

and determinations resulting from arbitration proceedings carried out under this section, upon objection by FIA or the Company, shall be inadmissible as evidence in any subsequent proceedings in any court of competent jurisdiction.

This Article shall indefinitely succeed the term of this Arrangement.

Article IX—Errors and Omissions

The parties shall not be liable to each other for damages caused by ordinary negligence arising out of any transaction or other performance under this Arrangement, nor for any inadvertent delay, error, or omission made in connection with any transaction under this Arrangement, provided that such delay, error, or omission is rectified by the responsible party as soon as possible after discovery.

However, in the event that the Company has made a claim payment to an insured without including a mortgagee (or trustee) of which the Company had actual notice prior to making payment, and subsequently determines that the mortgagee (or trustee) is also entitled to any part of said claim payment, any additional payment shall not be paid by the Company from any portion of the premium and any funds derived from any Federal Letter of Credit deposited in the bank account described in Article II, section E. In addition, the Company agrees to hold the Federal Government harmless against any claim asserted against the Federal Government by any such mortgagee (or trustee), as described in the preceding sentence, by reason of any claim payment made to any insured under the circumstances described above.

Article X—Officials Not to Benefit

No Member or Delegate to Congress, or Resident Commissioner, shall be admitted to any share or part of this Arrangement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Arrangement if made with a corporation for its general benefit.

Article XI—Offset

At the settlement of accounts the Company and the FIA shall have, and may exercise, the right to offset any balance or balances, whether on account of premiums, commissions, losses, loss adjustment expenses, salvage, or otherwise due one party to the other, its successors or assigns, hereunder or under any other Arrangements heretofore or hereafter entered into between the Company and the FIA. This right of offset shall not be affected or

diminished because of insolvency of the Company.

All debts or credits of the same class, whether liquidated or unliquidated, in favor of or against either party to this Arrangement on the date of entry, or any order of conservation, receivership, or liquidation, shall be deemed to be mutual debts and credits and shall be offset with the balance only to be allowed or paid. No offset shall be allowed where a conservator, receiver, or liquidator has been appointed and where an obligation was purchased by or transferred to a party hereunder to be used as an offset.

Although a claim on the part of either party against the other may be unliquidated or undetermined in amount on the date of the entry of the order, such claim will be regarded as being in existence as of the date of such order and any credits or claims of the same class then in existence and held by the other party may be offset against it.

Article XII—Equal Opportunity

The Company shall not discriminate against any applicant for insurance because of race, color, religion, sex, age, handicap, marital status, or national origin.

Article XIII—Restriction on Other Flood Insurance

As a condition of entering into this Arrangement, the Company agrees that in any area in which the Administrator authorizes the purchase of flood insurance pursuant to the Program, all flood insurance offered and sold by the Company to persons eligible to buy pursuant to the Program for coverages available under the Program shall be written pursuant to this Arrangement.

However, this restriction applies solely to policies providing only flood insurance. It does not apply to policies provided by the Company of which flood is one of the several perils covered, or where the flood insurance coverage amount is over and above the limits of liability available to the insured under the Program.

Article XIV—Access to Books and Records

The FIA and the Comptroller General of the United States, or their duly authorized representatives, for the purpose of investigation, audit, and examination shall have access to any books, documents, papers and records of the Company that are pertinent to this Arrangement. The Company shall keep records that fully disclose all matters pertinent to this Arrangement, including premiums and claims paid or payable

under policies issued pursuant to this Arrangement.

Records of accounts and records relating to financial assistance shall be retained and available for three (3) years after final settlement of accounts, and to financial assistance, three (3) years after final adjustment of such claims. The FIA shall have access to policyholder and claim records at all times for purposes of the review, defense, examination, adjustment, or investigation of any claim under a flood insurance policy subject to this Arrangement.

Article XV—Compliance With Act and Regulations

This Arrangement and all policies of insurance issued pursuant thereto shall be subject to the provisions of the National Flood Insurance Act of 1968, as amended, the Flood Disaster Protection Act of 1973, as amended, the National Flood Insurance Reform Act of 1994, and Regulations issued pursuant thereto and all Regulations affecting the work that are issued pursuant thereto, during the term hereof.

Article XVI—Relationship Between the Parties (Federal Government and Company) and the Insured

Inasmuch as the Federal Government is a guarantor hereunder, the primary relationship between the Company and the Federal Government is one of a fiduciary nature, i.e., to assure that any taxpayer funds are accounted for and appropriately expended.

The Company is not the agent of the Federal Government. The Company is solely responsible for its obligations to its insured under any flood policy issued pursuant hereto.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance").

Dated: July 12, 1996.

Harvey G. Ryland,
Deputy Director.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-95-321]

RIN 2105-AC22

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Insufficient Specimens and Other Issues

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

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

DATES: This rule is effective August 19, 1996.

FOR FURTHER INFORMATION CONTACT: Mary Bernstein, Director, Office of Drug Enforcement and Program Compliance, 400 7th Street, SW., Room 10317, 202-366-3784; or Robert Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, 202-366-9306.

SUPPLEMENTARY INFORMATION:

"Shy Bladder"

Background

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 sample collections) 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 (DHHS) 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 results in 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."

In response to these concerns, the Department proposed changing the procedures to 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 (60 FR 38201; July 25, 1995). The employee would be directed to drink 8 ounces of fluid each 30 minutes during this period until the 40 ounce maximum is reached.

We also proposed to incorporate language from the parallel provision of the alcohol testing procedures concerning the task of the physician who evaluates the employee, in order to make the alcohol and drug portions of Part 40 more consistent.

Comments: The Department received substantial comment on this issue, from employers, employee organizations, and medical and testing service providers. Thirty-five comments, mostly from employers and testing service organizations, opposed the proposal to lengthen the time period for collections. Several commenters mentioned that actual shy bladder situations were very rare, meaning that there would be few benefits gained from increasing the time period. On the other hand, a number of commenters, particularly in the transit industry, expressed the concern that the proposed increase to four hours would increase costs for employers. Already, commenters said, some employees stretch out the time spent at the collection site to the maximum two hours, in order to avoid returning to work. If we increased the time, time permitted for this gold-bricking would increase, raising lost-time costs for employers. Some collection sites were concerned about having to remain open longer after hours to accommodate longer shy bladder situations, increasing their overtime and other operating costs. Two medical service providers mentioned that an individual with a normally-functioning urinary system should be able to provide a sufficient sample under the existing rule.

Seventeen commenters, mostly employee organizations but also including some testing service organizations and employers, supported the proposed extension to four hours. They said this would avoid situations, which had happened, of people being unable to provide a sufficient sample in two hours. A longer time frame would also reduce costs by eliminating unnecessary medical referrals, they said. Two testing service industry commenters suggested that three hours would be a reasonable middle ground, while two unions supported eight hours or no time limit at all.

Twenty-one comments, mostly from unions but including some from other sources, supported the NPRM's proposal of having the employee drink 40 ounces of fluid. This would better allow employees to deal with the effects of on-the-job dehydration, they said. One commenter favored upping the fluids to 48 ounces. Twenty-five commenters, mostly employers and testing service organizations, suggested smaller amounts (e.g., 24 or 32 ounces). Some of

these commenters said that increasing the amounts was objectionable because doing so went along with the extended time period, which they opposed. One commenter thought that increasing the water amount could lead to increased numbers of dilute specimens, while two commenters thought 32 ounces provided a better margin of safety with respect to water intoxication. Two comments suggested that the 8 ounces every 30 minutes schedule was too restrictive and difficult to supervise. One commenter favored allowing an additional 8 ounces (or 30 minutes) when an employee claimed dehydration.

Nine commenters favored, and 11 opposed, retaining the existing requirement that employee make a first, unsuccessful attempt at providing a complete sample before the shy bladder procedure and its time period began. Opponents of this requirement, in other words, would start the clock without a first collection attempt, when the employee asserted at the beginning of the collection process that he or she could not provide a sufficient sample. Two comments suggested allowing a first, insufficient, specimen to be combined with a second specimen to form a sufficient specimen as part of the same collection.

There were a number of comments on the subject of the medical evaluations that follow a collection that does not result in a sufficient specimen. The NPRM had suggested that only a medical explanation pertaining to a physiological reason for the inability to provide would be adequate, as distinct from an assertion of "situational anxiety" or other psychological causes. Three comments on this point approved and three disagreed with the NPRM's suggestion. One of the comments that favored limiting the basis for a medical explanation to physiological causes did note, however, that there were situations in which a psychological explanation might be sufficient (e.g., a documented pre-existing condition, diagnosed before the collection in question, that is represented in Diagnostic and Statistical Manual IV).

One union objected to the provision of the NPRM that limits examining physicians to those acceptable to the employer, and two commenters supported having the employer, rather than the MRO, directing the employee to have a post-collection medical evaluation. Two commenters suggested that the employer should receive, from the examining physician, only a conclusory statement about whether there was an adequate medical explanation, rather than a complete

diagnostic work-up. This would help protect the confidentiality of medical information. Three commenters said the medical evaluation should be done promptly after the collection, and two suggested that refusal to attend or cooperate with the evaluation should be regarded as a refusal to test.

There were a number of comments on miscellaneous shy bladder-related subjects. Two commenters supported making the language of the provision parallel to that in the alcohol testing procedures. Two commenters supported, and one opposed, specifying that refusing to drink water, or other non-cooperation, constitutes a refusal to be tested. One comment suggested specifying that only water, and not other drinks, could be consumed. Others suggested using blood tests when enough urine could not be produced and allowing collectors to proceed to other collections while an employee was waiting and drinking before a second attempt.

DOT Response: The basic purpose of the NPRM proposal was fairness to employees. That is, if an employee is unable to produce a sufficient quantity of urine within the two-hour period presently provided, giving the employee a longer time to provide a specimen might allow the employee to produce sufficient urine to avoid the necessity for a medical evaluation and the possibility of a refusal finding. The most significant objection to the proposal in the comments centered on the perception by some employers that employees already spent the maximum time possible at collection sites, apparently with the aim of being paid for not working. If we said that employees could take four hours to provide a sufficient sample, we could look forward to employees taking twice as long off the job, while employers' costs mounted. In addition, having to keep a collection site open for a longer time (e.g., for an employee who came to the site at 4:30 p.m. and forced the site to stay open until 8:30) would increase collection costs.

On the surface, these concerns are plausible. The comments to this effect were impressionistic, however, and were not accompanied by data. There is substantial uncertainty, therefore, about how factually based these concerns are. Recently, the Substance Abuse Program Administrators' Association (SAPAA) shared with us information from a survey they conducted concerning the time it took to complete a DOT collection. The survey results concerned about 18,800 tests conducted over a two-week period at nearly 500 collection sites affiliated with SAPAA.

The mean time reported for a DOT urine collection, from the time the employee started filling out the paperwork (not the time the employee first walked into the collection site) until the time the collection was completed and the employee was told he or she could leave the site, was about 12.4 minutes.

About 1.7% of the collections took 90 minutes or more to complete, and slightly less than a third of these took two hours or more. About 1.2% of the total number of tests were "shy bladder" situations, in which a collection could not be completed because of insufficient volume.

The results of this survey have some limitations. They are not based on a statistically representative sample of collection sites or a scientifically rigorous survey design, and some responses contain ambiguities. They represent a two-week "snapshot" of the experience of the particular collection sites that responded to SAPAA's request. However, the data are suggestive with respect to the "stretch-out" issue raised by commenters.

That is, it does not appear that many tests were stretched out to near or over the two-hour time frame of the existing rule. Indeed, the average running time of tests was far short of the two-hour time frame of the current regulation. Suppose that the time period for shy bladder situations were three or four hours instead of two. Is it reasonable to infer that tests that average 12.4 minutes in length (or even if they averaged twice that duration) would suddenly jump to close to the new maximum? If less than two percent of tests now exceed 90 minutes in a two-hour time period, is it reasonable to infer that a much greater percentage of tests would approach a three or four-hour time period? The likelihood of such dramatic changes appears low. Consequently, while there may be a number of individual instances of employees seeking to prolong their time at collection sites in preference to returning to the job, the available information suggests that this is not a pervasive problem that would lead to prohibitive cost increases if we provided additional time for collections.

Also, given that lengthy collections and shy bladder situations appear to arise in a very small percentage of cases, it appears that cost increases based on keeping collection sites open longer than usual would probably be low. Some SAPAA survey responses, as well as anecdotal information that DOT staff have received, suggests that some collection sites may follow a practice of simply sending an employee home when the normal closing time approaches, even if the employee has

not completed the collection process. This practice is contrary to the rules. Once begun, a collection process must be completed. We also recommend that collection sites begin to process employees as soon as they arrive at the collection site. Some collection sites apparently permit employees to wait a significant period of time before beginning the collection process. Such waiting appears to create inefficiencies and unnecessary costs in the system.

Given that we do not have any data, beyond anecdotal expressions of concern, showing that stretched-out collections are a pervasive problem, and that we have some data that suggest the contrary conclusion, the Department believes the fairness rationale for extending the collection time period is more persuasive, at this time, than the cost rationale for not doing so.

Consequently, the final rule will extend the time period in "shy bladder" situations. In order to minimize any potential adverse effects, the time period will be three hours, rather than four as proposed in the NPRM. Given the medical service provider comments about the speed of urine production, this additional time should provide a comfortable margin of safety to employees who may need additional time to generate a sufficient specimen.

With respect to the amount of fluids to be consumed, the Department will retain the 40 ounce level proposed in the NPRM. This amount could as easily be consumed within a three-hour period as within a four-hour period. As discussed in the preamble to the NPRM, the 40 ounce level is appropriate, in light of evidence in the medical literature concerning water intoxication. Compared to smaller amounts, it offers an enhanced chance of assisting employees in providing a sufficient specimen. It is sufficiently limited that the probability of it resulting in dilute specimens is low. The Department will not mandate the proposed schedule for drinking fluids (i.e., 8 ounces each half hour until the 40-ounce level is reached), out of concern that it would make the collection process unnecessarily complicated to administer. The rule will require simply that the fluids be administered at reasonable intervals throughout the three-hour period. While we anticipate that collection sites will provide water in the vast majority of instances, the Department does not think it necessary to prohibit the administration of other appropriate fluids.

If an employee refuses to drink the water needed to produce a sufficient specimen, it seems clear that the employee is failing to cooperate with

the testing process in a way that can frustrate its completion. The same can be said of an employee who is directed to report for a medical evaluation and either declines to do so or does not comply with the directions of the physician in the course of the examination. In both cases, the Department believes it is appropriate to treat the employee's behavior as a refusal to be tested, which has the same consequences as a positive test. The final rule so provides.

The issue of what constitutes an adequate medical explanation for a failure to provide a sufficient specimen is one that ultimately must be decided by the examining physician on a case-by-case basis. The final rule clarifies the determination the physician must make by providing, first, that a finding of a physiological cause (e.g., urinary system dysfunction) for the insufficient specimen is a ground for making a determination of an adequate medical explanation.

The rule also provides that there are some narrow and limited circumstances in which a psychological explanation will suffice. This is true only in a case where there is documentation of a diagnosed pre-existing psychological disorder (i.e., one designated in DSM IV) that can account for the failure to provide a complete specimen. By a pre-existing disorder, the Department means one the symptoms of which were documented before the shy bladder incident took place. This is to avoid basing determinations solely on information developed after the fact of the collection in question. Assertions of "situational anxiety" or of dehydration are essentially unverifiable, and the final rule directs physicians not to determine that there is an adequate medical explanation based on such assertions.

The Department does not believe there is any compelling reason to require the MRO, as distinct from the employer, to refer an individual for a medical evaluation under this portion of the rules. The employer may delegate this function to the MRO, and in many cases it might be efficient to do so. In other cases, however, the MRO may not be conveniently located to the employer and/or employee, and would not know appropriate physicians in their vicinity. However, the evaluating physician, if someone other than the MRO, would provide the results of the evaluation to the MRO, rather than directly to the employer. The MRO would then provide his or her conclusion to the employer, as under the current rule.

Allowing urine from different voids to be combined increases the possibility of

error or contamination in the collection process, and is, in any event, inconsistent with the DHHS guidelines. The Department also declines to change the requirement that employees attempt to provide a specimen at the beginning of the collection process. Forty-five ml. is not a tremendous amount of urine. Many employees who do not subjectively feel ready to do so may well be able to provide such an amount. In any case, the failure of the first attempt to provide a sufficient specimen is a clear, easily understandable point to start the clock for the three hour time period for the shy bladder procedure. A new collection kit would be used for the second or any subsequent attempts at collecting a complete specimen.

The rule contemplates the following sequence of events. For example, the employee arrives at the collection site at 1:45 p.m. The employee and collection site person begin the testing process by filling out the initial portions of the chain of custody and control form. The collection site person directs the employee to go to the bathroom and provide a specimen (whether or not the employee claims to be "ready" to do so). The employee returns the collection container to the collection site person.

It is now 2 p.m. If the employee asserts that he or she has tried and failed to produce a specimen or the specimen is short of the required amount of urine, the employee will have until 5 p.m. (i.e., three hours from the time the employee returned the initial collection container to the collection site person) to drink up to 40 ounces of fluid and make another attempt to provide a sufficient specimen. The Department emphasizes that collection site personnel should not attempt to hurry the process unreasonably. There have been instances in which, by asking an employee to "try again" too soon, a collection site person has created a situation in which the employee produces two or three "short" specimens instead of one complete specimen. Collection site personnel should take care to avoid this problem.

The Department believes that commenters made good suggestions concerning limiting information provided to employers, allowing collectors to work on other tests while an employee was waiting and drinking, and requiring medical examinations to take place promptly after the collection. The final rule incorporates these comments. On the other hand, the Department believes it is necessary to retain the requirement that the examining physician be acceptable to the employer. Employers have the responsibility for the safety of their

operations and for compliance with the Department's rules. Employees may have an incentive to shop for a friendly evaluation. The Department has consistently declined to permit the use of blood tests in the context of alcohol testing, and we believe, for much the same set of reasons, that it is inadvisable in the context of drug testing. Under the Omnibus Employee Testing Act of 1991 and Part 40, only urine drug testing is permitted.

Body Temperature

Currently, § 40.25(e)(1)(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. Because 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, the NPRM proposed to delete the word "oral," with the result that taking the individual's temperature by any medically-accepted means (including oral) would be permitted.

Eleven comments supported the proposal and none opposed it. Four comments suggested that the use of rectal thermometers should be precluded or limited, because of the intrusiveness and unpleasantness of that method. We agree with these comments, and the final rule adopts the proposal with that modification.

MRO/Laboratory Relationships

The NPRM contained a discussion of MRO/laboratory relationship issues, including a proposal to delete § 40.33(b)(2), which could cause confusion in relation to the more recent and definitive language of § 40.29 (n)(6), which prohibits laboratory/MRO conflicts of interest. The NPRM also asked questions about how the Department could best frame regulatory provisions on this general subject.

The four commenters who mentioned the proposal to delete § 40.33(b)(2) all agreed with it. The Department is adopting this proposal. Eleven commenters favored either existing provisions requiring laboratories and MROs to be independent of one another or of adding more stringent requirements on this subject. Some of these commenters mentioned other relationships that concerned them, such as those between MROs and consortia/third-party administrators, collectors, or employers. On the other hand, six other commenters favored liberalizing MRO/laboratory relationship rules, permitting

laboratories to refer MROs to clients, for example.

The marketplace for drug testing services has changed considerably since the Department issued its original rules, with mergers producing ever-larger laboratories and a strong trend towards integration of services manifesting itself. While these changes are understandable in economic terms, the Department is concerned lest checks and balances fundamental to the fairness and integrity of the Department's rules be compromised. In a forthcoming proposal to revise and update Part 40, the Department anticipates taking a comprehensive look at the relationships among MROs, laboratories, employers, consortiums and third-party administrators, collection sites, and other parties in the testing service business to determine how best to preserve needed checks and balances. The Department is not taking further final action at this time, however.

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.

As noted in the NPRM, 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 proposed 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 would be instructed to verify the laboratory result positive and report it to the employer as such. The same provisions allowing the employer to reopen the verification would apply as in the case where the employer did contact the employee and the employee failed to contact the MRO within 5 days.

Twenty-eight commenters, all of whom were employers or testing industry companies, favored the proposal, one mentioning that they currently have 115 unresolved tests on record that they could close out under such a provision. Only one commenter, a union, opposed it as too harsh on workers. Of the supporters, nine favored the proposed 30-day time period while the remaining 19 favored shorter periods, mostly ranging from five to 15 days. The Department will adopt the proposal, while reducing the time period to 14 days. This reduction is made in the interest of safety, as well as to enable employers and others to have reasonably expeditious closure in the process. A month seems like an unnecessarily long time to hold such a case open: an employee who is out of touch and unavailable for that amount of time likely does not want to be contacted. On the other hand, the five-day period proposed by some commenters (parallel to the time an employee is given to contact the MRO after being told to do so) may be too short, since employees might often have legitimate reasons for being out of contact for that length of time. In any case, the employee will have the opportunity to re-open the matter for good cause, as the NPRM provided.

Seven commenters supported, and three opposed, treating confirmed opiate positives the same as confirmed positives for other drugs for this purpose. While the MRO verification procedure is different for opiates, the employee has an obligation in all cases to participate in the verification process. Employees who, without adequate justification, are unavailable to participate in the verification process should be treated the same, regardless of the drug for which they tested positive. For this reason, the Department will not differentiate among drugs in this provision.

Some commenters made procedural suggestions concerning this provision. For example, two commenters discussed sending certified mail letters to employees to officially start the clock with respect to the time period. While doing so may be a reasonable step for employers to take, the Department will not require it, lest we introduce more procedural complexity, and opportunity for administrative error, into the system.

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—the NPRM proposed to add language to this effect.

Ten commenters, all employers and testing service companies, supported the proposal, while two unions opposed it, saying that the employee should be able to keep the report from the employer in this circumstance. The Department does not agree with these latter two comments. All drug testing results pertain to the safety of the transportation services provided by employers. The employer is responsible for compliance with these regulations. In the Department's view, the employer, in order to perform its functions under DOT safety rules, must have access to

all results of the drug testing process. The Department's rules do not specify who ultimately pays for testing services, including tests of split specimens, but the identity of the person making payment is irrelevant to how the results are treated under the rules. Both the employer and the employee have a need to know the outcome of all tests that are part of the system, and the final rule adopts the NPRM proposal.

Program participants continue to raise a number of other questions about carrying out the split sample requirements of Part 40. In the Part 40 revision project, the Department will consider clarifying changes to the regulatory text itself. Meanwhile, the Department would like to take this opportunity to repeat guidance it has provided on certain split sample-related issues.

First, when an employee makes a timely request to the MRO for a test of the split specimen, the MRO is required to pass on the request to the laboratory possessing the specimen, which is required to send the specimen to a second DHHS-certified laboratory, which is required to test the split specimen. The employer is responsible for making sure that all actions required under the regulations occur.

Consequently, while the Department's rules do not specify who ultimately must pay the cost of testing the split specimen, the employer is responsible for ensuring payment in the first instance. For this reason, if the employee chooses not to pay "up front" for the test of the split specimen, the employer must ensure, nevertheless, that the test takes place. An employer, MRO, or laboratory cannot require, as a prerequisite to conducting the test of a split specimen, that the employee first produce payment. Subsequently, the employer could seek reimbursement from the employee.

Second, the rule is silent with respect to who chooses the second laboratory at which the split specimen is tested. The rule does not give employees a right to choose a particular laboratory (though such a laboratory could be designated in a labor-management agreement). All the rule requires is that the second laboratory be certified by DHHS; whether it is chosen by the employer, employee, MRO, or first laboratory does not matter from the point of view of Part 40.

Third, a technical problem that sometimes occurs in testing of split samples is that samples may occasionally fail to reconfirm because of differences in specific methodologies or equipment among laboratories. Each laboratory has one or more methods for

clearly identifying drug metabolites in a specimen and dealing with impurities in the specimen that may delay or interfere with clearly identifying the metabolites (so-called "derivitization" methods). The chemical composition of urine samples differs from one specimen to another, however, and may change with the age of the specimen. The derivitization method used by a given laboratory may, on infrequent occasions, not work well enough on a particular specimen to identify a drug metabolite clearly enough to meet quality control guidelines that tell the laboratory when they may call a test positive.

If Laboratory A has identified the primary specimen as positive, but Laboratory B, because of the problem described above, believes that the drug or metabolite is present in the split specimen but cannot call it positive, is it appropriate for Laboratory B to send it to Laboratory C for further analysis?

DOT and DHHS representatives, at a November 1995 conference with laboratory representatives, said that, in such a situation, after consultation with the MRO, referral to Laboratory C was appropriate. Reconfirmation by Laboratory C would be recognized under Part 40. To avoid the necessity for such a procedure, the Department strongly recommends that participants take care to ensure that the laboratory that tests the split specimen be one that uses the same methods as the laboratory that determined that the primary specimen was positive.

Electronic Signatures

The NPRM asked for comments on the issue of the use of electronic signatures in the drug and alcohol testing process (e.g., to sign alcohol testing forms). In the NPRM, the Department noted that, in an electronic signature system, an individual (e.g., the employee taking an alcohol test) using a pen-like stylus signs an electronic pad connected to a computer system (e.g., attaching the electronic signature to an electronic version of the alcohol testing form). 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 NPRM noted a number of issues that this kind of application may raise in the context of the Department's testing programs. For example, Part 40 currently calls for signatures on a multiple-copy paper form, and does not 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?

The NPRM also mentioned 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?

Six commenters to the NPRM favored the use of these technologies, and four others thought the idea was worth exploring. Several commenters in both categories mentioned a number of issues, such as security, legal sufficiency of electronic signatures, confidentiality safeguards, etc., that should be worked out. It is fair to say that the comments did not thoroughly address the questions and concerns the Department has on this issue.

The Department believes that electronic signature technology has promise, and that, together with industry, we should continue to explore and discuss its use in the DOT alcohol and drug testing program. Meanwhile, we emphasize that pen-and-ink signatures on hard copy forms are mandatory in the program. The use of electronic signatures by any participant in the program (e.g., the collector, donor, BAT, STT, MRO, certifying scientist) is not currently authorized. Any testing services company that uses electronic signatures is acting contrary to the express requirements of DOT regulations, and employers who use the services of a testing services company that uses electronic signatures are out of compliance with these rules.

Regulatory Analyses and Notices

This is not a significant rule under Executive Order 12866 or under the Department's Regulatory Policies and Procedures. 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. The basis of this certification is that the changes to the shy bladder procedure, as noted above, are unlikely to significantly increase program costs for regulated entities, and the other changes to the rule are minor or technical and should not have any measurable cost impacts.

List of Subjects in 49 CFR Part 40

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

Issued this 9th day of July, 1996, at Washington, DC.

Federico Peña,
Secretary of Transportation.

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

PART 40—[AMENDED]

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

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

2. Section 40.25 is amended by removing the word "oral" from paragraph (e)(2)(i)(A) and paragraph (e)(2)(i)(B), and adding after the word "temperature," in paragraph (e)(2)(1)(A), the following words: "(taken by a means other than use of a rectal thermometer)".

3. Section 40.25(f)(10)(iv) is 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 the specimen 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 up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, 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 employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the 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 possible after the attempted provision of urine, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's 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. For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration. The physician shall provide to the MRO a brief written statement setting forth his or her conclusion and the basis for it, which shall not include detailed information on the medical condition of the employee. Upon receipt of this statement, the MRO shall report his or her conclusions to the employer in writing.

(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 to the MRO a brief written statement setting forth his or her conclusion and the basis for it, which shall not include detailed information on the medical condition of the employee. Upon receipt of this statement, the MRO shall report his or her conclusions to the employer in writing.

* * * * *

4. Section 40.33 is 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 (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 three 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 14 days of the date on which the MRO receives the confirmed positive 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 (c)(4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative.

(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)(ii) 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 metabolites(s), the MRO shall notify the employer and employee of the results of the test.

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[FR Doc. 96-18015 Filed 7-18-96; 8:45 am]

BILLING CODE 4910-62-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 960129018-6018-01; I.D. 071596A]

Groundfish of the Gulf of Alaska; Pacific Ocean Perch in the Central Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting retention of Pacific ocean perch in the Central Regulatory Area of the Gulf of Alaska (GOA). NMFS is requiring that catches of Pacific ocean perch in this area be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the Pacific ocean perch total allowable catch (TAC) in the Central Regulatory Area of the GOA has been reached.

EFFECTIVE DATE: 1200 hrs, Alaska local time (A.l.t.), July 15, 1996, until 2400 hrs, A.l.t., December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the GOA (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

The TAC for Pacific ocean perch in the Central Regulatory Area of the GOA was established by the Final 1996 Harvest Specifications of Groundfish (61 FR 4304, February 5, 1996), as 3,333 metric tons. (See § 679.20(c)(3)(ii).)

The Director, Alaska Region, NMFS, has determined that the TAC for Pacific ocean perch in the Central Regulatory Area of the GOA has been reached. (See § 679.20(d)(2).) Therefore, NMFS is requiring that further catches of Pacific ocean perch in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action is taken under 50 CFR 679.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 15, 1996.

Richard W. Surdi,
Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96-18305 Filed 7-15-96; 4:54 pm]

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