of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 25, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.609 is amended by revising the following entries in the table in paragraph (a)(1) to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Peanut	0.02
* * * * *	
Peanut, refined oil	0.06
* * * * *	

* * * * *

[FR Doc. 2012–10704 Filed 5–3–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2010–0026]

RIN 2105–AE14

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: 6-acetylmorphine (6–AM) Testing

AGENCY: Office of the Secretary, DOT.

ACTION: Interim final rule.

SUMMARY: The Department is amending certain provisions of its drug testing procedures for 6-acetylmorphine (6–AM), a unique metabolite of heroin. Laboratories and Medical Review Officers (MROs) will no longer be required to consult with one another regarding the testing for the presence of morphine when the laboratory confirms the presence of 6–AM. This rule is intended to streamline the laboratory process for analyzing and reporting 6–AM positive results and will facilitate MRO verification of 6–AM positive results.

DATES: The rule is effective July 3, 2012. Comments to this interim final rule should be submitted by June 4, 2012. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., West Building Ground Floor Room W12–140, Washington, DC 20590–0001;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329;

Instructions: You must include the agency name and docket number DOT-OST–2010–0026 or the Regulatory Identification Number (2105–AE14) for the rulemaking at the beginning of your comments. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE., Washington, DC 20590; 202–366–3784 (voice), 202–366–3897 (fax), or *bohdan.baczara@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

For its drug testing regulation, the Department of Transportation (DOT) is required by the Omnibus Transportation Employee Testing Act of 1991 (Omnibus Act) to incorporate the laboratory testing protocols and standards established by the U.S. Department of Health and Human Services (HHS). The Omnibus Act requires that we utilize HHS-certified laboratories and that we follow the HHS Mandatory Guidelines for identifying the specific drugs for which we test and the scientific methodologies the laboratories must use for testing. Because of these requirements and to create consistency with certain aspects of the new HHS Mandatory Guidelines effective October 1, 2010 [73 FR 71858], the DOT published its final rule on August 16, 2010 [75 FR 49850], also effective October 1, 2010, to harmonize with many aspects of the revised Mandatory Guidelines.

One item with which the DOT harmonized was the laboratory testing for 6-acetylmorphine (6–AM) without a morphine marker. 6–AM is a unique metabolite produced when a person uses the illicit drug heroin. Prior to the October 1, 2010 rulemaking, both HHS and DOT regulations required the laboratory to first test for morphine, and if it detected morphine at the HHS/DOT cutoff of 2000ng/mL, the lab would then test for 6–AM.

In our final rule, we discussed the concern some commentors had about whether morphine needed to be present with a confirmed positive 6–AM result. We discussed the data and studies submitted to the docket addressing the question of whether there was research or studies showing that morphine must also be present and at what quantitations. As stated at 75 FR 49856, based on the comments to the docket and multiple scientific publications, the facts were:

- 6–AM confirmed positive tests do not need a morphine marker;
- Data showed that when one looks for morphine as a marker, it most always exists above the morphine confirmation cutoffs or above Limit of Detection (LOD); and
- If the morphine marker does not exist on a 6–AM positive result, there is ample scientific reason to strongly suggest recent heroin use.

We decided that, until more experience was gained with the new testing procedures for 6–AM, we would place additional requirements on the laboratories and the MROs. Specifically, when morphine was not detected at the HHS/DOT cutoff of 2000ng/mL, we added a requirement for the laboratory and MRO to determine whether morphine was detected at the laboratory's LOD. If morphine was not detected at the laboratory's LOD, the laboratory and MRO were to report that result to DOT's Office of Drug and Alcohol Policy and Compliance (ODAPC). After consulting with ODAPC, the MRO would make a verified result determination, keeping in mind that there is no legitimate explanation for 6–AM in the employee's specimen [see § 40.151(g)].

Policy Discussion

From the October 1, 2010 effective date of the final rule through September 30, 2011, ODAPC has received, on average, 14 results per month from the laboratories and MROs that a specimen was positive for 6–AM with no morphine at the laboratory's LOD. During this period, we learned that the laboratory LODs ranged from 100ng/mL to 600ng/mL, and were set in accordance with National Laboratory Certification Program guidance to them.

As part of our monitoring process and with the varying LODs in mind, DOT worked with HHS to have their contractor, RTI International (RTI), conduct a study of those DOT specimens reported to ODAPC as confirmed positive for 6–AM and negative for morphine. The scope of the study was ''* * * to verify the atypical results obtained by the laboratories, to determine if other drugs or metabolites present in the specimen could explain the absence of morphine, and to determine if something other than heroin use could explain the presence of 6–AM.'' [1] The study consisted of aliquots (from the A bottles) of DOT specimens received by the laboratories between October and December 2010 and reported by the laboratory to the MRO as confirmed positive for 6–AM and negative for morphine.

The study reconfirmed the presence of 6–AM in all the specimens. By reconfirming the 6–AM results, the study confirmed ''* * * that the presence of 6–AM in these specimens was not due to laboratory contamination or 6–AM production during analysis.'' Morphine levels of >5ng/mL were also detected in all but 6 of the specimens. For these 6 specimens, the report went on to say that, ''While atypical for heroin exposure and metabolism, the remaining 6 specimens' results are consistent with literature reports of atypical 6–AM results after heroin exposure.'' The authors determined that other drugs or metabolites present in the specimen were not responsible for the absence of morphine. Furthermore, the study concluded, ''There was no evidence indicating that the 6–AM originated from a source other than heroin.'' [2]

Based upon these facts and research-based conclusions, there is no longer a need for laboratories to detect the present of morphine below the HHS/DOT established morphine cutoff of 2000ng/mL and for MROs to confer with ODAPC on verifying these 6–AM results. Based on the RTI study, morphine may be present below the laboratory's LOD. As we indicated in the preamble of the final rule [75 FR 49856], for those specimens where morphine was not present we believe there is a scientific explanation. Therefore, we will amend 49 CFR 40.87 and 40.97 to say that if the laboratory confirms a specimen as positive for 6–AM, and morphine is not at or above the 2000ng/mL cutoff, the laboratory will report the specimen results to the MRO without any additional testing for morphine. We will also revise 49 CFR 40.139 and remove section 40.140. Furthermore, the MRO will conduct the verification as he or she would for any other laboratory confirmed positive test result, with the understanding there is no legitimate explanation for the presence of 6–AM in the employee's specimen regardless of the morphine result.

Regulatory Analyses and Notices

Authority

The statutory authority for this rule derives from the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

Administrative Procedure Act

The Department has determined this rule may be issued without a prior opportunity for notice and comment because providing prior notice and comment would be unnecessary, impracticable, or contrary to the public interest since this rule was thoroughly discussed in a prior final rule effective October 1, 2010 [75 FR 49850]. This rule will reduce the burden on laboratories and MROs since it will remove certain provisions of the drug testing regulation which currently require the laboratories and MROs to confer with each other and ODAPC regarding laboratory tests positive for 6–AM with no morphine at the laboratory's LOD. It will also remove requirements for further laboratory testing where 6–AM is detected without the presence of morphine.

Providing an opportunity for prior notice and comment before publishing this interim final rule (IFR) would be unnecessary since it is based upon a final rule [75 FR 49850, August 16, 2010] that followed public notice and comment. In that rule we indicated we would determine what our first year of testing would reveal regarding the screening and confirmation testing of 6–AM and the presence of morphine. The first year has passed and from the information provided by the laboratories and MROs, and the collaborative scientific study with HHS, we learned morphine may be present below the laboratory's LOD. In addition, for those few specimens where morphine was not present the study stated that such results were consistent with literature reports of atypical 6–AM results after heroin use.

Providing an opportunity for notice and comment before publishing this IFR is also unnecessary since it makes only minor procedural and burden-relieving amendments to the rule text. Specifically, the rule will no longer require laboratories and MROs to consult with one another regarding the testing for the presence of morphine when the laboratory confirms the

[1] Anomalous Results of Morphine and 6-Acetylmorphine in Urine Specimens, Abstract at the 2011 Joint Meeting of Society of Forensic Toxicologists (SOFT) & The International Association of Forensic Toxicologists (TIAFT), San Francisco, CA, September 25–30, 2011.

[2] *Ibid.*

presence of 6–AM. In addition, laboratories and MROs will no longer be required to notify ODAPC of 6–AM only positive results.

Executive Order 12866 and Regulatory Flexibility Act

This Interim Final Rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. The rule makes minor procedural amendments to its rule text. The rule will impose no new burdens on any parties, and will actually decrease the burden upon the laboratories and the MROs. The Department consequently certifies, under the Regulatory Flexibility Act, that this rule does not have a significant economic impact on a substantial number of small entities.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 24th Day of April 2012, at Washington, DC.

Ray LaHood,

Secretary of Transportation.

For reasons discussed in the preamble, the Department of Transportation amends Title 49 of the Code of Federal Regulations, Part 40, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority citation for 49 CFR part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

§ 40.87 [Amended]

■ 2. In § 40.87 remove paragraph (e).

§ 40.97 [Amended]

■ 3. In § 40.97 remove paragraph (g).

■ 4. Section 40.139 is revised to read as follows:

§ 40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory confirms the presence of 6-acetylmorphine (6–AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6–AM, if the laboratory confirms the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (e.g., poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

(c) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (i.e., morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (c)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (c)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph (c). If you cannot make this determination (e.g., there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

§ 40.140 [Removed]

■ 5. Remove § 40.140.

[FR Doc. 2012–10665 Filed 5–3–12; 8:45 am]

BILLING CODE 4910–9X–P