(ii) A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period.

(iii) If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period shall be apportioned to each cost reporting period.

(iv) An example of the computation of interest using the effective interest method follows:

Facts

Life of zero coupon bond: 15 years.

Value at maturity: $50,000.

Bondholder pays $6,996 for the bond.

Annual interest rate is 13.5506% compounded semi-annually.

From the table below, interest for the first year would be $980.11 ($474.00 plus $506.11).

Col 1 Six-month periods	Col 2 Book value beginning of period	Col. 3 Effective interest*	Col. 4 Book value end of period (columns 2 + 3)
1	$6,996.00	$474.00	$7,470.00
2	7,470.00	506.11	7,976.11
3	7,976.11	540.40	8,516.51
4	8,516.51	577.02	9,093.53
29	43,855.94	2,971.37	46,827.31
30	46,827.31	3,172.69	50,000.00

*Computed by multiplying the book value at the beginning of each period (Column 2) by 6.7753% (the annual interest rate of 13.5506% 2 = 6.7753%).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 23, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 96–17895 Filed 7–15–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

49 CFR Part 40

[OST Docket No. OST–96–1532]

RIN 2105–AC37

Amendments to Laboratory Certification Requirements

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: This final rule establishes provisions that would permit drug testing laboratories located outside the U.S. to participate in the Department's drug testing program. The Department of Transportation would take action permitting the laboratories to participate based on recommendations from the Department of Health and Human Services.

EFFECTIVE DATE: This rule is effective on July 16, 1996.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Room 10424, (202–366–9306); 400 7th Street, SW., Washington DC 20590; or Mary Bernstein, Director, Office of Drug Enforcement and Program Compliance, same street address, Room 10317, (202) 366–3784.

SUPPLEMENTARY INFORMATION: Recently, the Federal Highway Administration (FHWA) issued a final rule applying its drug and alcohol testing requirements to foreign-based drivers operating in the United States (60 FR 49322; September 22, 1995). Under the rule, Canadian and Mexican drivers who come into the United States will be subject to testing on the same basis as U.S. drivers, beginning July 1, 1996, for employees of larger carriers and a year later for employees of smaller carriers.

In any case, Canadian and Mexican employers who collect drug urine specimens under FHWA rules will be able to have the specimens tested in U.S. laboratories certified by the Department of Health and Human Services (DHHS), on the same basis as U.S. employers. In the interest of facilitating program implementation, the Department hopes that it will be possible for Mexican and Canadian laboratories to participate in the program as well. (If Canadian and Mexican laboratories are not authorized to participate in the program as provided in this rule, Canadian and Mexican employers must send specimens to DHHS-certified laboratories in the U.S. for testing.)

Canadian and Mexican laboratories may participate in the DOT-mandated testing program only if their participation is consistent with the Department's statutory authority. Strict safeguards for the accuracy and quality of laboratory tests are a key mandate of the Omnibus Transportation Employee Testing Act of 1991.

The motor carrier portion of the Act (49 U.S.C. 31306(b), which parallels the other modal sections of the Act), provides that, in carrying out the requirement to establish a motor carrier drug testing program , the Secretary ''shall'' develop requirements ''that shall''

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing; * * *

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section.

(3) require that a laboratory involved in testing under this section have the capability and facility, at the laboratory, of performing screening and confirmation tests; * * *

The language of these provisions is clearly mandatory, a point which the legislative history reinforces. Senate Report 102–54 (May 2, 1991), concerning S. 676, the bill that became the Act, notes, in response to concerns about testing accuracy and false positive tests, that ''By incorporating laboratory certification and testing procedures developed by HHS and DOT * * * the Committee has taken affirmative steps to ensure accuracy.'' (S. Rept. 102–54 at 7.) Later, in speaking of the laboratory and other safeguards in the bill, the report says that

These safeguards are critical to the success of any testing program. They are designed to ensure that * * * there is accountability and accuracy of testing. They provide what the Committee believes are the basic minimums * * * the Secretary is urged to carefully review the safeguards in any testing program to ensure they are adhered to in a vigorous manner. (*Id.* at 31)

More specifically on laboratory matters, the Committee said that

Incorporating the HHS guidelines relating to laboratory standards and procedures * * * as DOT has done in Part 40 * * * is an essential component of the procedural safeguards specified in this subsection.* * * Realizing that these guidelines may be subject to future modification, the Committee has acted to specify that the basic elements of certain provisions now in effect are mandated, including the need for comprehensive standards and procedures for all aspects of laboratory testing of drugs * * * [and] the establishment of standards and procedures

for the periodic review of laboratories and the development of criteria for laboratory certification or revocation of such certification. (*Id.* at 32)

It is noteworthy that Congress explicitly accepts an active DOT role in establishing and carrying out the laboratory-related provisions of the statute. What is mandatory is not that one agency or the other play any particular administrative role in the process, but that the protections embodied in the DHHS guidelines be applied, through DOT's rules, to participants in the program. There is no bar in the statutory language to a DOT rule assigning to DOT the task of reviewing and certifying laboratories, so long as these actions by DOT are based on the conformity of the laboratories to DOT's incorporation of DHHS laboratory standards. Consequently, DOT has broad legal discretion to take action in the area of drug testing procedures, extending to the certification of laboratories.

DOT and DHHS are working closely together with respect to the potential certification of foreign laboratories. As the two agencies envision the process, there could be two different ways in which foreign laboratories become certified. First, DHHS could review the application of the foreign laboratory, in the same manner that it reviews applications from U.S. laboratories. If the laboratory meets DHHS standards, DHHS would recommend that DOT certify the laboratory under DOT authority. (The direct certifying authority of DHHS extends only to laboratories that would participate in the Federal employee testing program.) Second, DHHS could review the standards and procedures of a foreign certifying agency. If DHHS determined that the foreign agency had standards, procedures, and authority equivalent to those of DHHS, DHHS would recommend to DOT that DOT deem the foreign agency to be an equivalent certifying authority. Laboratories that the foreign agency certified would then be permitted to participate in the DOT testing program.

DOT and DHHS have discussed laboratory issues with officials of Transport Canada, the Canadian Trucking Association and its affiliates, and the Standards Council of Canada (a potential laboratory certification organization in Canada), as well as representatives of some Canadian laboratories. We have also had discussions with Mexican officials concerning program and laboratory matters. Following these discussions, the Department proposed a change to 49 CFR 40.39 to accommodate the possibility that foreign laboratories may be able to participate in DOT-mandated drug testing (61 FR 13809; March 28, 1996).

The NPRM proposed to add a new paragraph to authorize the participation of foreign laboratories in the DOT drug testing program in the two circumstances outlined above (i.e., based on a recommendation by DHHS that a particular laboratory meets DHHS certification requirements, or based on a certification by a foreign certifying organization whose standards and process had been deemed equivalent to those of DHHS). The Department received three comments on the proposal, all of which supported it. Two of the comments sought assurances that the rule would result in foreign laboratories that fully met all DHHS requirements, including periodic inspections and re-certifications.

The Department is adopting the proposal without change. The rule will result in full compliance with DHHS procedures and standards for laboratory certification by foreign laboratories authorized to participate in the program, including inspection and re-certification provisions. It should be emphasized that the rule does not have the effect of actually certifying any foreign laboratories. It simply puts in place a mechanism that would allow such laboratories to participate, if and when DOT and DHHS determine that all issues had been resolved satisfactorily, in full compliance with DHHS requirements for laboratory certification. Once authorized to participate in the DOT drug testing program by this process, a Canadian or Mexican laboratory would be on the same footing as any DHHS-certified laboratory concerning program participation, including the ability to test specimens collected in the U.S. by U.S. employers.

Regulatory Process Matters

The proposed rule is considered to be a nonsignificant rulemaking under DOT Regulatory Policies and Procedures, 44 FR 11034. It also is a nonsignificant rule for purposes of Executive Order 12886. The Department certifies, under the Regulatory Flexibility Act, that the rule does not have a significant economic effect on a substantial number of small entities. The rule does not impose any costs or burdens on regulated entities, since it deals with a subject (applying for laboratory certification) that is completely voluntary. Laboratories that are able to meet DHHS standards are typically not small entities, in any case. The rule makes it possible for Canadian and Mexican motor carriers to use laboratories that are closer to them than laboratories in the U.S., which may result in somewhat lower costs for these carriers, which include some small entities. The rule has also been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The rule is being made effective immediately. The Department has good cause to do so, on the basis that in order to give the Department the opportunity to authorize foreign laboratories to participate in the DOT drug testing program by the July 1, 1996, compliance date for Canadian and Mexican motor carriers, the Department needs this rule to be in place. Making this rule effective now will permit the Department to respond in a timely way if DHHS determines that foreign laboratories or certifying organizations meet DHHS standards. Even if foreign laboratories are not in a position to be approved for participation by July 1, it is important that the Department's authority to approve foreign laboratories be in place, as a matter of good faith on our part toward our trading partners.

List of Subjects in 49 CFR Part 40

Drug Testing, Alcohol Testing, Reporting and Recordkeeping Requirements, Safety, Transportation.

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

1. The authority citation for part 40 continues to read as follows:

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

2. Section 40.39 is revised to read as follows:

§ 40.39 Use of certified laboratories.

(a) Except as provided in paragraph (b) of this section, employers subject to this part shall use only laboratories certified under the DHHS ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' April 11, 1988, and subsequent amendments thereto.

(b) Employers subject to this part may also use laboratories located outside the United States if—

(1) The Department of Transportation, based on a written recommendation from DHHS, has certified the laboratory as meeting DHHS laboratory certification standards or deemed the laboratory fully equivalent to a laboratory meeting DHHS laboratory certification standards; or

(2) The Department of Transportation, based on a written recommendation

from DHHS, has recognized a foreign certifying organization as having equivalent laboratory certification standards and procedures to those of DHHS, and the foreign certifying organization has certified the laboratory, pursuant to those equivalent standards and procedures.

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

Federico Peña,

Secretary of Transportation.

[FR Doc. 96–18063 Filed 7–15–96; 8:45 am]

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