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U.S. Department of Transportation
Federal Railroad Administration

Memorandum

Date: JUL 23 1993 Reply to Attn. of: OP-93-05

Subject: Seriological or DNA Testing of Urine Samples

From: Edward R. English
Director, Office of Safety Enforcement

To: Regional Directors

The attached letter to Mr. Ronald P. McLaughlin, President of the Brotherhood of Locomotive Engineers (BLE), deals with the issue of whether individual specimens collected under current procedures should be available for testing to determine seriological characteristics or for DNA classification. It is provided as interpretive guidance to Operating Practices Specialists and Inspectors in the discharge of their drug and alcohol enforcement duties.

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RRS-10

U.S. Department of Transportation
Federal Railroad Administration

Office of the Administrator

400 Seventh St., S.W.
Washington, D.C. 20590

MAY 6 1993

Mr. Ronald P. McLaughlin
International President
Brotherhood of Locomotive Engineers
Standard Building
Cleveland, Ohio 44113-1702

Dear Mr. McLaughlin:

Thank you for your March 5 letter enclosing an arbitration decision and asking if additional testing may be performed on urine samples obtained pursuant to Federal Railroad Administration (FRA) testing programs. Though you raised the question in the context of a single case, FRA has received correspondence from another inquirer suggesting a desire to utilize serological or DNA testing quite routinely to challenge otherwise unquestioned positive drug test results. Because of that background, we are writing at greater length and in more detail than might otherwise be appropriate to respond to your inquiry.

The testing of urine specimens pursuant to FRA random, pre-employment, return-to-duty, follow-up, and reasonable cause provisions is governed by 49 CFR Part 219 (Subpart H) and the Department of Transportation (DOT) regulation "Procedures for Transportation Workplace Drug Testing Programs" 49 CFR Part 40. As you know, these requirements are patterned after Department of Health and Human Services (DHHS) guidelines.

Urine specimens obtained pursuant to FRA/DOT regulations may not normally be tested for other substances. See 49 CFR Part 40.21(c). Part 40 requires that urine specimens be tested for five drugs for which DHHS has developed testing protocols. It is designed to protect the integrity of the testing process and protect employees from unreasonable constitutional searches by testing for other drugs or substances. These protections are further assured by the requirement that any analysis (for drugs of abuse or adulteration) be performed in laboratories certified and monitored by DHHS.

DOT's urine collection and drug testing protocols (49 CFR sections 40.23 and 40.25) contain specific chain of custody procedures designed to ensure that the sample tested is, in fact, that of the donor. The Medical Review Officer is responsible for reviewing the basic documentation (chain of custody and lab report) prior to verifying any positive result. In any investigation or grievance process, the employee (or his/her representative) has complete access to the litigation package prepared by the laboratory, which contains all of the documentation pertaining to that specific specimen.

If proper procedures are followed and documented, donor identity is established and specimen integrity is protected. In light of the disputed facts in the Ireland arbitration, we will assume for discussion that a colorable issue might remain as to whether a specimen could have been adulterated upon aliquoting (a very unlikely possibility given standard laboratory procedures). Collection of a split specimen, as proposed in a pending DOT regulatory proposal under the Omnibus Transportation Employee Testing Act of 1991, should provide excellent additional assurance that this possibility will not occur without remedy. That is, an early retest of the "split" by another laboratory would resolve the issue of any claimed adulteration at the laboratory.

The question remains whether individual specimens collected under current procedures should be available for testing to determine serological characteristics or for DNA typing. FRA's review of current scientific literature regarding serological and DNA testing of urine raises questions regarding the effectiveness of such testing.

There is no standardization in DNA testing procedures among various laboratories and no standard methodology for ensuring internal or external quality control (such as the open and blind proficiency testing currently used to test DHHS certified laboratories). This is not to say that DNA testing is not performed with a high degree of reliability at a small number of laboratories, but the capability is not generally available. Additionally, urine is a poor body fluid to use for DNA analysis. Environmental factors, such as microbial contamination, exposure to light, exposure to heat, and age of specimen could impact on the quality of urine DNA testing. Although the state of the art in urine DNA testing is improving, experts tell us that, at the present time, only rarely will results of DNA testing of occupational urine specimens be meaningful.

Statistical probability work suggests that in many cases serological testing will not provide a meaningful result. We are advised that urine serology can be technically difficult and misleading, and laboratories vary in their technical capabilities to render satisfactory interpretations.

Therefore, FRA believes that *routine* use of these techniques is not warranted, since the percentage of incidents where donor identity could be resolved through additional testing is small. Even where testing was conclusive so as to establish that the urine did not come from the donor of record, the better decision in most cases of unobserved collections would be that the *donor* adulterated or substituted the specimen at the collection site.

The question of further analysis of an *individual specimen*, in the case of a contested proceeding involving legitimate issues of fact, stands on a different footing. DOT has not opposed compliance by employers with orders of courts and administrative law judges to provide specimen material for additional analysis in connection with review of decisions relying on positive drug test results. In such cases, a threshold showing will normally have been made to warrant further examination of the specimen. Further, careful supervision by the court or administrative body can ensure that the analysis conducted is as meaningful as possible, given the nature of the specimen and limitation of the science, and that the analysis is subject to appropriately secure procedures (both as to the original specimen and fresh body fluids offered for comparative analysis). It was in anticipation of such circumstances that DHHS, DOT, and FRA provided for retention of the specimen well after completion of any drug of abuse retest (i.e., for one year, or greater on request or upon notice of legal challenge).

Any question regarding a contested Federal drug test for a locomotive engineer might eventually be at issue with respect to a certificate action appealed to FRA. The question of further testing could be presented in that context for review and decision.

Finally, DOT is currently re-examining urine testing procedures in Part 40 in response to the Omnibus Transportation Employee Testing Act of 1991. On December 15, 1992, DOT published a Notice of Proposed Rulemaking asking for comment on proposed revisions to Part 40. Any comments that you wish to submit to the docket would be welcome. An additional opportunity for comment on Part 40 changes is expected in the near future, as well.

Sincerely yours,

S. Mark Lindsey
Acting Administrator