DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST 95–321; Notice 95–8]

RIN 2105–AC22

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation proposes to modify current procedures governing situations in which employees are unable to provide sufficient specimens for urine drug testing. The proposed changes would allow additional time to collect a sufficient sample. In addition, the Department proposes to clarify requirements concerning relationships between laboratories and medical review officers; provide procedures for situations in which employees do not have contact with medical review officers following a laboratory-confirmed positive test; and make explicit that MROs are to report split specimen test results to employers, regardless of who pays for the test.

DATES: Comments should be received by September 25, 1995. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent to Docket Clerk, Att: Docket No. OST–95–321, Department of Transportation, 400 7th Street, SW., Room PL401, Washington DC, 20590. For the convenience of persons wishing to review the docket, it is requested that comments be sent in triplicate. 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: Albert Alvarez, Director, Office of Drug Enforcement and Program Compliance, 400 7th Street, SW., Room 10317, 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:

"Shy Bladder"

In the February 15, 1994, revision of 49 CFR Part 40 (59 FR 7340), the Department established new ''shy bladder'' procedures, for situations in which employees cannot provide a sufficient urine sample. These procedures were established in conjunction with a reduction in the required sample volume from 60 to 45 milliliters (mL) (for split samples) or 30 mL (single specimen collections). For employees who are unable to provide this reduced sample volume, the rule (§ 40.25(f)(10)(iv)) directs the collection site person to ''instruct the individual to drink not more than 24 ounces of fluid and, after a period of up to two hours, again attempt to provide a complete sample.'' If the individual cannot do so, the medical review officer (MRO) is directed to ''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.'' (This referral is not mandated in the case of pre-employment testing where the employer does not want to hire the individual.)

There were several reasons for this action. First, the Department of Transportation and the Department of Health and Human Services had both received information indicating that forcing large quantities of fluids over a longer period of time could result in water intoxication (i.e., a condition resulting from rapid, copious water intake, that may result in dilution of the plasma and an influx of water into the brain), which if severe can result in harm to employees' health (e.g., lethargy, confusion, or seizures). Second, ingesting large quantities of fluids can help to dilute specimens, giving drug-using employees a mechanism for trying to ''beat the test.'' Third, the Department's Drug Enforcement and Program Compliance Office consulted with the medical community, learning that most adults, in most circumstances, could produce 45 mL of urine following the ingestion of 24 ounces of fluid over a two-hour period. Fourth, allowing up to eight hours for testing had resulted in employees remaining off the job for long periods of time, with consequent costs to employers, including some employees who appeared to intentionally and unnecessarily delay the provision of a specimen.

Since the adoption of this provision, employers, employees and MROs have expressed various concerns to the Department. Since, absent an adequate medical explanation, a ''shy bladder'' constitutes a refusal to test, and a refusal to test is equivalent to a positive test, program participants (especially in the railroad industry, where a refusal to test can carry a nine-month suspension) have become concerned about the operation of this provision. The principal concern expressed has been that two hours is too short a time to allow employees to generate sufficient urine, particularly if employees have become somewhat dehydrated on the job (e.g., railroad unions have said that their members are sometimes on the job for several hours without relief, with little fluid intake). Another concern is that the regulation does not provide sufficient guidance on the factors on which physicians should rely in determining whether the employee's inability to provide a sufficient specimen is medically ''genuine.''

The Department is willing to consider changing the ''shy bladder'' provision of the rule in response to these concerns. We will propose several changes for purposes of soliciting comment on them. These changes are intended to balance the considerations favoring the present rule (e.g., lower probability of water intoxication, less likelihood of producing a dilute specimen, fewer hours off the job) and those favoring a longer period of time (e.g., greater probability of producing a complete specimen). The amendment would provide up to four hours for an employee to drink up to 40 ounces of fluid before making the second attempt to provide a complete specimen. The employee would be directed to drink 8 ounces of fluid each 30 minutes during this period until the 40 ounce maximum is reached. Obviously, this process would be cut short if the employee provided a sufficient specimen. Refusal to drink the fluids or make another attempt to provide a new specimen would be treated as a refusal to test.

The quantity of water consumed under these provisions would be unlikely to result in water intoxication. A medical journal article addressing this issue that has recently come to our attention (''Acute Water Intoxication as a Complication of Urine Drug Testing in the Workplace,'' David Klonoff and Andrew Jurow, Journal of the American Medical Association, January 2, 1991, pp. 84–85) related that, in every reported case of water intoxication the authors found in their literature search, the patient consumed at least 1.35 liters of water. (In a particular case cited at length in the article, the patient, in the course of a drug test, consumed 3 liters of water in a 3-hour period.) They also noted that it was common medical practice to administer up to 1 liter of water over a period of 1 hour to distend the bladder for ultrasound examination. Forty fluid ounces is approximately equivalent to 1.2 liters, less than the

1.35 liters or more that the authors found in water intoxication cases reported in the medical literature. While greater than the 1 liter the authors found to be common medical practice, the fluids provided under these procedures would be administered in stages over a two-hour period, rather than in one hour. While avoiding water intoxication, this approach would provide 16 more ounces of fluids and 2 more hours than the current rules, allowing a greater probability of the individual being able to provide a sufficient specimen.

The Department seeks comment from the medical community, employers, employees, and other interested persons concerning the appropriateness of the proposed 4 hour/40 ounce rule. In particular, we are seeking comments, with rationales and information attached, about whether a longer or shorter time period or greater or lesser water intake would be desirable. In addition, we seek comment on whether an unsuccessful attempt to provide a sufficient specimen should be required in every instance before the four-hour clock begins to run. (This is the Department's interpretation of its current rule.) That is, if an individual comes to the collection site and reports that he or she cannot provide a sample immediately, should the collection site person have the discretion to skip the first collection attempt and proceed immediately to the shy bladder procedure?

To further clarify the rule, we would incorporate language from the parallel provision of the alcohol testing procedures concerning the task of the physician who evaluates the employee. Section 40.69(d) provides as follows:

(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), 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.

The NPRM proposes similar language for ''shy bladder'' situations. By a ''medical condition,'' we mean an ascertainable physiological condition (e.g., a urinary system dysfunction), as distinct from assertions of ''situational anxiety'' or unsupported claims of dehydration.

The Department is not proposing to allow urine from different voids to be combined. That is, if an individual voids and provides 25 mL of urine, that specimen must be discarded. It could not be added to a subsequent 20 mL void to create a combined 45 mL specimen. Testing a specimen consisting of urine from two different voids at two separate times adds too much uncertainty to the testing process. Nor is the Department proposing to allow individuals who have failed to provide a sufficient specimen to provide a subsequent urine sample when they visit the physician for the assessment of whether a medical condition exists that prevents them providing a complete sample. Such a provision would allow employees time to take steps to avoid a positive test by drinking enough fluids to dilute the specimen or otherwise to ''beat the test.'' In addition, producing a specimen at the doctor's office a short time after failing to provide it at the testing site might well be viewed as evidence that there is, in fact, no medical condition preventing the individual from providing a sufficient sample.

Body Temperature

Currently, § 40.25(e)(i) refers to measurements of oral body temperature that are made as part of the process of determining whether the temperature of a urine specimen is consistent with the temperature of the employee. The reference to ''oral'' may unnecessarily restrict the means used to test body temperature, since other ways of taking body temperature (e.g., tympanic temperature) exist. We propose to delete the word ''oral,'' with the result that taking the individual's temperature by any medically-accepted means (including oral) would be permitted.

MRO/Laboratory Relationships

In its August 19, 1994, amendments to Part 40 (59 FR 42996), the Department added § 40.29(n)(6). Based on a Department of Health and Human Services regulatory provision, it provides that

The laboratory shall not enter into any relationship with an employer's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an employer use a specific MRO.

This language is the definitive, and most recent, statement by the Department of the rules governing relationships between MROs and laboratories. As such, it was intended to supersede the older language of § 40.33(b)(2), which provided that

The MRO shall not be an employee of the laboratory conducting the drug test unless the laboratory establishes a clear separation of functions to prevent any appearance of a conflict of interest, including assuring that the MRO has no responsibility for, and is not supervised by or the supervisor of, any persons who have responsibility for the drug testing or quality control operations of the laboratory.

In the August 19, 1994, amendments to part 40, the Department inadvertently failed to remove the latter provision. While the two provisions have a common purpose—ensuring that there is not even the appearance of a conflict of interest between the laboratory and the MRO—it has been pointed out to the Department that, considered together, they may cause confusion as to the Department's intent. To avoid the possibility of any such confusion, this NPRM would remove § 40.33(b)(2).

The Department is also seeking comment on a related issue, concerning the application of this conflict of interest provision. In response to an inquiry from a laboratory, the Department determined that a ''closed panel'' type of operation—in which a laboratory that packaged drug testing services to clients provided a list of MROs to the clients from which the clients had to choose—was inconsistent with this provision. The rationale of this determination was that since there is a financial advantage to MROs to be on such a list (i.e., it directs business to them), there could be an incentive for the MROs to be less than ideally independent in their reviews of test results from the laboratory establishing the list. This, in turn, can create at least the appearance of a conflict of interest. (Though the issue did not arise in the context of this determination, we note that the conflict of interest provision works both ways, and would apply to arrangements in which MROs select laboratories as well as to arrangements in which laboratories select MROs.)

The laboratory in question and other participants have responded that arrangements of this kind are common and accepted in the industry and provide for a higher level of quality control in the drug testing process, since

laboratories have a market incentive to provide only the best-qualified MROs to their clients. Other parties have suggested that MRO/laboratory arrangements that are not arms-length, however configured, will compromise the independence of the parties in the process to an unacceptable degree. The Department wishes to maintain this independence, but also wishes to avoid interfering unreasonably with rational arrangements that may serve employers well. The Department seeks comment on whether there are some specific provisions that should be included in the regulation, or in guidance, that strike an appropriate balance.

Unresolved Confirmed Positive Tests

Section 40.33 establishes procedures for MROs and employers to follow when it is difficult for the MRO to contact an employee following a report from the laboratory of a confirmed positive drug test. If, after making all reasonable efforts to contact the employee, the MRO cannot do so, the MRO asks a designated management official to contact the employee. If the designated management official cannot do so, then the employer may place the employee on medical leave or similar status. The confirmed positive does not become a verified positive—the only result having consequences under the rule—in this situation. There can be a ''non-contact positive'' only if the employee declines an opportunity to discuss the test with the MRO or the employer has contacted the employee and the employee fails to contact the MRO within five days. In the latter circumstances, the MRO can reopen the verified positive test if there is a showing that illness, injury, or other circumstances beyond the control of the employee prevented a timely contact.

The Department has become aware of a situation these procedures do not cover. If neither the MRO nor employer ever succeeds in contacting the employee (e.g., the applicant never gets back in touch with the employer in a pre-employment test case, an employee quits or never shows up again following a random test), a confirmed laboratory positive test is left in limbo, with no way to verify it either as a positive or negative test. This creates problems for MROs, who have the unresolved tests on their books indefinitely.

This situation can also create problems for subsequent employers and the Department's program. For example, under the Federal Highway Administration's drug testing requirements (49 CFR part 382), the new employer is required to seek information on previous drug test results from other employers. In the unresolved test situation described above, however, a previous employer will not have a drug test result that it can report, because only a verified positive or negative test can be reported. The employee, in this case, may be able to obtain employment with another employer because the ''limbo'' positive was never reported.

To avoid this difficulty, the Department is proposing to add language to § 40.33. In any situation where neither the MRO nor the employer has been able to contact the employee within 30 days from the date the MRO receives the confirmed positive test result from the laboratory, the MRO will be instructed to verify the laboratory result positive and report it to the employer as such. The same provisions allowing the employee to reopen the verification will apply as in the case where the employer did contact the employee and the employee failed to contact the MRO within 5 days. The Department seeks comment on this approach and on the appropriate amount of time before a ''non-contact positive'' can be declared. We also seek comment on what, if any, documentation of the efforts to contact the employee should be maintained by the MRO and/or designated employer representative.

The Department also seeks comment on how this provision should apply in the case of opiate positives. Once an MRO has a confirmed positive laboratory test result for other drugs, the MRO verifies the test as positive unless he or she determines that there is a legitimate medical explanation for the presence of the drug. By contrast, the MRO cannot verify a confirmed opiate positive unless the MRO finds independent clinical evidence supporting the positive result. In the Department's experience, a high percentage of confirmed laboratory positives for opiates are verified negative. Given this background, should there be different procedures for ''non-contact positives'' involving laboratory results that are positive only for opiates? If so, how should the procedures differ?

We also seek comment on whether a similar provision should be extended to situations in which an employee has contacted the MRO and, in the course of the verification interview, asserted that there is documentation of a legitimate medical explanation for the presence of a drug or metabolite. If the individual, or the individual's physician, does not produce this documentation after 30 days or some other reasonable time period, should the rule explicitly authorize the MRO to verify the test positive at that time?

Reporting of Split Sample Results

Section 40.33 goes into some detail concerning the procedures the MRO must follow concerning reporting the split specimen test results to the employer and employee. The section is quite specific on the consequences of a test of the split specimen that does not reconfirm the positive result of the primary sample. However, the section does not explicitly specify what the MRO does in the case of a split specimen test that does reconfirm the positive result of the test of the primary specimen. The Department has encountered situations in which employees who have paid for the test of the split specimen have objected to the MRO reporting the positive result to the employer. To clarify that the Department intends that the result of the test of a split specimen be reported to both the employer and the employee—regardless of who pays for the test—we propose to add language to this effect.

Electronic Signatures

Various inquiries from drug and alcohol testing industry sources have raised the question of the place that technological developments, such as electronic signatures, should play in the Department's programs. In an electronic signature system, an individul using a pen-like stylus signs an electronic pad connected to a computer system. The signature is recorded electronically by the computer system and incorporated into a data base, without any technical need for a paper signature or printout.

The use of this technology raises a number of issues in the context of the Department's testing programs. Part 40 currently calls for signatures on a multiple-copy paper form, and does not, absent future modification, provide for the use of electronic signatures. Copies of the form are distributed to various parties (e.g., the employer, employee, laboratory, MRO). It is unclear how a ''paperless'' system would provide equivalent service. While one could presumably use an electronic signature device in something short of a literally paperless system, combining electronic signatures with a system using paper forms creates its own set of questions. For example, would there be both a paper and an electronic signature? Would an electronic signature somehow be transferred to the paper form? What efficiencies are gained if one has both an electronic and paper signature?

There are also important issues concerning the security and identification of electronic signatures. What kinds of technical requirements (e.g., electronic encryption for

signatures, computer security software) and operational safeguards (e.g., access restrictions) should surround their use? Should such controls be part of DOT regulations? Are there industry consensus standards that have been or could be developed to address these issues, to which DOT rules could refer? What are the electronic equivalents of the physical security measures and controls the Department requires for paper records?

While the Department is not, at this time, making specific proposals in this area, we are interested in receiving thoughts and information from interested parties on how the Department can best respond to technological changes of this kind that can affect its program. We invite comment on these matters.

Regulatory Analyses and Notices

This is not a significant rule under Executive Order 12866 or under the Department's Regulatory Policies and Procedures. It does not impose costs on regulated parties. It merely clarifies provisions of the regulations and addresses certain administrative problems that have arisen in the drug testing program. There are not sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The Department certifies that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 49 CFR Part 40

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

Issued this 11th Day of July, 1995, at Washington, D.C.

Federico Peña,

Secretary of Transportation.

For the reasons set forth in the preamble, 49 CFR Part 40 is proposed to be amended as follows:

PART 40—[AMENDED]

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

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, 45101–45106.

2. Section 40.25 is proposed to be amended by removing the word ''oral'' from paragraph (e)(2)(i)(A) and by removing the words ''Oral body'' from paragraph (e)(2)(i)(B) and adding ''Body'' in their place.

3. Section 40.25(f)(10)(iv) is proposed to be revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(f) * * *

(10) * * *

(iv)(A)(*1*) 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 a single specimen collection or 45 milliliters of urine for a split specimen collection.

(*2*) If the individual has not provided the required quantity of urine, the specimen shall be discarded. The collection site person shall direct the individual to drink 8 ounces of fluid immediately. The individual shall be directed to drink an additional 8 ounces of fluid each 30 minutes thereafter up to a total of 40 ounces or until the individual has provided a new urine specimen, whichever occurs first. If the employee refuses to drink fluids as directed or to provide a new urine specimen, the collection site person shall terminate the collection and notify the employer that the employee has refused to submit to testing.

(*3*) If the individual has not, within four hours from the time the original insufficient urine specimen was presented to the collection site person, provided a sufficient specimen, the collection site person shall discontinue the collection and notify the employer.

(B) The employer shall direct any employee who does not provide a sufficient urine specimen (see paragraph (f)(10)(iv)(A)(*3*) of this section) to obtain, as soon as practical after the attempted provision of urine, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide an adequate amount of urine.

(*1*) 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 urine, the employee's failure to provide an adequate amount of urine 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.

(*2*) If the physician, in his or her reasonable medical judgment, is unable to make the determination set forth in paragraph (f)(10)(iv)(B)(*1*) of this section, the employee's failure to provide an adequate amount of urine shall be regarded as a refusal to take a test. The physician shall provide a written statement of the basis for his or her conclusion to the employer.

* * * * *

4. Section 40.33 is proposed to be amended by removing and reserving paragraph (b)(2), by revising paragraphs (c)(5) and (c)(6), by designating the existing text of paragraph (f) as paragraph (f)(1), and by adding paragraph (f)(2) to read as follows:

§ 40.33 Reporting and review of results.

* * * * *

(c) * * *

(5) The MRO may verify a test as positive without having communicated directly with the employee about the test in four circumstances:

(i) The employee expressly declines the opportunity to discuss the test;

(ii) Neither the MRO nor the designated employer representative, after making all reasonable efforts, has been able to contact the employee within 30 days of the date on which the MRO receives the confirmed positive test result from the laboratory;

(iii) The designated employer representative has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see paragraphs (c)(3) and (4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative; or

(iv) Other circumstances provided for in DOT agency drug testing regulations.

(6) If a test is verified positive under the circumstances specified in paragraph (c)(5) (ii) or (iii) of this section, the employee may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented the employee from being contacted by the MRO or designated employer representative (paragraph (c)(5)(iii) of this section) or from contacting the MRO (paragraph (c)(5)(iii) of this section) within the times provided. The MRO, on the basis of such information, may reopen the verification, allowing the employee to present information concerning a legitimate explanation for the confirmed positive test. If the MRO concludes that there is a legitimate explanation, the MRO declares the test to be negative.

* * * * *

(f)(1) * * *

(2) If the analysis of the split specimen is reconfirmed by the second laboratory for the presence of the drug(s) or drug metabolite(s), the MRO shall notify the employer and employee of the results of the test.

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[FR Doc. 95–18041 Filed 7–24–95; 8:45 am]

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