

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