A test for performance appears not to meet this statutory requirement.

• Performance tests are very unspecific, which could result in positives caused by a wide variety of things other than alcohol use (e.g., illness, prescription or over-the-counter medication, fatigue, emotional distress). This would lead to many unnecessary confirmation tests and could result in employees being taken off the job while awaiting confirmation test results, adding extra costs for employers and employees.

• The accuracy of many performance testing devices is unproven.

• Many performance testing devices do not generate a record of the test. Ascertaining whether a particular employee took a particular test and had a particular result, or that the test took place at all, could be difficult.

• Most performance testing devices require the establishment of individual baseline data for each employee, which can be a time-consuming and costly procedure.

• In many systems, performance evaluation must relate to critical job skills, measures of which have not been established for many occupations.

• Performance testing devices or systems on the market appear to vary greatly in quality and accuracy. Until NHTSA criteria are established for these devices, it is premature to permit their use in the DOT program.

• The Department would have to establish additional procedures, training requirements, quality control requirements, etc. for performance testing, adding further complexity to the program.

This discussion is in the context of an extensive, multi-modal testing program, including pre-employment and random testing as well as reasonable suspicion and post-accident testing. Greater protections are needed in such a program, particularly in the absence of procedural protections present in some existing programs that may use non-evidential testing in some circumstances. For example, the Coast Guard post-accident alcohol testing program can involve administrative proceedings in which the employee has the opportunity to challenge test results before a license is revoked or an investigative inquiry at which further evidence could be introduced.

Breath Alcohol Technicians

The NPRM proposed that breath alcohol technicians (BATs) be trained to proficiency in using EBTs and in DOT alcohol testing procedures, using a NHTSA- or state-approved course. The competence of the BAT would have to be documented. Additional (i.e., refresher) training would be required, as needed, to maintain proficiency. An employee's supervisor could not act as the BAT for that employee unless allowed by a DOT rule and no other qualified BAT were available.

Commenters spoke to several provisions of this section. Six commenters favored, and 15 opposed, requiring BATs to be tested to ensure that they are alcohol free (an issue about which the Department had asked a question in the NPRM preamble). A number of the opponents said that this issue should be decided by the BATs' employers. The Department is not adopting this idea, which we believe to be unnecessary to the program.

Forty-nine comments addressed the training and qualification of BATs. All these commenters favored training,

though two mentioned that training might be very costly or difficult, especially for smaller companies. Sixteen comments said that it was not necessary for the regulation to specify that BATs be trained in the pharmacology and physiology of alcohol, about which the NPRM preamble had asked a question. Three commenters took the opposite position. The Department agrees that this training is not needed for BATs, whose training should be focused on the proper operation of testing devices.

Seventeen commenters supported the NPRM approach (including the concept of "training to proficiency"), while two thought the NPRM too vague. Eleven favored specific numbers of hours of training, ranging from 4 to 40, with most of the comments suggesting something between 4 and 8 hours. Two expressed support of recurrent training, one asking for a more specific requirement than the NPRM proposed. The Department believes it is most relevant to ensure the BATs' proficiency. Our goal is to ensure that BATs are able to use the testing devices that they will operate. The Department believes that the best way to make sure that BAT training results in proficient operators is to require that BAT training include a course that is equivalent to the DOT Model Course. Courses followed by state law enforcement agencies and other organizations appear to vary substantially from one another, and may be focused on breath testing in other contexts (e.g., enforcement of DUI laws). NHTSA will review training courses and issue determinations concerning whether they are equivalent to the NHTSA Model Course.

Who should be a BAT? Twenty-two of 23 commenters supported permitting a trained law enforcement officer to act as a BAT. The Department agrees that it is appropriate to authorize trained law enforcement officers to act as BATs (e.g., off-duty officers under contract to an employer), as long as they have been certified by a state or local law enforcement agency. The officers would have to follow DOT testing requirements, including this part, and to be certified to operate the EBT used in the DOT-mandated test. The officers could perform any type of DOT test. Except for the FHWA rule, the OA rules do not permit the substitution of law enforcement tests for tests conducted under DOT procedures.

There was less consensus on the issue of supervisors as BATs. Sixteen commenters favored allowing properly trained supervisors to act as BATs, pointing out that, particularly in reasonable suspicion or post-accident testing, or at remote sites, supervisors may be the most readily available, or perhaps the only available, trained BATs. Eleven other commenters disagreed, most saying that an employee's supervisor should never be the employee's BAT. These commenters appeared concerned about the appearance or reality of a conflict of interest between the supervisor's managerial role and his objectivity as a BAT. The Department believes that, when possible, someone other than an employer's supervisor must act as a BAT for the employee's test. However, a supervisory BAT is better than no BAT at all. To enable a test to go forward when no other BAT is available in a timely manner, the Department will permit a BAT-trained supervisor to conduct the test. However, if a DOT operating administration regulation prohibits the use of a supervisor in this role (e.g., in reasonable suspicion testing), the supervisor may not act as the BAT even in this circumstance.

EBT Technology

The NPRM required EBTs used for screening and confirmation testing to be on the NHTSA CPL, have the capacity to print out triplicate (or three consecutive identical) results, assign a sequential number to each test, distinguish alcohol from acetone at the 0.02 alcohol concentration level, and have the capability for performing both air blanks and external calibration checks. Commenters addressed a number of points concerning EBT technology.

Some commenters pointed to what they viewed as shortcomings of the CPL itself, particularly that it did not require EBTs to be accurate at the 0.02 level. This was true of the CPL at the time the NPRMs were issued; however, NHTSA has since modified the model specifications for the CPL to require accuracy and precision at the 0.02 level. Other commenters said that since inclusion on the CPL is based on testing of a prototype, rather than testing of each device, the CPL was an inadequate assurance of accuracy. The final rule does not rely on the CPL alone to ensure accuracy, however. The rule requires there to be a quality assurance plan (QAP) for the instrument as well as air blanks and external calibration checks.

As noted above, a number of commenters criticized the requirement for printing results and sequential numbering capability, saying that these features were unnecessarily costly. Any device on the CPL should be able to be used, one of these commenters said. The final rule responds to these comments by allowing any device on the CPL to be used for screening tests, with the additional features required only on those machines used for confirmation testing. This should reduce the number of the more expensive models employers will have to obtain.

Some commenters expressed concern about radio frequency interference (RFI) affecting the results of some types of EBTs. The concern is that, in airports and other locations where communications or other electronic equipment is operating, alcohol concentration readings could be distorted. DOT asked manufacturers about this issue, who said that most models of EBTs are shielded to avoid this problem. NHTSA tested three models of EBTs at Washington National Airport and detected no RFI effects on their readings. In addition, NHTSA plans, as part of its process for reviewing quality assurance plans (see discussion below), to have manufacturers establish operational guidelines to avoid RFI problems. The Department believes that it is not necessary to modify the regulatory text to address the commenters' concerns.

Commenters also expressed concern that some EBTs might not be able to distinguish acetone from some alcohols. Commenters also questioned the suitability of the CPL for instruments measuring alcohol concentrations at the 0.02/0.04 levels, since the CPL, at the time of the NPRM, did not address testing at these levels. As noted above, NHTSA has revised the model specifications on which CPL listing of devices is based. The revised specifications address both issues, and EBTs on the CPL will distinguish acetone from alcohol and be accurate at the 0.02/0.04 levels.

A few comments raised other technical issues about the use of EBTs. One issue was the effect of altitude on external calibration standards. Altitude affects gas aerosol standards; NHTSA will address this problem by requiring gas aerosol standards on its CPL for calibration devices to be criterion-referenced for various altitudes.

Another concern was based on the belief that EBTs that display results to only two, rather than three, decimal places would round up. That is, commenters were concerned that someone whose actual alcohol concentration was .036 would be reported as a 0.04, subjecting the individual to heavier sanctions. EBTs on the CPL provide three-digit displays, so this problem does not arise for these devices.

Finally, some commenters expressed concern that defining alcohol concentration in terms of grams of

alcohol per 210 liters of breath was not as accurate as desirable (or as accurate as a blood alcohol reading), because this ratio could vary among individuals. The Department's information is that any variation is very minor and unlikely to affect the results of a breath test or its consequences under these rules. In addition, EBTs are typically calibrated to account for any variation by slightly undercounting alcohol concentration.

Quality Assurance Plans

The NPRM proposed that EBT manufacturers would develop a quality assurance plan (QAP) for each EBT model. The plan would cover such matters as external calibration methods, tolerances and intervals and inspection and maintenance requirements. The manufacturer would have to obtain NHTSA approval of the QAP, and employers would have to comply with it. This compliance includes making external calibration checks as called for in the QAP and taking EBTs out of service if they "flunk" an external calibration check. In addition, the employer would have to ensure that inspection, calibration and maintenance of EBTs is done by the manufacturer, a representative certified by the manufacturer, or an appropriate state agency.

On the basic concept of the QAP, five commenters supported the NPRM's approach, while another eight said that NHTSA, rather than the manufacturer, should establish the standards. Some of the latter commenters appeared concerned that manufacturers may have incentives to establish requirements for their devices that were not optimal. The Department believes that NHTSA approval of the QAPs should be sufficient to ensure that the manufacturer's standards are adequate and that the manufacturers are better positioned than we are to establish model-specific requirements for individual EBTs. For this reason, we are retaining the proposed approach. QAPs would be required for all EBTs on the NHTSA CPL that would be used in DOT-required alcohol testing, whether or not a particular EBT met the additional requirements of this part for use in confirmation testing.

Commenters suggested a wide variety of requirements concerning how frequently an external calibration test must be performed. Some of the ideas included performing such checks before and/or after every test, after every positive test, before, during and after the testing shift, every day, after every five tests, every thirty days, or before disciplinary action is taken on the basis of a positive test. All these comments respond to a basic point: if an EBT "flunks" an external calibration check, positive tests conducted on that device since the last previous successful external calibration check must be regarded as invalid. This fact provides a strong incentive to employers and BATs to conduct these checks frequently enough to avoid retroactive invalidations of positive tests. In conjunction with the manufacturer's instructions on the QAP, this incentive should be sufficient to induce employers acting in good faith and testers to conduct these checks at appropriate intervals. A generally applicable regulatory requirement for external checks of calibration at a stated interval, on the other hand, would provide less flexibility and might not fit a variety of situations well.

A few commenters suggested specific types of calibration solutions or obtaining such solutions from certified laboratories. Others suggested that the Department establish particular standards for external calibration devices, or allow use of only those external calibration devices that are on the NHTSA CPL. Others suggested particular tolerance standards (e.g., +/— .005). The Department does agree that the employers should use external calibration devices that are on the NHTSA CPL, and this requirement has been incorporated into the final rule. The Department does not certify laboratories for production of external calibration solutions, so we could not reasonably require employers to obtain solutions from certified laboratories. For the types of solution that work best with a particular machine, or for the tolerance standard that is most relevant, we believe that reliance on the QAP, based on the manufacturer's knowledge of the behavior of its product, makes the most sense.

On the subject of maintenance, most commenters supported the NPRM's proposal for maintenance by manufacturers, or their representatives, and careful documentation of this activity. These provisions have been retained.

Testing Location

The NPRM called for a testing site that afforded visual and aural privacy to the employee, though in unusual circumstances a test could be conducted elsewhere. The site would have to be secured. A mobile facility (e.g., a van) that met the requirements could be used. At the site, the BAT was to supervise only one employee's use of an EBT at a time, and the BAT could not leave the site when testing was in progress. The Department, with some modifications, is adopting this provision in the final rule. In our view, privacy in the context of breath alcohol testing is primarily for the purpose limiting other persons' access to information about the employee's test result. In contrast to urine drug testing, where private elimination functions are involved, privacy need not be as strict for breath alcohol testing. We have also eliminated references to the site being "secured," as such, because this term could lead to confusion. Our concern is that unauthorized persons not be in a position to see or overhear test results. We are not requiring that testing take place behind locked doors, in a totally enclosed space, or in a dedicated facility that is not used for other purposes.

There were few comments on this provision. Two commenters noted that privacy could be hard to achieve at a remote site. The NPRM already made allowance for this problem, however, by saying that a testing location did not have to provide full privacy in unusual circumstances such as a post-accident or reasonable suspicion test in a remote location. Other comments included a concern that privacy be protected adequately, that too much privacy could sharpen the concern about confrontations between BATs and employees, and that privacy requirements should not exclude a witness (e.g., a union representative) from the testing site. The provision establishes a general performance standard for privacy of the physical site: It does not address the issue of whether a witness may be present (that is a matter for labor-management negotiation). It does not require a site that is so isolated that a BAT could not find assistance if needed. One commenter asked for a DOT-operated national inspection program for test sites, analogous to the DHHS laboratory certification program. The Department believes that such a system would not be practicable, given the very high number of testing sites likely to be involved with the program.

Testing Form and Log Book

The NPRM proposed to require the use of a standard form for DOT-mandated testing, which employers could not modify. It would be a triplicate form, with copies for the BAT, employer, and employee. The colors of each copy of the form are intended to be consistent with the colors of the Department's drug testing form. The Department has decided to adopt this provision with minor modifications.

Seven commenters supported the NPRM provision as drafted. Thirteen commenters favored having space on

the form for recording a repeat of a test, in order to reduce paperwork. The Department believes that adding space for this purpose would result in a longer, more complicated form. Moreover, it is likely to be only in a minority of cases that a test will have to be repeated, meaning that the extra complexity of the form would not serve a useful purpose in most cases. For this reason, the Department is not adopting this comment.

Two commenters suggested that a combined drug/alcohol form be developed. The Department responds that, because of the differences between drug and alcohol testing, it would be difficult to develop a combined form that would not be too cumbersome and would work in both situations.

Two commenters asked that employers be able to modify the form. The Department's experience with the drug testing program, where some modification of the form has been permitted, is that the resulting variety of forms leads to confusion, errors, and difficulty in completing the form by collection site personnel. The Department believes that an unvarying, standard form will minimize these problems. Employers would have to use the form exactly as presented in Appendix A to this regulation (though a form directly generated by an EBT could be smaller and would not need a space to affix a separate printed result.) One commenter suggested that DOT provide the forms to employers free of charge. The Department does not believe that this is an appropriate use of Federal funds.

Two commenters asked that the form specify that the test is being conducted under the authority of DOT regulations. The Department's experience under the drug testing program is that, for lack of such a statement, some employees have been confused about whether a particular test was being conducted under DOT authority or simply under the employer's policy. The form being published with this rule includes such a statement. The result of including such a statement is that employers are not permitted to use the "DOT form" for a test not conducted under DOT authority.

Two commenters questioned the option to have the EBT or printer print results directly on the form, preferring to use a separate form. The regulation's requirements for EBTs used in confirmation testing provides this option, which is appropriate to provide flexibility. An employer who is uncomfortable with one approach can use the other.

This section of the rule includes a new provision requiring the use of a log book with EBTs, used for screening tests, that do not have the sequential numbering and printing capabilities required for devices used for confirmation tests. This section spells out the requirement for the log book and what it must contain; the rationale for the log book requirement is discussed below.

Preparation for Testing

The NPRM proposed that the BAT and the employee provide identification to one another and that the BAT explain the testing procedure to the employee. A commenter suggested that written information be provided to the employee, so that the briefing could be more detailed and the BAT had less verbal work to perform. The employer may provide the information in this fashion, though the regulation will not require it. Other comments were few and supportive. The NPRM provisions have been retained. Some provisions of this NPRM section, concerning filling out of forms and refused or incomplete tests, have been moved to the next section.

Initial Breath Test Procedures

The NPRM proposed to require an air blank before and after the screening test, which the machine had to pass in order to stay in service. The NPRM also included proposed requirements concerning completing the test paperwork.

Fifteen commenters addressed the issue of air blanks. Seven commenters agreed with the NPRM that air blanks should be required before and after each screening test. Two said that air blanks are not technically relevant with some types of EBTs. Six commenters said that an air blank should not be required after a test when the result was less than 0.02, as this was a waste of time. Some of these commenters favored pre-test air blanks, however. One commenter supported only pre-test air blanks.

The Department has decided that it will not require air blanks either before or after a screening test. First, most screening test results will be below 0.02, making post-test air blanks of limited value in those cases. Second, pre-test air blanks, at the screening stage, are not crucial in preventing "false positives" for employees, since no action against an employee may be taken without a confirmation test. Third, the Department will require air blanks before confirmation tests, which will build this protection into the testing process where it matters most. Fourth, the Department is permitting all EBTs on the NHTSA CPL to be used in screening tests, and some of these instruments would not provide any durable record of an air blank, even if they were able to perform air blanks. Finally, the absence of a requirement for air blanks on the more frequent screening tests will result in some cumulative savings of BAT and employee time and wear on the machines.

The NPRM called for a 15–20 minute waiting period before the confirmation test; no such waiting period was proposed for before the screening test. Seven commenters favored a waiting period before the screening test, eight opposed it, and two favored employer discretion. Because the confirmation testing procedures do provide for a waiting period, and since action against an employee can be taken only on the basis of a confirmation test, we believe that requiring an additional waiting period before the screening test would be superfluous.

The NPRM provision addressed situations in which the printed and displayed results did not match, proposing that such tests would be invalid. The final rule modifies this provision, since it is irrelevant concerning instruments that do not print out a result. The NPRM provision remains in effect for EBTs that do print out.

The additional flexibility the Department has provided in screening testing procedures, by permitting the use of EBTs that do not have sequential numbering and result printing capabilities, makes it more difficult to determine that a test of a particular employee, with a particular result, has taken place, raising the possibility of cheating by employers. To mitigate this potential problem, the final rule will require a log book to be kept with each EBT used for screening that does not have the sequential numbering and printout capabilities. (This requirement does not apply to EBTs meeting the requirements for devices used for confirmation testing.) The BAT will fill out a log book entry for each test in addition to completing the alcohol testing form. The log book entries are intended to serve as a cross-check on the performance and result of a test.

There were several comments both to this section and the next section concerning whether the cutoff level for a test to which consequences for the employee would attach should be 0.02, 0.04, or, as the NPRM proposed, a bifurcated 0.02/0.04 standard, with different consequences at each level. The rule takes the latter approach, for reasons discussed in the common preamble to the OA rules.

The employee is told to sign the form after the test has been taken. If the employee does not do so, it is not regarded as a refusal to take the test. Obviously, it would be silly to regard as a refusal to take the test a refusal to sign the form after the test had already been successfully conducted. In this situation, the BAT is required to not the failure to sign in the remarks section of the form.

Confirmation Breath Test Procedures

The NPRM instructed the BAT to tell the employee to avoid eating, drinking, etc. during a 15–20 minute interval between the screening and confirmation test, though the test would continue even if the employee did not follow the directions. The BAT would also give the employee a notice not to drive or perform other safety-sensitive functions if the employee's alcohol concentration were 0.04 or greater. After performing the same steps as with the screening test, the BAT would note the alcohol concentration reading and transmit the results to the employer in a confidential manner. The lower of the two readings—screening and confirmation—would control the result.

There were 29 comments concerning the waiting period before the confirmation test, fifteen of which supported the 15-minute minimum time proposed in the NPRM. Four comments wanted a shorter interval (e.g., two or five minutes) and four supported a longer interval (e.g., 20 or 30 minutes). Two comments opposed any requirement concerning an interval. Six comments either wanted no maximum waiting time or preferred to rely on the employer's or EBT manufacturer's discretion.

The waiting period is important. It is intended to give the employee the opportunity to ensure that any residual mouth alcohol does not influence the result of the confirmation test. According to the Department's information, fifteen minutes is the minimum period after which one can be confident that any residual mouth alcohol has disappeared. A shorter interval is not feasible for this reason. At the same time, waiting a long period between tests can be costly in terms of lost employee time and could influence the outcome of the confirmation test. In order to guard against lengthy delays in the performance of confirmation tests, which can allow alcohol concentration levels to fall, the final rule retains the 20-minute maximum. It should be pointed out that failing to observe the minimum 15-minute period is a "fatal flaw" (see § 40.79 (a)), automatically invalidating a test. This is because the Department believes it is important to prevent artificially high readings due to mouth alcohol residue. However, taking longer than 20 minutes between tests is not a "fatal flaw." The Department is aware that circumstances may sometimes result in stretching the time between tests for a few additional minutes.

Another issue addressed by commenters in a variety of ways was that of whether the screening or confirmation test result prevails when one is higher than the other. Eighteen commenters believed that the confirmation test should prevail in all cases. Two commenters supported using the higher of the two results, while three supported using the lower of the two results. The Department believes that it is more understandable, and less potentially confusing, for the confirmation test result to determine the outcome of the test. The confirmation test will always have to be performed using the most reliable methods. Also, alcohol concentration can still be rising at the time of the screening test. Although it is also possible for alcohol concentration to have dropped since the screening test, the Department's requirement for the confirmation test to be conducted a short time after the screening test should minimize any problem. Finally, this approach is consistent with that the Department takes in drug testing. Consequently, in situations in which a confirmation test is needed, the final rule will attach consequences only to the confirmation test result.

Nine commenters asked that the final rule, unlike the NPRM, provide for medical review officer (MRO) review of the confirmation test result, as the Department requires in drug testing. Among their reasons were that there could be valid medical or food-related reasons for alcohol concentrations, that there could be inadvertent alcohol consumption, that someone should review results for procedural errors, that an MRO should play the role assigned to the substance abuse professional (SAP) by the proposed rules, or that the alcohol rules should mirror the drug rules as much as possible.

In the drug testing context, an MRO determines whether there is a legitimate medical explanation for an individual having in his or her system a substance which is otherwise illegal. The alcohol rules are different in this respect. They prohibit safety sensitive employees from having alcohol concentrations above certain levels, regardless of the source of the alcohol. An alcohol concentration of 0.04 resulting from drinking beverage alcohol has the same consequences under the rules as an alcohol concentration of 0.04 resulting from ingesting medication. Both uses of alcohol are legal (as long as they do not violate OA rules concerning on-duty use, pre-duty abstinence, etc.); the resulting alcohol concentration is prohibited by DOT regulations equally in both cases. In this context, there is nothing for an MRO to decide. Inserting an MRO into the process without this key function would add to the complexity and cost of the system without providing any benefits. For these reasons, the Department will not require MRO review of alcohol testing results.

The NPRM proposed that employers could use the same EBT for both the screening and confirmation tests. Fifteen commenters objected to this proposal. Some said that an entirely different methodology should be used for the two tests. The legal issues section of the preamble discusses this point. Others said that a different EBT should be used for each test, some making the argument that using the same machine for both tests constituted "repetition," but not "confirmation." This semantic argument is not persuasive. The statute does not require different machines to be used, as long as the machine used for the second test meets statutory requirements. (Of course, where an employer chooses to use a preliminary EBT for the screening device, it will necessarily use two different machines.) Because of the reliability of EBTs meeting the requirements of this rule, we believe it would be unnecessarily expensive to require a second device to be used, which could have the effect of roughly doubling the capital equipment costs of the program.

Twelve of thirteen commenters opposed requiring a second confirmation test after the first confirmation test had been positive, a matter about which the NPRM preamble asked a question. The Department does not see a basis for requiring a second confirmation test, and we are not adding this requirement to the final rule.

A few commenters suggested getting rid of the requirement for the BAT to notify someone testing positive that he or she should not drive. The Department has decided to include a notice to this effect on the alcohol testing form, making direct participation by the BAT unnecessary.

Two commenters suggested that the rule be clarified to indicate that an employer could have more than one representative to whom results are transmitted. The Department has done so.

Two comments supported, and two opposed, the practice of back extrapolation to obtain a result. The Department's NPRMs proposed that the consequences of test results attach only to employees whose EBT readings were in fact at the stated levels. The Department did not propose to attach these consequences to inferences from EBT readings about what an employee's alcohol concentration might have been at an earlier point. For example, if an employee's EBT test result were .03, the requirement that the individual not again perform safety-sensitive functions until he or she was evaluated by a substance abuse professional (SAP) and had passed a return-to-duty test, and the requirement that the individual be subject to follow-up testing, would not apply because the employer, SAP, or other party believed that the individual's alcohol concentration had been 0.04 or greater prior to the test. Given the wide individual variations in alcohol metabolism among individuals, such inferences involve considerable uncertainty. The Department is retaining the NPRM provision on this point. This would not prevent an OA from making use of back extrapolation in certain situations (e.g., FRA makes some use of back extrapolation in its existing toxicological testing program, in a context involving the use of samples of two different body fluids; inquiries into accident causation or proceedings to revoke DOT-issued certificates or licenses held by employees, where expert testimony can be produced with the protection of the due process procedures of a hearing). These situations are different from the use of back extrapolation by employers in interpreting the results of tests conducted under part 40, however.

There will be some cases in which the BAT who conducts the screening test and the BAT who conducts the confirmation test are different people. For example, BAT #1 conducts a screening test, using an EBT not having sequential numbering or printout capabilities, in location A. The confirmation test, using a device that has these features, happens subsequently in location B, and is conducted by BAT #2. In such a case, to minimize the possibility of lost forms or other errors, the final rule provides that BAT #1 would complete the form for the screening test and give the employee his or her copy of the form. BAT #2 would then start a new form. The sections of the rule concerning screening and confirmation testing procedures have been modified to this effect.

Refused and Incomplete Tests

The final rule, in § 40.67, picks up paragraphs from the NPRM that do not fit conveniently in other sections. The first provides that employee refusals to take certain actions (e.g., complete and sign Step 2 of the form, provide breath) constitute a refusal to be tested. Such refusals, under the operating administration rules, have the same consequences as a test result of 0.04 or greater. The NPRM provision on which this paragraph is based was not the subject of comment. The second paragraph provides that if a test cannot be completed, or an event occurs that would invalidate the test, the BAT would, if practicable, run a retest. All seventeen comments on the subject favored this approach, and the Department is including it in the final rule.

Inability to Provide Sufficient Breath

The NPRM proposed that if an employee were unable to provide enough breath for an adequate sample, the BAT would ask the employee to try again. If the same result occurred, then the employee would be referred to a doctor for a medical evaluation. If the doctor determined that the inability to provide breath was due, or probably due, to a medical condition, the failure to provide the sample would be excused. If not, it would be treated as a refusal.

Four comments supported the NPRM provision. Three others thought that this situation was unlikely to arise, since only an employee who was seriously disabled, unconscious, or dead would be unable to provide the modest quantity of breath required to complete a test. We agree that this situation should not occur frequently, but we believe it is sensible to have a procedure in place to handle the occasional occurrence.

Nine commenters suggested that, if the employee cannot provide sufficient breath, the employee should be required to provide a sample of a body fluid (e.g., blood, urine). Two comments urged employer discretion in these cases. Ten commenters said that there should be a medical evaluation in all cases where an employee cannot produce sufficient breath, though these commenters disagreed with each other about whether the employee should be held out of safety-sensitive functions pending the result of the evaluation.

Under the final rule, the employer is required to direct the employee to be medically evaluated in "shy lung" cases. The final rule directs the employer to ensure that this evaluation occurs as soon as possible. Employers, under their own authority, could choose to "stand down" an employee pending the result of a medical evaluation, but the rule does not require this step.

In addition, the accompanying NPRM proposes that blood testing may be used in post-accident and reasonable suspicion testing when an EBT is not readily available. Since blood testing, and procedures for it, may become part of the rule for these purposes, the Department is responding to these comments by proposing blood testing as an option (regardless of the type of testing involved) when an employee cannot provide a sufficient breath sample. If the NPRM's proposal is made part of a final rule, the employer would have discretion concerning which alternative (blood alcohol testing or a medical evaluation) to select. Persons interested in this issue are asked to comment to the NPRM docket.

Invalid Tests

The original NPRM listed nine "fatal flaws" that would invalidate breath tests. An invalid test is neither positive nor negative, and it has no consequences for an employee. The NPRM being published today proposes a similar list of fatal flaws for blood tests.

The NPRM proposed that failure to observe the 15-minute minimum waiting period before the confirmation test would be a fatal flaw; going over the 20-minute maximum would not. Comments generally agreed with this approach, some noting that if exceeding a maximum waiting time were to be a fatal flaw, the outer limit should be 30 or 60 minutes rather than 20. One commenter opposed making observance of the minimum a fatal flaw. The Department is retaining the NPRM provision on this point.

The Department is changing the provision concerning air blanks to reflect the final rule's requirement of an air blank before only the confirmation test. Likewise, the NPRM provision making the device's failure to print out a result a fatal flaw has been changed to apply only to confirmation tests. The provision on disagreement between the printout and the machine display concerning sequential test numbers or alcohol concentration has been modified for the same reason. If the employee fails to sign Step 4 of the form, that is not a fatal flaw; the BAT's failure to note the employee's failure to sign that portion of the form would be a fatal flaw, however.

The NPRM proposed that if an EBT fails an external calibration check, every test performed on the device since the

last valid external calibration test would be invalidated. Ten commenters opposed this provision, pointing out that it would cause numerous problems for employers if they had to invalidate tests after the fact, and perhaps had to reverse personnel actions as well. Four commenters supported the proposed requirement. The Department is well aware that after-the-fact invalidations of tests can create serious problems for employers. The Department does not see a workable alternative, however. If a valid external calibration check was performed after test A, and an invalid external calibration test was performed after test K, all we know for certain is that the machine went out of kilter somewhere between tests B and K. We cannot say for certain that test B or C was valid, or assume that the error occurred only on test K. Since we cannot determine that these tests were valid, we must, in fairness to the employees involved, treat them as invalid. Tests with results of 0.02 and above would be deemed invalid in this situation. This is surely incentive for employers to conduct frequent external calibration checks, particularly after positive tests.

One commenter suggested additional fatal flaws, such as failure to use a clean mouthpiece, inadequate grounds for reasonable suspicion, etc. One commenter suggested that all flaws should be regarded as fatal. The Department believes that only certain serious problems in the process, that directly affect the integrity of the test or accuracy of the result, should automatically invalidate the test. Other errors, particularly in combination with one another, could form the basis for a determination that a test is invalid (i.e., the listed fatal flaws are not intended to be the only possible grounds for invalidation). The Office of Drug Enforcement and Program Compliance is charged with providing, on behalf of the Department, definitive guidance on issues concerning the invalidation of tests.

Availability of Testing Information

The NPRM proposed provisions on alcohol test information availability parallel to the existing provisions on the availability of drug testing information, as the Department has interpreted them. Employers could release information to a third party only with the specific written consent of the employee, must keep confidential information secure, but may make the information available in certain litigation situations. Employers must make information available to DOT or, under some circumstances, to the National Transportation Safety Board (NTSB). Employers must also make information about an employee's test available to that employee.

Seven commenters, most of whom were from the motor carrier industry, asked that employers be authorized or required to make testing information available to third parties without the employee's consent. In this industry, the commenters said, there was a high turnover rate. Employees move rapidly from employer to employer. In the absence of authorization or requirement for a former employer to provide testing information to a potential new employer, either the hiring process would be slowed or important information about positive tests in the employee's past would be unavailable to the new employer.

In response, the Department points out that an employer may, without authorization from DOT, require an applicant, as a condition of employment, to give written consent to the disclosure of this information by a former employer. The Department is adding a sentence to this provision of the rule telling employers that they must provide the information when the employee consents to its transmission to a third party. However, in order to maintain the confidentiality of sensitive information, in which employees have a significant privacy interest, the Department will not authorize the transmission of this information among employers or potential employers without written employee consent.

The Department emphasizes that the consent involved must be a specific written consent for information to be sent from one named party to another named party. Blanket consents (i.e., a consent for testing information to be sent to all present or future employers or members of a consortium) are not permitted. Each consent must pertain to one specific employer providing the information about a particular employee to another specific employer.

Two commenters suggested that an employee should not have to pay for obtaining information in his or her own file concerning alcohol tests. The Department believes that this is a matter better left to employer-employee agreements. As the Department interprets this provision, employers may impose reasonable charges to cover the cost of retrieval, copying, and transmission of the records requested. The employer is also expected only to provide copies within its possession or control (including documents that may be maintained by a consortium or third-party provider that conducted testing for the employer).

Records Concerning BATs and EBTs

The NPRM proposed that the employer maintain various records concerning EBTs and BATs for five years. One commenter suggested that consortia and third-party providers be authorized to keep the records instead of the employer. The Department agrees that this is reasonable, and the final rule requires the employer or its agent to maintain the records. The employer retains ultimate responsibility for producing the records, however. Two commenters suggested we reduce the record retention period to two years, while one commenter said that the recordkeeping requirements in the NPRM were not burdensome. Consistent with the OA rules, the final part 40 rule establishes a 5-year retention period for calibration records and a two-year retention period for other records.

Other Issues

A number of commenters asked that we modify the definition of alcohol to include alcohols other than ethanol (e.g., methanol, isopropanol), in order to avoid loopholes in the program that would allow an employee to claim that his or her alcohol concentration reading was the result of ingesting a non-ethanol substance. The Department agrees that the definition should be broadened to avoid any potential problems with the use of non-ethanol alcohols, and the final rule includes a modified definition to this effect. This revised definition is consistent with that used by NHTSA in its model specifications for evidential EBTs. We have also added a companion definition of alcohol use, which emphasizes that any consumption of a preparation including alcohol (e.g., beverages, medicines) counts as alcohol use.

A few commenters asked that, for convenience, we centralize all the definitions in part 40 in one section. We have done so, and all the definitions are now in § 40.3.

The NPRM preamble asked for suggestions on how to deal with situations in which an arbitrator overturns an employer's personnel action based on an alcohol test result. Employers had expressed concern about perceived conflicts between the arbitrator's decisions and DOT regulations, and several commenters echoed these concerns. The Department is not convinced, however, that this problem is either frequent enough or serious enough to warrant a mandate in the regulatory text. Such a mandate, because it could not anticipate all the nuances of the factual situations involved, might interfere with

reasonable resolutions of particular disputes.

However, it is clear that employers are obligated to comply with DOT safety regulations, which have the force and effect of law. As a matter of law, no decision by an employer, employee organization, or individual or group appointed by those or other parties, can have the effect of excusing noncompliance by an employer with a provision of a DOT safety regulation. If a violation of DOT rules has occurred, then the consequences prescribed by DOT rules must follow (e.g., the employee must be removed from performing a safety-sensitive function).

In the NPRM preamble, the Department included a discussion of handling of perceived conflicts between part 40 and operating administration regulations, exemptions, and the obligations of consortia and third-party providers (57 FR 59410; December 15, 1992). This discussion applies to the implementation of the final part 40 as well. The relevant language is reprinted below:

> Although implementation of part 40 generally would be done through an operating administration, part 40 is an Office of the Secretary of Transportation (OST) regulation. As such, requests for exemption would be processed under 49 CFR part 5, an existing regulation covering requests for exemption from or amendment to all OST rules, rather than through separate operating administration exemption procedures. This would add an additional element of consistency. This approach is consistent with the existing part 40 drug testing procedures, from which exemptions would also be granted under part 40. (See 54 FR 49863; December 1, 1989).
>
> The grant of an exemption under part 40 must be based on special or exceptional circumstances. It is not appropriate to carve out a generally applicable exception to a rule. Also, an exemption must be based on circumstances not contemplated as part of the rulemaking. The exemption process is not designed to revisit issues settled in the rulemaking process.
>
> Section 40.1 would also emphasize that other parties involved in the testing process—such as consortia, contractors, and agents—"stand in the shoes" of the employer. They are, therefore, subject to the same obligations and requirements as the employer. If an employer is required to-do something, so is the consortium that is conducting testing for the employer. If the consortium fails to do something correctly, the employer is in noncompliance.

Since, as noted above, part 40 is a regulation of the Office of the Secretary of Transportation, the source of definitive interpretations of the rule is the Office of the Secretary. Interpretations have been and will continue to be made in close coordination among the OAs, the Office of Drug Enforcement and Program Compliance (DEPC), and the Office of General Counsel.

Regulatory Analyses and Notices

Because of substantial public interest and substantial impacts on a wide range of private and public sector organizations, the Department has determined that this rule—in conjunction with the operating administration alcohol and drug testing rules—is significant under Executive Order 12866. The rule has been reviewed under this Order. It is also significant under the Department's regulatory policies and procedures. The Department has prepared a regulatory evaluation for part 40, which we have included in the docket. The costs of the application of part 40 procedures to the programs of the various OAs are estimated in each of the OAs' regulatory evaluations for their drug and alcohol rules being published today.

This rule, in conjunction with the operating administration drug and alcohol testing rules, is likely to have a significant economic impact on a substantial number of small entities. These impacts are assessed in the OAs' regulatory evaluations. The Federalism impacts of this rule are either minimal or required by statute; for these reasons, we have not prepared a Federalism assessment.

This rule also contains collection of information requirements. The Department has submitted these requirements to the Office of Management and Budget for review and approval under the Paperwork Reduction Act (44 U.S.C. 350, *et. seq.*). Please see the Common Preamble on the status of Paperwork Reduction Act approvals.

List of Subjects in 49 CFR Part 40

Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

Issued This 25th day of January, 1994, at Washington, D.C.

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Secretary of Transportation.
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Acting Administrator, Research and Special Programs Administration.
Adm. J. William Kime,
Commandant, United States Coast Guard.

For the reasons set forth in the preamble, the Department of Transportation amends Title 49, Code of Federal Regulations, part 40, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

1. The authority citation for Part 40 is revised to read as follows:

Authority: 49 U.S.C. 102,301,322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

2. §§ 40.1 through 40.19 are designated as subpart A and revised to read as follows:

Subpart A—General

Subpart A—GENERAL

§ 40.1 Applicability.

This part applies, through regulations that reference it issued by agencies of the Department of Transportation, to transportation employers, including self-employed individuals, required to conduct drug and/or alcohol testing programs by DOT agency regulations and to such transportation employers' officers, employees, agents and contractors (including, but not limited to, consortia). Employers are responsible for the compliance of their officers, employees, agents, consortia and/or contractors with the requirements of this part.

§ 40.3 Definitions.

The following definitions apply to this part:

Air blank. A reading by an EBT of ambient air containing no alcohol. (In

EBTs using gas chromatography technology, a reading of the device's internal standard.)

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol use. The consumption of any beverage, mixture or preparation, including any medication, containing alcohol.

Aliquot. A portion of a specimen used for testing.

Blind sample or blind performance test specimen. A urine specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from employee specimens, and which is spiked with known quantities of specific drugs or which is blank, containing no drugs.

Breath Alcohol Technician (BAT). An individual who instructs and assists individuals in the alcohol testing process and operates an EBT.

Canceled or invalid test. In drug testing, a drug test that has been declared invalid by a Medical Review Officer. A canceled test is neither a positive nor a negative test. For purposes of this part, a sample that has been rejected for testing by a laboratory is treated the same as a canceled test. In alcohol testing, a test that is deemed to be invalid under § 40.79. It is neither a positive nor a negative test.

Chain of custody. Procedures to account for the integrity of each urine or blood specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. With respect to drug testing, these procedures shall require that an appropriate drug testing custody form (see § 40.23(a)) be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account(s) for the sample or sample aliquots within the laboratory.

Collection container. A container into which the employee urinates to provide the urine sample used for a drug test.

Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes a screening examination of the urine specimen provided by those individuals.

Confirmation (or confirmatory) test. In drug testing, a second analytical procedure to identify the presence of a specific drug or metabolite that is independent of the screening test and that uses a different technique and chemical principle from that of the screening test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.) In alcohol testing, a second test, following a screening test with a result of 0.02 or greater, that provides quantitative data of alcohol concentration.

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency of the United States Department of Transportation administering regulations related to drug or alcohol testing, including the United States Coast Guard (for drug testing purposes only), the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Federal Transit Administration, the Research and Special Programs Administration, and the Office of the Secretary.

Employee. An individual designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. As used in this part "employee" includes an applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, *employer* includes an industry consortium or joint enterprise comprised of two or more employing entities.

EBT (or evidential breath testing device). An EBT approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath and placed on NHTSA's "Conforming Products List of Evidential Breath Measurement Devices" (CPL).

Medical Review Officer (MRO). A licensed physician (medical doctor or doctor of osteopathy) responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's confirmed positive test result together with his or her medical history and any other relevant biomedical information.

Screening test (or initial test). In drug testing, an immunoassay screen to eliminate "negative" urine specimens from further analysis. In alcohol testing, an analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath specimen.

Secretary. The Secretary of Transportation or the Secretary's designee.

Shipping container. A container capable of being secured with a tamper-evident seal that is used for transfer of one or more urine specimen bottle(s) and associated documentation from the collection site to the laboratory.

Specimen bottle. The bottle that, after being labeled and sealed according to the procedures in this part, is used to transmit a urine sample to the laboratory.

§§ 40.5—40.19 [Reserved]

2. §§ 40.21 through 40.39 are designated subpart B.

Subpart B—Drug Testing

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

3. In § 40.25, paragraph (f)(10) is revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(f) * * *

(10) The collection site person shall instruct the employee to provide at least 45 ml of urine under the split sample method of collection or 30 ml of urine under the single sample method of collection.

(i)(A) Employers with employees subject to drug testing only under the drug testing rules of the Research and Special Programs Administration and/or Coast Guard may use the "split sample" method of collection or may collect a single sample for those employees.

(B) Employers with employees subject to drug testing under the drug testing rules of the Federal Highway Administration, Federal Railroad

Administration, Federal Transit Administration, or Federal Aviation Administration shall use the "split sample" method of collection for those employees.

(ii) Employers using the split sample method of collection shall follow the procedures in this paragraph (f)(10)(ii):

(A) The donor shall urinate into a collection container or a specimen bottle capable of holding at least 60 ml.

(B) If a collection container is used, the collection site person, in the presence of the donor, pours the urine into two specimen bottles. Thirty (30) ml shall be poured into one bottle, to be used as the primary specimen. At least 15 ml shall be poured into the other bottle, to be used as the split specimen.

(C) If a single specimen bottle is used as a collection container, the collection site person shall pour 30 ml of urine from the specimen bottle into a second specimen bottle (to be used as the primary specimen) and retain the remainder (at least 15 ml) in the collection bottle (to be used as the split specimen).

(D) Both bottles shall be shipped in a single shipping container, together with copies 1,2, and the split specimen copy of the chain of custody form, to the laboratory.

(E) If the test result of the primary specimen is positive, the employee may request that the MRO direct that the split specimen be tested in a different DHHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the primary specimen. The MRO shall honor such a request if it is made within 72 hours of the employee having been notified of a verified positive test result.

(F) When the MRO informs the laboratory in writing that the employee has requested a test of the split specimen, the laboratory shall forward, to a different DHHS-approved laboratory, the split specimen bottle, with seal intact, a copy of the MRO request, and the split specimen copy of the chain of custody form with appropriate chain of custody entries.

(G) The result of the test of the split specimen is transmitted by the second laboratory to the MRO.

(H) Action required by DOT agency regulations as the result of a positive drug test (e.g., removal from performing a safety-sensitive function) is not stayed pending the result of the test of the split specimen.

(I) If the result of the test of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, the MRO shall cancel the test, and report the cancellation and the reasons for it to the DOT, the employer, and the employee.

(iii) Employers using the single sample collection method shall follow the procedures in paragraph:

(A) The collector may choose to direct the employee to urinate either directly into a specimen bottle or into a separate collection container.

(B) If a separate collection container is used, the collection site person shall pour at least 30 ml of the urine from the collection container into the specimen bottle in the presence of the employee.

(iv) In either collection methodology, upon receiving the specimen from the individual, the collection site person shall determine if it has at least 30 milliliters of urine for the primary or single specimen bottle and, where the split specimen collection method is used, an additional 15 ml of urine for the split specimen bottle. If the individual is unable to provide such a quantity of urine, the collection site person shall instruct the individual to drink not more than 24 ounces of fluids and, after a period of up to two hours, again attempt to provide a complete sample using a fresh collection container. The original insufficient specimen shall be discarded. If the employee is still unable to provide an adequate specimen, the insufficient specimen shall be discarded, testing discontinued, and the employer so notified. The MRO shall refer the individual for a medical evaluation to develop pertinent information concerning whether the individual's inability to provide a specimen is genuine or constitutes a refusal to test. (In preemployment testing, if the employer does not wish to hire the individual, the MRO is not required to make such a referral.) Upon completion of the examination, the MRO shall report his or her conclusions to the employer in writing.

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4. In § 40.29, paragraph (b)(2) is revised and paragraph (b)(3) is added, as follows:

§ 40.29 Laboratory analysis procedures.

* * * * *

(b) * * * *

(2) In situations where the employer uses the split sample collection method, the laboratory shall log in the split specimen, with the split specimen bottle seal remaining intact. The laboratory shall store this sample securely (see paragraph (c) of this section). If the result of the test of the primary specimen is negative, the laboratory may discard the split specimen. If the result of the test of the primary specimen is positive, the laboratory shall retain the split specimen in frozen storage for 60 days from the date on which the laboratory acquires it (see paragraph (h) of this section). Following the end of the 60-day period, if not informed by the MRO that the employee has requested a test of the split specimen, the laboratory may discard the split specimen.

(3) When directed in writing by the MRO to forward the split specimen to another DHHS-certified laboratory for analysis, the second laboratory shall analyze the split specimen by GC/MS to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen. Such GC/MS confirmation shall be conducted without regard to the cutoff levels of § 40.29(f). The split specimen shall be retained in long-term storage for one year by the laboratory conducting the analysis of the split specimen (or longer if litigation concerning the test is pending).

* * * * *

6. In § 40.33 paragraphs (e), (f) and (g) are revised; paragraph (h) is redesignated as paragraphs (i), and a new paragraph (h) is added, as follows:

§ 40.33 Reporting and review of results.

* * * * *

(e) In a situation in which the employer has used the single sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a reanalysis of the original specimen, if the test is verified positive. If requested to do so by the employee within 72 hours of the employee's having been informed of a verified positive test, the Medical Review Officer shall direct, in writing, a reanalysis of the original sample. The MRO may also direct, in writing, such a reanalysis if the MRO questions the accuracy or validity of any test result. Only the MRO may authorize such a reanalysis, and such a reanalysis may take place only at laboratories certified by DHHS. If the reanalysis fails to reconfirm the presence of the drug or drug metabolite, the MRO shall cancel the test and report the cancellation and the reasons for it to the DOT, the employer and the employee.

(f) In situations in which the employer uses the split sample method of collection, the MRO shall notify each employee who has a confirmed positive test that the employee has 72 hours in which to request a test of the split specimen, if the test is verified as positive. If the employee requests an analysis of the split specimen within 72 hours of having been informed of a verified positive test, the MRO shall

direct, in writing, the laboratory to provide the split specimen to another DHHS-certified laboratory for analysis. If the analysis of the split specimen fails to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen, or if the split specimen is unavailable, inadequate for testing or untestable, the MRO shall cancel the test and report cancellation and the reasons for it to the DOT, the employer, and the employee.

(g) If an employee has not contacted the MRO within 72 hours, as provided in paragraphs (e) and (f) of this section, the employee may present to the MRO information documenting that serious illness, injury, inability to contact the MRO, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the MRO. If the MRO concludes that there is a legitimate explanation for the employee's failure to contact the MRO within 72 hours, the MRO shall direct that the reanalysis of the primary specimen or analysis of the split specimen, as applicable, be performed.

(h) When the employer uses the split sample method of collection, the employee is not authorized to request a reanalysis of the primary specimen as provided in paragraph (e) of this section.

* * * * *

7. A new subpart C is added to part 40, to read as follows:

Subpart C—Alcohol Testing

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

§ 40.51 The breath alcohol technician.

(a) The breath alcohol technician (BAT) shall be trained to proficiency in the operation of the EBT he or she is using and in the alcohol testing procedures of this part.

(1) Proficiency shall be demonstrated by successful completion of a course of instruction which, at a minimum, provides training in the principles of EBT methodology, operation, and calibration checks; the fundamentals of breath analysis for alcohol content; and the procedures required in this part for obtaining a breath sample, and interpreting and recording EBT results.

(2) Only courses of instruction for operation of EBTs that are equivalent to the Department of Transportation model course, as determined by the National Highway Traffic Safety Administration (NHTSA), may be used to train BATs to proficiency. On request, NHTSA will review a BAT instruction course for equivalency.

(3) The course of instruction shall provide documentation that the BAT has demonstrated competence in the operation of the specific EBT(s) he/she will use.

(4) Any BAT who will perform an external calibration check of an EBT shall be trained to proficiency in conducting the check on the particular model of EBT, to include practical experience and demonstrated competence in preparing the breath alcohol simulator or alcohol standard, and in maintenance and calibration of the EBT.

(5) The BAT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that he or she will use.

(6) The employer or its agent shall establish documentation of the training and proficiency test of each BAT it uses to test employees, and maintain the documentation as provided in § 40.83.

(b) A BAT-qualified supervisor of an employee may conduct the alcohol test for that employee only if another BAT is unavailable to perform the test in a timely manner. A supervisor shall not serve as a BAT for the employee in any circumstance prohibited by a DOT operating administration regulation.

(c) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. In order for a test conducted by such an officer to be accepted under Department of Transportation alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT that was used for the test.

§ 40.53 Devices to be used for breath alcohol tests.

(a) For screening tests, employers shall use only EBTs. When the employer uses for a screening test an EBT that does not meet the requirements of paragraphs (b) (1) through (3) of this section, the employer shall use a log book in conjunction with the EBT (see § 40.59(c)).

(b) For confirmation tests, employers shall use EBTs that meet the following requirements:

(1) EBTs shall have the capability of providing, independently or by direct link to a separate printer, a printed result in triplicate (or three consecutive identical copies) of each breath test and of the operations specified in paragraphs (b) (2) and (3) of this section.

(2) EBTs shall be capable of assigning a unique and sequential number to each completed test, with the number capable of being read by the BAT and the employee before each test and being printed out on each copy of the result.

(3) EBTs shall be capable of printing out, on each copy of the result, the manufacturer's name for the device, the device's serial number, and the time of the test.

(4) EBTs shall be able to distinguish alcohol from acetone at the 0.02 alcohol concentration level.

(5) EBTs shall be capable of the following operations:

(i) Testing an air blank prior to each collection of breath; and

(ii) Performing an external calibration check.

§ 40.55 Quality assurance plans for EBTs.

(a) In order to be used in either screening or confirmation alcohol testing subject to this part, an EBT shall have a quality assurance plan (QAP) developed by the manufacturer.

(1) The plan shall designate the method or methods to be used to perform external calibration checks of the device, using only calibration devices on the NHTSA "Conforming Products List of Calibrating Units for Breath Alcohol Tests."

(2) The plan shall specify the minimum intervals for performing external calibration checks of the device. Intervals shall be specified for different frequencies of use, environmental conditions (*e.g.*, temperature, altitude, humidity), and contexts of operation (*e.g.*, stationary or mobile use).

(3) The plan shall specify the tolerances on an external calibration check within which the EBT is regarded to be in proper calibration.

(4) The plan shall specify inspection, maintenance, and calibration

requirements and intervals for the device.

(5) For a plan to be regarded as valid, the manufacturer shall have submitted the plan to NHTSA for review and have received NHTSA approval of the plan.

(b) The employer shall comply with the NHTSA-approved quality assurance plan for each EBT it uses for alcohol screening or confirmation testing subject to this part.

(1) The employer shall ensure that external calibration checks of each EBT are performed as provided in the QAP.

(2) The employer shall take an EBT out of service if any external calibration check results in a reading outside the tolerances for the EBT set forth in the QAP. The EBT shall not again be used for alcohol testing under this part until it has been serviced and has had an external calibration check resulting in a reading within the tolerances for the EBT.

(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.

(4) The employer shall maintain records of the external calibration checks of EBTs as provided in § 40.83.

(c) When the employer is not using the EBT at an alcohol testing site, the employer shall store the EBT in a secure space.

§ 40.57 Locations for breath alcohol testing.

(a) Each employer shall conduct alcohol testing in a location that affords visual and aural privacy to the individual being tested, sufficient to prevent unauthorized persons from seeing or hearing test results. All necessary equipment, personnel, and materials for breath testing shall be provided at the location where testing is conducted.

(b) An employer may use a mobile collection facility (*e.g.*, a van equipped for alcohol testing) that meets the requirements of paragraph (a) of this section.

(c) No unauthorized persons shall be permitted access to the testing location when the EBT remains unsecured or, in order to prevent such persons from seeing or hearing a testing result, at any time when testing is being conducted.

(d) In unusual circumstances (*e.g.*, when it is essential to conduct a test outdoors at the scene of an accident), a test may be conducted at a location that does not fully meet the requirements of paragraph (a) of this section. In such a case, the employer or BAT shall provide visual and aural privacy to the employee to the greatest extent practicable.

(e) The BAT shall supervise only one employee's use of the EBT at a time. The BAT shall not leave the alcohol testing location while the testing procedure for a given employee (see §§ 40.61 through 40.65) is in progress.

§ 40.59 The breath alcohol testing form and log book.

(a) Each employer shall use the breath alcohol testing form prescribed under this part. The form is found in appendix A to this subpart. Employers may not modify or revise this form, except that a form directly generated by an EBT may omit the space for affixing a separate printed result to the form.

(b) The form shall provide triplicate (or three consecutive identical) copies. Copy 1 (white) shall be retained by the BAT. Copy 2 (green) shall be provided to the employee. Copy 3 (blue) shall be transmitted to the employer. Except for a form generated by an EBT, the form shall be 8½ by 11 inches in size.

(c) A log book shall be used in conjunction with any EBT used for screening tests that does not meet the requirements of § 40.53(b) (1) through (3). There shall be a log book for each such device, that is not used in conjunction with any other device and that is used to record every test conducted on the device. The log book shall include columns for the test number, date of the test, name of the BAT, location of the test, quantified test result, and initials of the employee taking each test.

§ 40.61 Preparation for breath alcohol testing.

(a) When the employee enters the alcohol testing location, the BAT will require him or her to provide positive identification (*e.g.*, through use of a photo I.D. card or identification by an employer representative). On request by the employee, the BAT shall provide positive identification to the employee.

(b) The BAT shall explain the testing procedure to the employee.

§ 40.63 Procedures for screening tests.

(a) The BAT shall complete Step 1 on the Breath Alcohol Testing Form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test.

(b) An individually-sealed mouthpiece shall be opened in view of the employee and BAT and attached to the EBT in accordance with the manufacturer's instructions.

(c) The BAT shall instruct the employee to blow forcefully into the mouthpiece for at least 6 seconds or until the EBT indicates that an adequate amount of breath has been obtained.

(d)(1) If the EBT does not meet the requirements of § 40.53(b)(1) through (3), the BAT and the employee shall take the following steps:

(i) Show the employee the result displayed on the EBT. The BAT shall record the displayed result, test number, testing device, serial number of the testing device, time and quantified result in Step 3 of the form.

(ii) Record the test number, date of the test, name of the BAT, location, and quantified test result in the log book. The employee shall initial the log book entry.

(2) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (*e.g.*, tamper-evident tape).

(3) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(e)(1) In any case in which the result of the screening test is a breath alcohol concentration of less than 0.02, the BAT shall date the form and sign the certification in Step 3 of the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) If the employee does not sign the certification in Step 4 of the form or does not initial the log book entry for a test, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign or initial in the "Remarks" section of the form.

(3) If a test result printed by the EBT (see paragraph (d)(2) or (d)(3) of this section) does not match the displayed result, the BAT shall note the disparity in the remarks section. Both the employee and the BAT shall initial or sign the notation. In accordance with § 40.79, the test is invalid and the employer and employee shall be so advised.

(4) No further testing is authorized. The BAT shall transmit the result of less than 0.02 to the employer in a

confidential manner, and the employer shall receive and store the information so as to ensure that confidentiality is maintained as required by § 40.81.

(f) If the result of the screening test is an alcohol concentration of 0.02 or greater, a confirmation test shall be performed as provided in § 40.65.

(g) If the confirmation test will be conducted by a different BAT, the BAT who conducts the screening test shall complete and sign the form and log book entry. The BAT will provide the employee with Copy 2 of the form.

§ 40.65 Procedures for confirmation tests.

(a) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall follow the procedures of § 40.61.

(b) The BAT shall instruct the employee not to eat, drink, put any object or substance in his or her mouth, and, to the extent possible, not belch during a waiting period before the confirmation test. This time period begins with the completion of the screening test, and shall not be less than 15 minutes. The confirmation test shall be conducted within 20 minutes of the completion of the screening test. The BAT shall explain to the employee the reason for this requirement (*i.e.*, to prevent any accumulation of mouth alcohol leading to an artificially high reading) and the fact that it is for the employee's benefit. The BAT shall also explain that the test will be conducted at the end of the waiting period, even if the employee has disregarded the instruction. If the BAT becomes aware that the employee has not complied with this instruction, the BAT shall so note in the "Remarks" section of the form.

(c) (1) If a BAT other than the one who conducted the screening test is conducting the confirmation test, the new BAT shall initiate a new Breath Alcohol Testing form. The BAT shall complete Step 1 on the form. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test. The BAT shall note in the "Remarks" section of the form that a different BAT conducted the screening test.

(2) In all cases, the procedures of § 40.63 (a), (b), and (c) shall be followed. A new mouthpiece shall be used for the confirmation test.

(d) Before the confirmation test is administered for each employee, the BAT shall ensure that the EBT registers 0.00 on an air blank. If the reading is greater than 0.00, the BAT shall conduct one more air blank. If the reading is greater than 0.00, testing shall not proceed using that instrument. However, testing may proceed on another instrument.

(e) Any EBT taken out of service because of failure to perform an air blank accurately shall not be used for testing until a check of external calibration is conducted and the EBT is found to be within tolerance limits.

(f) In the event that the screening and confirmation test results are not identical, the confirmation test result is deemed to be the final result upon which any action under operating administration rules shall be based.

(g) (1) If the EBT provides a printed result, but does not print the results directly onto the form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the breath alcohol test form in the designated space, using a method that will provide clear evidence of removal (*e.g.*, tamper-evident tape).

(2) If the EBT prints the test results directly onto the form, the BAT shall show the employee the result displayed on the EBT.

(h) (1) Following the completion of the test, the BAT shall date the form and sign the certification in Step 3 of the form. The employee shall sign the certification and fill in the date in Step 4 of the form.

(2) If the employee does not sign the certification in Step 4 of the form or does not initial the log book entry for a test, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign or initial in the "Remarks" section of the form.

(3) If a test result printed by the EBT (see paragraph (g)(1) or (g)(2) of this section) does not match the displayed result, the BAT shall note the disparity in the remarks section. Both the employee and the BAT shall initial or sign the notation. In accordance with § 40.79, the test is invalid and the employer and employee shall be so advised.

(4) The BAT shall conduct an air blank. If the reading is greater than 0.00, the test is invalid.

(i) The BAT shall transmit all results to the employer in a confidential manner.

(1) Each employer shall designate one or more employer representatives for the purpose of receiving and handling alcohol testing results in a confidential manner. All communications by BATs to the employer concerning the alcohol testing results of employees shall be to a designated employer representative.

(2) Such transmission may be in writing, in person or by telephone or electronic means, but the BAT shall ensure immediate transmission to the employer of results that require the employer to prevent the employee from performing a safety-sensitive function.

(3) If the initial transmission is not in writing (e.g., by telephone), the employer shall establish a mechanism to verify the identity of the BAT providing the information.

(4) If the initial transmission is not in writing, the BAT shall follow the initial transmission by providing to the employer the employer's copy of the breath alcohol testing form. The employer shall store the information so as to ensure that confidentiality is maintained as required by § 40.81.

§ 40.67 Refusals to test and uncompleted tests.

(a) Refusal by an employee to complete and sign the breath alcohol testing form (Step 2), to provide breath, to provide an adequate amount of breath, or otherwise to cooperate with the testing process in a way that prevents the completion of the test, shall be noted by the BAT in the remarks section of the form. The testing process shall be terminated and the BAT shall immediately notify the employer.

(b) If a screening or confirmation test cannot be completed, or if an event occurs that would invalidate the test, the BAT shall, if practicable, begin a new screening or confirmation test, as applicable, using a new breath alcohol testing form with a new sequential test number (in the case of a screening test conducted on an EBT that meets the requirements of § 40.53(b) or in the case of a confirmation test).

§ 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 so 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 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.

(i) If the physician determines, in his or her reasonable medical judgment, that a medical condition has, or with a high degree of probability, could have, precluded the employee from providing an adequate amount of breath, the employee's failure to provide an adequate amount of breath shall not be deemed a refusal to take a test. The physician shall provide to the employer a written statement of the basis for his or her conclusion.

(ii) If the licensed physician, in his or her reasonable medical judgment, is unable to make the determination set forth in paragraph (d)(2)(i) of this section the employee's failure to provide an adequate amount of breath shall be regarded as a refusal to take a test. The licensed physician shall provide a written statement of the basis for his or her conclusion to the employer.

§§ 40.71-40.77 [Reserved]

§ 40.79 Invalid tests.

(a) A breath alcohol test shall be invalid under the following circumstances:

(1) The next external calibration check of an EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this event, every test result of 0.02 or above obtained on the device since the last valid external calibration check shall be invalid;

(2) The BAT does not observe the minimum 15-minute waiting period prior to the confirmation test, as provided in § 40.65(b);

(3) The BAT does not perform an air blank of the EBT before a confirmation test, or an air blank does not result in a reading of 0.00 prior to or after the administration of the test, as provided in § 40.65;

(4) The BAT does not sign the form as required by §§ 40.63 and 40.65;

(5) The BAT has failed to note on the remarks section of the form that the employee has failed or refused to sign the form following the recording or printing on or attachment to the form of the test result;

(6) An EBT fails to print a confirmation test result; or

(7) On a confirmation test and, where applicable, on a screening test, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result.

(b) [Reserved]

§ 40.81 Availability and disclosure of alcohol testing information about individual employees.

(a) Employers shall maintain records in a secure manner, so that disclosure of information to unauthorized persons does not occur.

(b) Except as required by law or expressly authorized or required in this section, no employer shall release covered employee information that is contained in the records required to be maintained by this part or by DOT agency alcohol misuse rules.

(c) An employee subject to testing is entitled, upon written request, to obtain copies of any records pertaining to the employee's use of alcohol, including any records pertaining to his or her alcohol tests. The employer shall promptly provide the records requested by the employee. Access to an employee's records shall not be contingent upon payment for records other than those specifically requested.

(d) Each employer shall permit access to all facilities utilized in complying with the requirements of this part and DOT agency alcohol misuse rules to the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations).

(e) When requested by the Secretary of Transportation, any DOT agency with regulatory authority over the employer, or a state agency with regulatory authority over the employer (as authorized by DOT agency regulations), each employer shall make available copies of all results for employer alcohol testing conducted under the requirements of this part and any other information pertaining to the employer's alcohol misuse prevention program. The information shall include name-specific alcohol test results, records and reports.

(f) When requested by the National Transportation Safety Board as part of an accident investigation, an employer shall disclose information related to the employer's administration of any post-accident alcohol tests administered following the accident under investigation.

(g) An employer shall make records available to a subsequent employer upon receipt of a written request from a covered employee. Disclosure by the subsequent employer is permitted only as expressly authorized by the terms of the employee's written request.

(h) An employer may disclose information required to be maintained under this part pertaining to a covered employee to that employee or to the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual, and arising from the results of an alcohol test administered under the requirements of this part, or from the employer's determination that the employee engaged in conduct prohibited by a DOT agency alcohol misuse regulation (including, but not limited to, a worker's compensation, unemployment compensation, or other proceeding relating to a benefit sought by the employee).

(i) An employer shall release information regarding a covered employee's records as directed by the specific, written consent of the employee authorizing release of the information to an identified person. Release of such information is permitted only in accordance with the terms of the employee's consent.

§ 40.83 Maintenance and disclosure of records concerning EBTs and BATs.

(a) Each employer or its agent shall maintain the following records for two years:

(1) Records of the inspection and maintenance of each EBT used in employee testing;

(2) Documentation of the employer's compliance with the QAP for each EBT it uses for alcohol testing under this part;

(3) Records of the training and proficiency testing of each BAT used in employee testing;

(4) The log books required by § 40.59(c).

(b) Each employer or its agent shall maintain for five years records pertaining to the calibration of each EBT used in alcohol testing under this part, including records of the results of external calibration checks.

(c) Records required to be maintained by this section shall be disclosed on the same basis as provided in § 40.81.

Appendix A to Subpart C of Part 40—The Breath Alcohol Testing Form

BILLING CODE 4910-62-U

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, Address, & Telephone No. _____

_____

_____ ( ) _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ ___/___/___
Signature of Employee Date Month Day Year

STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

_____

_____

_____ _____ ___/___/___
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Date Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

_____ ___/___/___
Signature of Employee Date Month Day Year

COPY 1 - ORIGINAL - BREATH ALCOHOL TECHNICIAN RETAINS

OMB No. 2105-0529

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE) USE TAMPER-EVIDENT TAPE	AFFIX CONFIRMATION TEST RESULTS HERE USE TAMPER-EVIDENT TAPE

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 1 - ORIGINAL - BREATH ALCOHOL TECHNICIAN RETAINS

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▸ STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, Address, & Telephone No. _____

_____

_____ ( ) _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

▸ STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ Date ___/___/___
Signature of Employee Month Day Year

▸ STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete only if the testing device is not designed to print the following.

Test No.	Testing Device Name	Testing Device Serial Number	Time AM PM	Result

Confirmation test: Confirmation test results MUST be affixed to the back of each copy of this form.

Remarks: _____

_____

_____

_____ _____ Date ___/___/___
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Month Day Year

▸ STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

_____ Date ___/___/___
Signature of Employee Month Day Year

COPY 2 - EMPLOYEE RETAINS

OMB No. 2105-0529

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE) USE TAMPER-EVIDENT TAPE	AFFIX CONFIRMATION TEST RESULTS HERE USE TAMPER-EVIDENT TAPE

Privacy Act Statement

(applicable in those cases where completed Breath Alcohol Testing Forms are retained in a Federal Privacy Act system of records)

Except for your Social Security Number (SSN), submission of the information on the front side of this form is mandatory. Incomplete submission of the information, failure to provide an adequate breath specimen for testing without a valid medical explanation, engaging in conduct that clearly obstructs the testing process, or failure to sign the certification statements on the front side of this form may result in delay or denial of your application for employment/appointment, your inability to resume performing safety-sensitive duties, removal from a safety-sensitive position, or other disciplinary action.

The authority for obtaining the breath specimen required by the U.S. Department of Transportation is the Omnibus Transportation Employee Testing Act of 1991, Pub. L. 102-143, Title V. The principal purpose for which the information sought is to be used is to ensure that you have submitted to breath alcohol testing and to ensure that you are promptly notified in the event of noncompliance with the U.S. Department of Transportation breath alcohol testing requirements.

Submission of your SSN is not required by law and is voluntary. If you object to the use of your SSN in this form, you will not be denied any right, benefit, or privilege provided by law; a substitute number or other identifier will be assigned.

The information provided in this form may be disclosed, as a routine use, to a Federal, State, or local agency for authorized investigative or enforcement purposes or to a court or an administrative tribunal when the Government or one of its agencies is a party to a judicial proceeding before the court or involved in administrative proceedings before the tribunal.

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug Enforcement and Program Compliance, Room 9404, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

COPY 2 - EMPLOYEE RETAINS

U.S. Department of Transportation (DOT) Breath Alcohol Testing Form

[THE INSTRUCTIONS FOR COMPLETING THIS FORM ARE ON THE BACK OF COPY 3]

▸ STEP 1: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

A. Employee Name _____
(PRINT) (First, M.I., Last)

B. SSN or Employee ID No. _____

C. Employer Name, Address, & Telephone No. _____

_____

_____ ( ) _____
Telephone Number

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post-accident ☐ Return to Duty ☐ Follow-up

▸ STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to breath alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on this form is true and correct.

_____ _____ / / _____
Signature of Employee Date Month Day Year

▸ STEP 3: TO BE COMPLETED BY BREATH ALCOHOL TECHNICIAN

I certify that I have conducted breath alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing devices identified, and that the results are as recorded.

Screening test: Complete **only if** the testing device is not designed to **print** the following.

_____ _____ _____ _____ AM PM _____
Test No. Testing Device Name Testing Device Serial Number Time Result

Confirmation test: Confirmation test results **MUST** be affixed to the back of each copy of this form.

Remarks: _____

_____

_____

_____ _____ / / _____
(PRINT) Breath Alcohol Technician's Name (First, M.I., Last) Signature of Breath Alcohol Technician Date Month Day Year

▸ STEP 4: TO BE COMPLETED BY EMPLOYEE

I certify that I have submitted to breath alcohol testing and the results are as recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment if the results are 0.02 or greater.

_____ / / _____
Signature of Employee Date Month Day Year

COPY 3 - FORWARD TO THE EMPLOYER

OMB No. 2105-0529

AFFIX SCREENING TEST RESULTS HERE (IF APPLICABLE) USE TAMPER-EVIDENT TAPE	AFFIX CONFIRMATION TEST RESULTS HERE USE TAMPER-EVIDENT TAPE

INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION BREATH ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D. number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The Breath Alcohol Technician (BAT) completes the information required in this step. After conducting the alcohol screening test, do the following (as appropriate):

If the breath testing device used in conducting the screening test is not capable of printing the screening test information located on the front of this form (test number, testing device name, testing device serial number, time of test and results), complete this information in the space provided on the front of this form,

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, i.e., 0.00, 0.02, 0.04, etc.

OR, If the breath testing device used in conducting the screening test is capable of printing the screening test information located on the front of this form, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. Go to STEP 4.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided above. Be sure to use tamper-evident tape.

Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 Instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks section in STEP 3.

Retain Copy 1 (white page) for BAT records.
Give Copy 2 (green page) to the employee.
Forward Copy 3 (blue page) to the employer.

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COPY 3 - FORWARD TO THE EMPLOYER

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