

## DEPARTMENT OF TRANSPORTATION

## Office of the Secretary

## 49 CFR Part 40

[Docket 49384, Notice 94-3]

RIN 2105-AB95

## Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

**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 proposed rule would establish circumstances in which blood alcohol testing could be used in these programs and procedures that would be used for blood alcohol testing.

**DATES:** Comments on this notice of proposed rulemaking should be received by May 16, 1994. Late-filed comments will be considered to the extent practicable.

**ADDRESSES:** Comments should be sent to Docket Clerk, Att: Docket No. 49384, Department of Transportation, 400 7th Street, SW., room 4107, Washington DC, 20590. For the convenience of persons wishing to review the docket, it is requested that comments be sent in duplicate. Persons wishing their comments to be acknowledged should enclose a stamped, self-addressed postcard with their comment. The docket clerk will date stamp the postcard and return it to the sender. Comments may be reviewed at the above address from 9 a.m. through 5:30 p.m. Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Donna Smith, Acting Director, Department of Transportation Office of Drug Enforcement and Program Compliance, 400 7th Street, SW., Washington DC, 20590, room 9404, 202-366-3784; or Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., room 10424, 202-366-9306.

**SUPPLEMENTARY INFORMATION:** Department published in today's Federal Register a final rule (49 CFR part 40) establishing testing procedures for the Department's new alcohol testing rules. The Department's December 1992 NPRM for these procedures did not propose to permit blood alcohol testing. Therefore, it did not include any proposed blood alcohol testing procedures. Today's NPRM proposes limited circumstances in which blood

alcohol testing would be permitted for the covered operating administrations and procedures that would be used for this purpose. We seek comments on these proposed procedures and on any additions, deletions, or modifications we should make to them. In addition, we seek comment on the broader question of whether the Department should adopt blood alcohol testing at all.

## Section-by-Section Analysis

## Section 40.71 Authorized Uses for Blood Alcohol Testing

We propose to allow blood alcohol testing only in a limited set of circumstances. Blood alcohol testing could be used in reasonable suspicion and post-accident testing, where an evidential breath testing device (EBT) is not readily available, and in place of a medical evaluation in "shy lung" situations. If breath testing were not readily available for a reasonable suspicion or post-accident test, employers would have to use blood alcohol testing to meet their regulatory obligations.

We are aware of certain advantages to blood alcohol testing. It is accurate, does not require expenditures for expensive new equipment, and can be conducted by qualified personnel who are generally readily available even in remote locations. At the same time, blood alcohol testing has a number of disadvantages, all of which are exacerbated with extensive use. It is the most intrusive form of testing, it does not provide an immediate confirmed result, and it necessitates additional procedural complexities such as collection, laboratory, and chain of custody requirements. There could be additional costs and litigation. Nevertheless, because we are aware that, in some circumstances the unavailability of EBTs meeting part 40 requirements may make breath testing impracticable, we believe that it may be useful to allow some flexibility. We think it better, in these circumstances, to allow testing using a method with some disadvantages than to be unable to complete a test at all.

Reasonable suspicion and post-accident tests are more likely than other kinds of test to happen at unpredictable times and in remote locations. (The time and, to some extent, place of random and pre-employment testing are more likely to be under the employer's control.) Consequently, as commenters suggested, unless an employer incurs the expense of having EBTs in all of its locations, or has an extensive rapid-deployment capability, it may be

substantially easier and less costly to arrange for a blood alcohol test in these circumstances. In some cases, it may be impossible to get an EBT to a remote location in time to conduct a meaningful test.

Particularly in remote locations, there could be situations in which the only person trained to conduct alcohol tests is the supervisor of an employee subject to a post-accident or reasonable suspicion test. Our current rules permit a supervisor to conduct breath alcohol tests, if the supervisor is a trained BAT and another BAT is not available, as long as operating administration rules do not prohibit this action by the supervisor. In the case of reasonable suspicion tests, the operating administration rules prohibit the supervisor who has made the reasonable suspicion determination from conducting either the screening or confirmation test. The purpose of this NPRM is to increase flexibility in post-accident and reasonable suspicion testing in circumstances in which testing would otherwise be difficult to accomplish. With that purpose in mind, would it make sense to permit supervisors to conduct screening tests in these situations? Should blood testing be treated any differently from breath testing for these purposes?

Moreover, the number of post-accident and reasonable suspicion tests is likely to be substantially lower than the numbers of pre-employment and random tests. This means that the disadvantages of blood alcohol testing noted above will occur in a limited number of cases. (The Department estimates that there will be around 2500 blood alcohol tests per year under this proposal and seeks comment on whether this estimate is reasonable.) If employers "stand down" employees on the basis of the event leading to the test, the safety impact of the lack of an immediate result may be further reduced.

One of the key conditions for allowing the use of blood alcohol testing is that EBTs not be "readily available." Because of its greater invasiveness and because it does not produce an immediate result, the use of blood alcohol testing is intended to be used only in those reasonable suspicion and post-accident testing circumstances where it is not practicable to use breath testing. Blood alcohol testing is not intended, under the proposal, to be an equal alternative method that an employer can choose as a matter of preference.

We seek comment on when the final rule should regard an EBT as being "readily available." For example, if a

breath test can be arranged within a given time (e.g., two hours) of the event requiring the test, should breath testing be regarded as readily available? What should the time frame be? What if the cost of obtaining an EBT and bringing it to the site for testing is a certain multiple of the cost of conducting blood alcohol testing in that case? What if it were simply more convenient or less expensive to use a blood alcohol test rather than breath testing in a particular case? Are there other criteria that could be used to determine when breath testing was readily available? Should this be left to the judgment of the employer? If so, how would the Department judge when this discretion had been exercised properly? Should the Department require the employer to document the facts that led to a decision to use blood alcohol testing?

In context of this discussion of "readily available," we would point out that the EBT involved need not be one that the employer owns. It could also be a device that is owned by another employer or a third-party provider. We do not think that it should be necessary for an employer to pre-position an EBT (or enter into a contract) at every possible testing location. However, we do believe it is fair to expect employers to make arrangements for the use of EBTs either through purchase, lease or contract, assuming normal deployment to do routine random and pre-employment testing. The Department seeks comment on whether, and how, these expectations should be made part of the text of the final rule.

The NPRM proposes that, if no EBT were readily available for even the screening test, a blood sample would be collected and sent to the laboratory, where two tests would be conducted on the primary specimen. Alternatively, if an EBT were available for the screening test, but an EBT meeting part 40 requirements for use in a confirmation test were not available, a blood confirmation test could be performed. Some questions arise about the former situation. Would this provision discourage employers from obtaining the less expensive alcohol screening devices permitted by part 40? Would employers be deterred from using blood as a collection method by fear of confrontations with or litigation by employees who resented the intrusiveness of blood alcohol testing all the more for the absence of a breath screening test? Would additional supervisor training be needed? On the other hand, would the majority of situations in which blood could be used under this proposal likely be situations in which no EBTs at all were available,

so that using blood for both screening and confirmation testing would be necessary in order to make the proposal meaningful?

The NPRM also proposes that employers could use blood alcohol testing for an employee covered under the "shy lung" provision of the Department's new alcohol testing procedures. If an employee was unable to provide sufficient breath for a breath test, the employer could choose either to refer the employee for a medical evaluation or to draw a blood sample as provided in this NPRM.

Whether for liability reasons or on the basis of the events leading to a post-accident or reasonable suspicion test, many employers might prefer to "stand down" the employee pending the receipt of the laboratory result of the blood alcohol test. Is it necessary for the Department's regulations to address this subject? If so, what should the rules provide?

#### *Section 40.73 Collection Procedures for Blood Alcohol Tests*

We think it will not be necessary to establish extensive new procedures for collecting blood samples, given the limited circumstances in which use of this method would be authorized. (The situation would probably be different if blood testing were being proposed for pre-employment and random testing as well.) Collection of blood specimens for forensic purposes such as law enforcement is considered standard procedure at many medical facilities. For these reasons, we believe that we should depend, to the extent possible, on existing resources and programs. We propose that anyone who is licensed, certified, or otherwise authorized under state law to draw blood could do so in the State for purposes of the DOT program. In most states, physicians, nurses, phlebotomists, and sometimes other medical personnel, have this authority.

It is our understanding that states, for law enforcement and other forensic purposes, have approved procedures for collecting blood specimens for the purpose of alcohol testing. Except to the extent that DOT rules specify certain requirements, the NPRM would allow a blood specimen to be collected for purposes of the DOT program in accordance with these existing state procedures. As with personnel qualifications and specimen collection procedures, chain of custody requirements would follow state requirements for law enforcement and other forensic blood collections. The Department seeks comment on whether reliance on state requirements would

produce too much confusion or inconsistency, such that nationwide, uniform DOT procedures would be preferable. On the other hand, would such uniform DOT procedures make it too difficult to operate a blood testing program for a relatively small number of samples, reducing flexibility that this proposal is designed to permit?

The NPRM would require 20 ml of blood to be drawn for the test. As explained in the preamble to the final rule for part 40 published today, there is a statutory requirement for collecting split samples of body fluids in FAA, FTA, FRA, and FHWA programs. In this situation, the sample would be subdivided into two 10 ml tubes. Collections under the RSPA rule, where split samples are not required, would require only 10 ml of blood, placed in one tube. The NPRM would require certain standard testing materials to be used, which would be provided by testing laboratories in a sealed kit. The kit would include the blood tubes, labels, chain of custody form, blood extraction device, and swab. We seek comment on whether it is advisable to require the inclusion of blood extraction devices. That is, is including these materials needed, in light of the resources available at testing sites? Would including them give rise to concerns about theft? We also seek comment on whether the kit should also include standardized collection instructions. The employer would be responsible for ensuring the kit was available at the testing location.

#### *Section 40.75 Laboratories for Blood Alcohol Testing*

The regulatory text of this proposed section is a place-holder. One of the most difficult questions facing the Department is how to ensure that appropriately well-qualified laboratories test blood specimens for alcohol. Absent a satisfactory answer to this question, the viability of this proposed rule is in question.

One approach the Department could take, which is consistent with the approach of using existing resources to the extent practicable, is to rely on those laboratories—whether state-operated or private—that conduct forensic blood alcohol tests for law enforcement and other purposes in each state. The final rule would assume, in effect, that a laboratory whose findings were deemed sufficient under state law to act as the basis for criminal or civil penalties against persons in DUI or similar cases was adequate for DOT workplace testing program purposes. In order for this approach to work, there would have to be state or state-approved laboratories in

a sufficient number of states that had the willingness and capacity to accept and process "DOT" blood specimens. We see no reason why laboratories in every state would necessarily have to participate. Since we expect few blood alcohol tests, large numbers of laboratories would not be necessary, and specimens could be sent to a laboratory in any state that accepts commercial business. The Department seeks comments on the capacity and suitability of such laboratories.

A second approach would be to construct a system based on the laboratories certified by the Department of Health and Human Services (DHHS) for urine drug testing. DHHS has carefully reviewed the overall proficiency and forensic capability of these laboratories, and they are available to users throughout the country. Many DHHS-certified laboratories currently perform blood alcohol testing, but there is no blood alcohol testing proficiency requirement involved with DHHS certification. Under this approach, the Department, in cooperation with DHHS, could develop a proficiency requirement for blood alcohol testing. Such a requirement could be implemented through a DOT-DHHS agreement calling for DHHS certification and inspection for blood alcohol testing purposes.

This approach would require DOT and DHHS to work out an agreement. The cost of the certification program—both to the Department and to laboratories—is not yet known, though the Department is working with DHHS to develop this information. The cost to the Federal government of this certification program would have to be recovered from the laboratories via user fees. Given the small number of tests, it is questionable whether laboratories would find it cost-effective to become certified for blood alcohol testing, though there could be some pressure from customers to process blood as well as urine samples. The Department seeks comments on the advantages and disadvantages of this approach.

There are other possibilities. For example, the Department could use laboratories certified by private certifying bodies, though the Department has expressly declined to do so in its drug testing program. DOT and DHHS both believe that the DHHS approval process for laboratories provides a more thorough and intense review of laboratory quality than existing private certification programs. The Department could also contract with one or more laboratories to conduct the needed tests. It is likely that user fees would be needed to fund such

an approach. The Department seeks comment on any additional approaches that commenters believe have merit.

This discussion of the need for laboratory certification is in the context of a testing program that does not provide for evidentiary proceedings in which an individual could challenge test results. Existing Coast Guard alcohol testing regulations provide for post-accident blood testing in some situations. The validity of these proceedings is subject to evidentiary hearings, has long been recognized in administrative and court decisions, and is not brought into question by the Department's proposals concerning laboratory certification.

#### *Section 40.77 Testing of Blood Specimens*

The basic scheme of this provision is similar to the process the laboratory uses for drug testing. An aliquot of the primary specimen is tested by gas chromatography (GC) or enzyme assay. (Because testing for alcohol is simpler chemically than testing for drug metabolites, mass spectrometry is not needed.) If the alcohol concentration is less than 0.04, the laboratory reports a negative test to the employer. If the result is 0.04 or above, then the laboratory conducts a GC test on a second aliquot of the primary specimen. If the alcohol concentration is less than 0.04, the laboratory reports a negative test to the employer. If the result is 0.04 or above, the laboratory reports the quantitative (positive) result to the employer.

The split sample procedure also operates in an analogous way to the drug testing procedures. If the employee requests a test of the split specimen within 72 hours of being informed of the positive result, the employer tells the laboratory to send the split specimen to a second laboratory, which runs a single GC test on the split specimen. As under the drug testing procedures, the employee would have the opportunity to present evidence that he or she had been unable to make the request within the 72-hour time frame. If the result is 0.04 or above, the positive test result stands. If the result is less than 0.04, the test result is invalid. The consequences of the test result would not be stayed pending the test of the split specimen; the employee would remain barred from performing safety-sensitive functions pending the receipt of the analysis of the split specimen, unless the employee had met the conditions in the applicable operating administration rule for return to duty.

Because the time when one could gain a safety benefit from removing from

safety-sensitive functions an employee testing between 0.02 and .039 will long since have passed, these procedures do not call for taking any action with respect to a test result in this range. The Department seeks comment on whether this approach makes sense and on whether there are any reasons to report such results to the employer. The Department also notes that the proposed procedure calls for two tests to be conducted on the primary specimen even if there has been a screening test on a preliminary EBT. The reason for this requirement is to avoid confusion at the laboratory by requiring a standard procedure in all cases, even where one of the two tests is, strictly speaking, unnecessary. The Department also seeks comment on this proposal.

#### *Section 40.79(b) Invalid Tests*

This paragraph would be added to the existing list of fatal flaws for breath alcohol tests. It would spell out those actions that would automatically cause a test to be deemed invalid. The paragraph is intended to provide protections for the accuracy of the process equivalent to those provided for breath alcohol testing and urine drug testing.

We seek comment on whether it should be a fatal flaw if an unauthorized person has succeeded in drawing a blood sample from an employee. Once the sample has been drawn, does the lack of authorization of the individual drawing the sample affect its accuracy? Should this be a fatal flaw simply as a means of ensuring that appropriately qualified people draw blood, regardless of the effects on sample accuracy?

In some circumstances, it may be unclear to the personnel involved what state a test occurs in (e.g., a post-accident test on a bridge between two states). The procedures of the two states may differ. Should the rule be modified to avoid the invalidation of a test just because the procedures used turned out to pertain to the wrong state?

#### *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 proposed rule—in conjunction with the operating administrations' alcohol and drug testing rules and the remainder of the alcohol testing portion of part 40—is significant under Executive Order 12866. OMB has reviewed this NPRM under that Order. The NPRM is also significant under the Department's regulatory policies and procedures.

The Department has prepared a regulatory evaluation for the alcohol portion of part 40, which we have included in the docket. The costs of the application of part 40 procedures to the programs of the various operating administrations are estimated in each of the operating administrations' regulatory evaluations for their final alcohol rules being published today. At the time of a final rule based on this NPRM, the covered operating administrations will supplement their part 40 alcohol testing rule regulatory evaluations as needed with respect to blood alcohol testing.

The Department expects that this proposal, if implemented, will lower costs to employers by providing more flexibility and decreasing the number of EBTs needed. As noted above, the Department estimates that there would be about 2500 blood alcohol tests annually, under all five affected operating administration rules. The Department expects that the amount of employee time involved in drawing blood would be about the same time involved in breath testing. We seek comment on these matters.

This NPRM, 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 operating administrations' supplements to their alcohol testing rule 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.

#### 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, DC.

**Federico Peña,**  
*Secretary of Transportation.*

**David R. Hinson,**  
*Administrator, Federal Aviation Administration.*

**Rodney E. Slater,**  
*Administrator, Federal Highway Administration.*

**Jolene M. Molitoris,**  
*Administrator, Federal Railroad Administration.*

**Gordon J. Linton,**  
*Administrator, Federal Transit Administration.*

**Ana Sol Gutiérrez,**  
*Acting Administrator, Research and Special Programs Administration.*

For the reasons set forth in the preamble, the Department of Transportation proposes to amend title 49, Code of Federal Regulations, part 40, as follows:

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

1. The authority for part 40 is proposed to continue to read as follows:

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

#### § 40.3 [Amended]

2. In § 40.3 of part 40, the period following the end of the definition of "alcohol concentration" in section 40.3 is proposed to be removed, and the following words added: "or the blood alcohol concentration indicated by a blood alcohol test under this part." In the definition of "screening test," the words "(or, where authorized, blood)" are proposed to be added between the word "breath" and the word "specimen."

3. A new paragraph (d)(1) is proposed to be added to section 40.69, to read as follows:

**§ 40.69 Inability to provide an adequate amount of breath.**

\* \* \* \* \*

(d) \* \* \*

(1) The employer may direct the employee to submit to a blood alcohol test in accordance with the procedures of §§ 40.71 through 40.77; or

\* \* \* \* \*

4. and 5. New sections §§ 40.71 through 40.77 are proposed to be added to subpart C of part 40, to read as follows:

#### § 40.71 Authorized uses of blood alcohol testing.

Blood alcohol testing is authorized only in the following circumstances:

(a) When operating administration rules require a post-accident or reasonable suspicion test, and an EBT is not readily available for either screening or confirmation tests, blood alcohol testing shall be used for both screening and confirmation test purposes.

(b) When operating administration rules require a post-accident or reasonable suspicion test, and an EBT is readily available for the screening test but an EBT suitable for confirmation testing is not readily available, blood alcohol testing shall be used for confirmation test purposes.

(c) When the employee attempts and fails to provide an adequate amount of breath, blood alcohol testing may be used for both screening and confirmation test purposes.

#### § 40.73 Collection procedures for blood alcohol tests.

(a) Personnel who conduct blood alcohol tests shall be licensed, certified, or otherwise authorized under state law to draw blood in the State in which the test takes place.

(b) The drawing of blood shall be conducted using a blood alcohol test kit containing the following items:

(1) Two evacuated gray-capped glass tubes (except that for a kit to be used only for testing under the Research and Special Programs Administration (RSPA) rule, there is required to be only one such tube);

(2) A chain of custody form;

(3) A label for each tube;

(4) A sterile, non-alcohol swab; and

(5) An appropriate, disposable blood extraction device.

(c) The employer shall use only a blood alcohol test kit obtained from a laboratory meeting the requirements of § 40.75. Employers shall use kits in accordance with the supplier's instructions, and shall not use a kit after its expiration date. Employers shall not re-use a blood extraction device.

(d) The drawing of blood shall be conducted in accordance with forensic blood alcohol collection procedures approved in the State in which the test takes place.

(e) (1) Except as provided in this paragraph, at least 20 ml of venous blood shall be drawn and subdivided into two equal portions of 10 ml each. The collector shall place each portion in a separate evacuated gray-capped tube, and label and seal the tubes. The collector shall designate one of the tubes as the primary specimen and the other as the split specimen.

(2) Blood samples collected pursuant to the RSPA alcohol testing rule are not required to be subdivided. For tests required by only the RSPA alcohol testing rule, the collector shall draw 10 ml of venous blood and place it in an evacuated gray-capped tube, and label and seal the tube.

(f) Blood specimens shall be shipped to the laboratory, together with documentation of the chain of custody meeting forensic standards acceptable under the law of the State in which the test takes place.

#### § 40.75 Laboratories for blood alcohol testing.

Blood alcohol testing under this part shall be conducted only in laboratories where such testing is authorized by Department of Transportation regulations.

#### § 40.77 Testing of blood specimens.

(a) When the split sample method has been used, the laboratory shall retain the tube designated as the split specimen in secure refrigerated storage, with the seal intact. If the seal on the tube designated as the primary specimen has been broken, or the primary specimen is otherwise unavailable for testing, the laboratory shall use the tube designated as the split specimen in its place.

(b) The laboratory shall analyze an aliquot of the primary (or sole) specimen for its alcohol concentration, using gas chromatography or an enzyme assay, at a cutoff level of 0.04. If the result of this analysis is an alcohol concentration of less than 0.04, the laboratory shall report the result of the test to the employer as negative. In this case, the laboratory may discard the split specimen. If the alcohol concentration is 0.04 or greater, the laboratory shall analyze a second aliquot of the primary specimen, using gas chromatography.

(c) If the result of the analysis of the second aliquot is an alcohol concentration of less than 0.04, the laboratory shall report the result of the test to the employer as negative. In this case, the laboratory may discard the split specimen.

(d) If the result of the analysis of the second aliquot is an alcohol concentration of 0.04 or greater, the laboratory shall report the quantitative result to the employer. In this case, where the split sample collection method has been used, the laboratory will retain the split specimen in secure

refrigerated or frozen storage, with the seal intact, for 60 days from the date the laboratory acquires the sample.

(e) (1) At the time the employer informs the employee that the employee's test result is 0.04 or greater, the employer shall inform the employee that the employee has 72 hours in which to request a test of the split specimen. If the employee requests a test of the split specimen within 72 hours, the employer shall direct the laboratory to release the split specimen for testing.

(2) If an employee has not contacted the employer within 72 hours, as provided in paragraph (e)(1) of this section, the employee may present to the employer information documenting that serious illness, injury, inability to contact the employer, lack of actual notice of the verified positive test, or other circumstances unavoidably prevented the employee from timely contacting the employer. If the employer concludes that there is a legitimate explanation for the employee's failure to contact the employer within 72 hours, the employer shall direct that the analysis of the split specimen be performed.

(3) Pending receipt of the result of the analysis of the split specimen, the employee shall not perform safety-sensitive functions, unless the employee has met conditions in the applicable operating administration rule for return to safety-sensitive functions following a test result of 0.04 or greater.

(4) The laboratory shall ship the split specimen, with seal intact, and with appropriate chain of custody documentation, to a second laboratory meeting the requirements of § 40.75. The second laboratory shall analyze the split specimen for its alcohol concentration, using gas chromatography, at a cutoff level of 0.04.

(5) If the result of the analysis of the split specimen is an alcohol concentration of 0.04 or above, the laboratory shall report to the employer that the result of the test of the primary specimen has been reconfirmed.

(6) If the result of this test is an alcohol concentration of less than 0.04, or if any of the circumstances set forth in § 40.79(b)(8) occur, the laboratory shall report to the employer that the result of the test of the primary specimen has not been reconfirmed, and therefore, the test is invalid.

6. A new paragraph (b) is proposed to be added to § 40.79, to read as follows:

#### § 40.79 Invalid tests.

(b) A blood alcohol test shall be invalid under the following circumstances:

(1) The person who draws the blood sample from the employee is not authorized to do so under the law of the State in which the sample is drawn;

(2) The test was not conducted in accordance with forensic blood alcohol collection procedures approved in the State in which the test takes place;

(3) The chain of custody does not meet forensic standards acceptable under the law of the State in which the blood is drawn or there is a break in the chain of custody;

(4) The volume of the specimen used for the primary blood alcohol test (i.e., as distinct from the split specimen) is less than 10 ml; except that if, upon arrival at the laboratory, the specimen volume is not less than 8 ml, the laboratory may accept the specimen if the laboratory can ensure that sufficient volume will be available for testing and any necessary reanalyses for quality control;

(5) The seal on both specimens (or the only specimen) is broken or shows evidence of tampering;

(6) The test did not take place in a laboratory meeting the requirements of § 40.75.

(7) The testing methods prescribed in § 40.77(b) are not used;

(8) If, after an employee makes a timely request for a test of the split specimen under § 40.77(e)—

(i) The split specimen is unavailable for testing;

(ii) There is insufficient blood to permit a valid reconfirmation test to be conducted;

(iii) The seal on the tube containing the split specimen has been broken prior to testing at the second laboratory, or otherwise shows evidence of tampering;

(iv) The split specimen has not been retained in secure and refrigerated storage prior to being transmitted to the second laboratory;

(v) The inter-laboratory chain of custody is incomplete; or

(vi) The test of the split specimen fails to reconfirm the presence of alcohol at a level of at least 0.04.

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