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Dated: October 25, 2005.

Brent Fewell,

Acting Assistant Administrator Office of Water.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-2003-15245]

RIN 2105-AD55

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing to amend certain provisions of its drug and alcohol testing procedures to change instructions to laboratories, medical review officers, and employers with respect to adulterated, substituted, diluted, and invalid specimen results. These proposed changes are intended to create consistency with specimen validity requirements established by the U.S. Department of Health and Human Services and to modify some measures taken in two of our own interim final rules. This NPRM also proposes to make specimen validity testing mandatory within the regulated transportation industries.

DATES: Comments to the notice of proposed rulemaking should be submitted by December 30, 2005. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may submit comments [identified by DOT DMS Docket Number 15245] by any of the following methods:

- Web Site: <http://dms.dot.gov>. Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1-202-493-2251.

- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-0001.

- Hand Delivery: Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to <http://dms.dot.gov>, including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Jim L. Swart, Deputy Director (S-1), Office of Drug and Alcohol Policy and Compliance, 400 Seventh Street, SW., Washington, DC 20590; telephone number 202-366-3784 (voice), 202-366-3897 (fax), or jim.swart@dot.gov (e-mail).

SUPPLEMENTARY INFORMATION:

Purpose

In its final rule of December 2000 [65 FR 79526], the U.S. Department of Transportation (DOT) made specimen validity testing (SVT) mandatory for the transportation industry contingent upon U.S. Department of Health and Human Services (HHS) publishing its Mandatory Guidelines on SVT. In late 2001, the DOT amended part 40 [66 FR 41952, August 9, 2001] to remove the mandatory requirement because HHS had not finalized its Mandatory Guidelines regarding SVT. We said that

SVT would remain authorized but not required.

On April 13, 2004, HHS published a **Federal Register** notice revising its Mandatory Guidelines [69 FR 19644] with an effective date of November 1, 2004. Among the revisions contained in the HHS Mandatory Guidelines were the requirements that laboratories modify substituted specimen and diluted specimen testing and reporting criteria. HHS revised laboratory requirements for adulterated specimen testing. HHS also required each Federal agency to conduct specimen validity testing (SVT) to determine if urine specimens collected under HHS Federal Workplace Drug Testing Programs have been adulterated or substituted.

In an interim final rule (IFR) [69 FR 64865] published on November 9, 2004, the DOT changed a number of items in part 40 to make part 40 and the HHS Mandatory Guidelines consistent. We did this to avoid conflicting requirements that implementation of both rules would have had on laboratories and medical review officers (MROs).

In the 2004 IFR, we indicated that we intended to fully address all aspects of the HHS changes to their Mandatory Guidelines in a notice of proposed rulemaking (NPRM). We also indicated that we would also take into consideration any subsequent HHS handbook materials (e.g., HHS MRO Manual) and update our cost figures for SVT in the context of making SVT mandatory. In this NPRM, we have considered the HHS Guidelines as well as the HHS MRO Manual, we propose to make SVT mandatory, and we have updated our cost figures accordingly.

In the 2004 IFR and an earlier IFR [68 FR 31626] from May 28, 2003, we solicited comments regarding SVT and substituted specimens. We will address the docket comments to both IFRs in this preamble.

Background

We issued the 2003 IFR in order to respond to scientific and medical information suggesting we modify testing criteria for some specimens that had been considered to be substituted and ultimately were treated as refusals to test. The 2003 IFR modified how MROs would deal with any substituted result with creatinine concentration greater than or equal to 2 mg/dL. It did not change the HHS substitution criteria that we had used.

In the 2004 IFR, we changed a number of items in part 40 to harmonize part 40 and the new HHS Mandatory Guidelines on SVT to avoid a number of inconsistent requirements that the

application of both rules would likely have created for laboratories and MROs. While the HHS Mandatory Guidelines approach to substituted test results allowed DOT to simplify its guidance to MROs on how to deal with those results, there were several important items upon which the 2004 IFR and the HHS Guidelines differed. The most important among them was the fact that SVT, though authorized by part 40 and the IFR, was not yet required.

The 2000 part 40 anticipated that HHS would, sometime in 2001, amend its Mandatory Guidelines to establish SVT requirements for HHS-certified laboratories. When it appeared that HHS would not establish final SVT requirements in 2001, we amended part 40 to remove the mandatory requirement. This was because we believed it was advisable to wait until HHS completed its amendment before making SVT mandatory throughout the transportation industries for all DOT specimens. This NPRM proposes that SVT be made mandatory, as the DOT said it intended to do in its final rule of December 2000.

Principal Policy Issues

Harmonization With HHS

In this NPRM we have sought to harmonize our SVT proposals for laboratories, MROs, and employers with the requirements contained in the HHS Mandatory Guidelines and the HHS Medical Review Officer Manual. Here are the most noteworthy of the coordinated proposals:

1. We propose to make SVT mandatory—like it is now with the HHS Federal employee testing program.

2. We would continue to utilize HHS instructions to laboratories for establishing and directing laboratory actions for SVT. We will also continue to look to HHS for establishing appropriate cutoffs. An HHS-certified laboratory's testing equipment and SVT parameters are all HHS-driven. Our proposed tables related to adulterated and invalid laboratory results are primarily designed to explain and instruct HHS criteria rather than establish new criteria.

3. We propose to modify some of our definitions and add a few new definitions in order to make them consistent with HHS Mandatory Guidelines definitions.

4. We would continue to require laboratories to contact MROs when the laboratories find specific types of invalid results.

5. Regarding multiple results actions and reporting for primary specimens, we would generally adopt HHS

procedures both for laboratories and MROs. Uniquely to part 40, we propose "categories" of results in order to make it easier for MROs to understand what they are to do when verifying laboratory results and reporting their verified results.

6. Regarding the numerous possible laboratory and MRO actions for split specimens, we would generally adopt HHS procedures both for laboratories and MROs. As with primary specimen results, we propose categories of split results designed to make it easier for MROs to verify and report results.

7. We propose to clarify that split testing is still not offered for invalid results. The HHS MRO Manual makes this a clear point.

8. We propose that if a second invalid result (collected under direct observation) occurs but for a different reason than the first invalid result, the verified result of the test event will be a refusal. This is also consistent with the HHS MRO Manual.

9. We propose to adopt HHS blind specimen certification criteria.

10. We propose to adopt HHS Semi-Annual Laboratory Report items.

While we have sought to harmonize our requirements with those of HHS, there remain a few issues for which we have not proposed changes to procedures that were in the 2004 IFR or in part 40. Perhaps the most important one is that we have not proposed to modify the requirement that MROs treat laboratory reported negative-dilute results with creatinine levels greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL (hereafter "2–5mg/dL range") as negative-dilutes that require immediate recollections under direct observation. We also have not proposed changes to the employer policy recollection option for other negative-dilutes. By contrast, HHS treats all negative-dilutes in the same fashion—a Federal agency may collect the employee's specimen under direct observation during the employee's next scheduled test event.

While we believe there are employees normally able to produce these 2–5 mg/dL range negative-dilute specimen results, there are others who cannot produce them without tampering with their specimens. We are also aware of challenges an employer faces in tracking an employee's test selection in order to have the next collection directly observed, especially as time passes between testing events. Therefore, some negative-dilutes will continue to require recollection under direct observation while others may continue to follow the employer policy options of immediate

recollections not under direct observation.

There is also a difference between the HHS Mandatory Guidelines and this NPRM concerning how we intend to address an MRO's receiving a series of invalid test results from the same employee for the same testing event. If the employee presents two invalid results for the same reason or when the employee has a long-term medical condition that causes an invalid result, we propose a way to have MROs obtain a negative result if one is needed for pre-employment, return-to-duty, and follow-up testing. Also, we propose to have MROs deal with an invalid result when the specimen is also positive, substituted, and/or adulterated.

For instance, the HHS MRO Manual directs MROs to report negative results if the initial invalid results and the subsequent directly observed results are invalid for the same reason. The DOT will continue to consider these to be cancelled tests because laboratories do not report invalid-negative results. If a negative result is needed because the testing event is pre-employment, return-to-duty, or follow-up, the NPRM proposes to have the MRO determine if there is clinical evidence that the employee is an illicit drug user. We propose the same clinical evidence determination if the employee has a long-term medical condition that causes the invalid result and needs a negative result. These clinical evidence evaluations are proposed to be identical to the evaluation currently required at § 40.195 when an employee is unable to provide a sufficient amount of urine because of a permanent or long-term medical condition.

Like HHS, we would have MROs follow review procedures, as appropriate, for all laboratory reported results and to report all verified results to employers. But unlike HHS, we propose having an exception that deals with MROs reporting multiple results when one of them is invalid. The NPRM would not require an MRO to report an invalid result if the MRO also verifies any other laboratory result for the specimen as positive and/or refusal to test. MROs have told us it is problematic for them to report cancelled-invalid tests in conjunction with positives or refusals. MROs and employers have questioned whether the required recollection under direct observation needs to take place.

We have not proposed adopting the HHS MRO Manual requirement that an MRO report a negative result if the medical explanation for a substituted specimen appears legitimate to the MRO. We believe that HHS has taken

ample measures to accurately identify substituted specimens by adjusting the creatinine concentration criteria laboratories need in order to report specimens as substituted. Part 40 will continue to have MROs report these verified results as cancelled, and report their determinations and basis for them to us. If the DOT begins to receive reports that MROs are canceling substituted specimen results because of legitimate medical reasons, we would be prepared to take measures needed for employees to obtain negative results (when negatives are needed for pre-employment, return-to-duty, and follow-up testing), perhaps by considering ways for MROs to determine if there is clinical evidence that an employee is an illicit drug user.

Making SVT Mandatory

As we said in 2000, mandatory laboratory testing for specimen validity is an appropriate response to those who would tamper with the DOT's drug test results. Again, we propose the same position. It was the correct position in 2000, and we think it is the correct position now. Over the past several years, there have been an increasing number of products designed and marketed to adulterate specimens. Currently, there are more than 400 different products available for adulterating specimens, although many contain the same component adulterants. There are also devices marketed with the promise to hide drug use by substituting "clean" urine for a drug user's own urine. The cheating industry is real, and we must counter it. Furthermore, cheating on a drug test through adulteration or substitution is a deliberate and direct attempt to thwart the testing process. Therefore, we are proposing to require SVT for all DOT specimens.

In their Mandatory Guidelines, HHS established SVT requirements with which laboratories must comply in order to become and remain HHS-certified. HHS has stated that their SVT standards are designed to produce the most accurate, reliable, and correctly interpreted test results. Currently, when DOT specimens are tested for validity, the SVT adheres to HHS procedural standards.

In 2000, we estimated an annual cost associated with SVT of about \$1.4 million. At that time, a majority of HHS-certified laboratories were already conducting SVT. The larger laboratories, who were receiving the vast majority of transportation industry specimens, were all conducting SVT. These facts led us to estimate approximately 80% of

industry specimens were being tested for specimen validity in 2000.

Because employers are deeply concerned about specimen tampering and because HHS certification relies (in part) upon a laboratory's ability to conduct SVT, we estimate that an even higher percentage of transportation industry specimens are undergoing SVT now than in 2000. We estimate that 95% of industry specimens are undergoing SVT, up from 80% in 2000.

That higher percentage coupled with the fact that fewer specimens are being collected now than were collected in 2000, leads us to believe the increased cost of requiring SVT for those specimens not currently undergoing SVT will be even less than our 2000 cost estimate. There were 6.67 million industry tests conducted in 2005, down from 7 million industry tests in 2000. Therefore, we estimate that the cost of new SVT will be about \$1 million, down from the \$1.4 million figure estimated in 2000.

2003 IFR Comments to the Docket

The comments to the May 28, 2003 IFR were generally supportive of the DOT's decision to modify the creatinine levels required to call a substituted specimen "a refusal to test." Some supported the DOT's diligence in pursuing the subject of creatinine levels of substituted specimens, and a few others expressed the desire to do away with SVT altogether. Another commenter said we were making an accommodation for a situation that was likely not to exist, so this commenter recommended that the DOT make no change with regard to substituted specimen refusals.

Most comments to the docket expressed, in one form or another, the desire to have SVT laboratory standards developed and issued in final guidance by HHS. That way, commenters reasoned, all laboratories would be responsible for adhering to the SVT standards and would be held accountable for them. These commenters had a variety of opinions related to the cutoff levels and testing ranges for SVT. Most indicated that they had provided similar comments to HHS when it proposed SVT for the Mandatory Guidelines. A few commenters discussed procedural issues for MROs in dealing with substituted specimens with creatinine in the 2–5 mg/dL range and with the period of time the IFR allowed for an employee's obtaining a required for medical evaluation.

Additionally, several comments (from an employee, two employee associations, and an attorney) expressed

the desire to have the DOT remedy the records of employees whose refusals to test prior to May, 2003, had been the result of having substituted specimens. Their specific gravity levels had been in the substituted range, but their creatinine had apparently been in the 2–5 mg/dL range. At least two commenters brought up issues totally unrelated to SVT.

2004 IFR Comments to the Docket

The comments to the November 9, 2004 IFR, especially those from laboratories, were favorable about the DOT's decision to take measures to align part 40 with HHS SVT procedures. One association requested that we go further with the alignment by making SVT mandatory rather than leaving it optional. One Third Party Administrator (TPA) recommended that we provide guidance on who (e.g., employer, laboratory, TPA) makes the decision to authorize SVT.

Two MROs favored the DOT's decision to keep their 2003 IFR requirement to order an immediate recollection under direct observation when a verified negative-dilute that contained creatinine in the 2–5 mg/dL range. One of those MROs spoke about what he considered the high rate of positive results for those recollections. However, one employee association was opposed to the recollection requirement for creatinine in the 2–5 mg/dL range. In fact, the association wanted the DOT to do away with the below 2 creatinine substitution criteria established by HHS, in essence wanting there to be no specimens considered substituted. Additionally, the association also expressed a desire to have the DOT expunge the records of those employees with substitution refusals prior to May, 2003. Their specific gravity levels had been in the substituted range, but their creatinine had tested in the 2–5 mg/dL range.

A laboratory requested that we require laboratories to report quantitative values on all dilutes (not just negative-dilutes) because, in the event a positive-dilute was downgraded by the MRO, the creatinine level would be important for the MRO to know. About negative-dilutes, one of the MROs suggested the category of dilute specimens having creatinine above 5 mg/dL was superfluous to the process. He suggested doing away with that category of dilute results altogether.

One of the TPAs recommended the Department find an easier way for employers to determine which laboratories use two SVT methodologies, rather than one, so that the number of invalid results would be

kept to a minimum. The TPA recommended that HHS amend its laboratory certification list to accommodate this request. Also, the TPA recommended that we use [for example], “As an MRO, you must “* * *” throughout part 40 as a means of making it easier to figure out whose actions are being directed.

DOT Response to the 2003 and 2004 IFR Comments to the Docket

A major factor in the DOT's decisions to withdraw part 40's mandatory SVT (in 2001) and to create the 2003 IFR regarding MRO actions on laboratory reported substituted specimens was the fact that HHS had not finalized or updated SVT in their Mandatory Guidelines. Likewise, our decisions to establish the 2004 IFR—which served to bring part 40's SVT more in-line with the HHS—and to write this NPRM were based upon the fact that HHS finalized and published its Mandatory Guidelines effective November 1, 2004.

The HHS Mandatory Guidelines have gone far toward alleviating many of the concerns of the commenters. Specifically, IFR commenters explained that no mandatory SVT standards existed for laboratories to follow. They were also concerned that the DOT program operated with different SVT criteria than the HHS program. They noted the laboratories were not certified for their abilities to conduct SVT, and that appropriate procedures and cutoff criteria for SVT had not been established by HHS. Under the new HHS Mandatory Guidelines, HHS has set mandatory SVT standards. HHS certification depends upon laboratory SVT capabilities (among other things), and HHS has established appropriate SVT reporting criteria and cutoff levels.

Nonetheless, there will continue to be some disagreement between those who desire to have no SVT and those who believe the established SVT criteria are not stringent enough. However, we are proposing that all DOT specimens be tested for all SVT, and that those tests will follow procedures and cutoff criteria established in the HHS Mandatory Guidelines. We believe the HHS has presented well-reasoned Mandatory Guidelines and have, in the preamble to that document, forthrightly explained their ongoing review and analysis of SVT results and scientific criteria.

Also, we believe the Mandatory Guidelines work well in harmonizing with the 2000 part 40's positions to make SVT mandatory, to grant employees the right of MRO review and split specimen testing for SVT, and to provide (in certain instances) for the

retesting of the primary specimen for SVT if the split specimen fails to reconfirm a drug metabolite. In addition, the Mandatory Guidelines reflect the DOT's desire (as made operational by the 2003 IFR) to change the creatinine criteria needed (in addition to the long-required specific gravity criteria) to call a specimen substituted.

IFR issues related to a laboratory's use of two SVT methodologies versus one, MRO and employer actions with negative-dilute specimens having creatinine in the 2–5 mg/dL range, and laboratories reporting creatinine values for positive-dilute specimens are fully expanded in a later section called Other NPRM Issues and Questions.

Regarding the 2004 IFR comment asking us to clarify which persons or entities currently provide authorization for a laboratory to conduct SVT under the DOT program, the authorization comes from part 40. Having said that, until part 40 makes SVT mandatory (rather than authorized), employers need to take active roles in determining the SVT they want laboratories to conduct on their behalf. The contracts between employers and laboratories are important. A laboratory needs to let employers know the SVT available to them and whether the laboratory uses two separate methodologies or one when conducting SVT. The more prudent employers will likely select a full range of SVT. The DOT appreciates the fact that most DOT-regulated specimens are undergoing SVT and would encourage employers to conduct the full range of SVT.

Finally, the DOT views the NPRM as an opportunity to consider our positions on SVT and propose modifications accordingly. It was not our intention to conduct a full review of part 40. Nor was it our intention to focus on issues that fall under the sole purviews of HHS Mandatory Guidelines (e.g., the contents of the HHS laboratory listing) and DOT agency regulations (e.g., the make-up of “actual knowledge” provisions). Therefore, we have no responses to IFR comments addressing such topics.

DOT Response to 2003 and 2004 IFR Comments Requesting That the Department Rectify Past Substitution Refusals

In both the 2003 and 2004 IFRs, there were calls for the DOT to take action to rectify what several commenters believed to be a mischaracterization of some employee refusals to test. Some of the comments suggest that we take measures to clear employee records of refusals to test if their substituted refusals showed creatinine in the 2–5

mg/dL range and those refusals were reported between September 1998 and May 2003.

For this discussion, there are several important time-lines and actions to take into consideration:

1. In September 1998, HHS established guidance regarding laboratory testing requirements for determining if a urine specimen should be reported to the MRO as being substituted. Specimens had two testing criteria in order to be reported as substituted: The specimen's creatinine level must have been 5 mg/dL or less *and* the specimen's specific gravity must have been less than or equal to 1.001 or greater than or equal to 1.020.

2. In December 2000, part 40 implemented procedures for MRO review and for split specimen testing for SVT, to include substituted specimens. Therefore, employees could show MROs that they had medical reasons for producing the result and proof they could naturally produce substituted specimens. By doing so, their results would be cancelled.

3. We issued the 2003 IFR so that MROs would not treat substituted specimens with creatinine concentration in the 2–5 mg/dL range as substituted specimens.

4. Nearly a year later, HHS revised their Mandatory Guidelines with an effective date of November 1, 2004. Among the revisions contained in the HHS Mandatory Guidelines was the requirement that laboratories modify substituted specimen criteria. As a result, there are no specimens with creatinine levels greater than or equal to 2 mg/dL being reported by laboratories as substituted.

The question now is whether we should so do something about those employees who may have been incorrectly charged with refusing their drug tests because they had substituted specimens with creatinine in the 2–5 mg/dL range. The answer is that we should.

Consequently, the DOT will issue an Informational Notice, separately from this NPRM, directing action on this matter. The notice permits employees to present information to us showing that they had a refusal to test before May 2003. The reason for the refusal must be based upon the employee's having a substituted specimen result with a creatinine concentration in the 2–5 mg/dL range. Employees will also have to present proof that they are able to produce such specimens by virtue of medical evaluations. If the DOT determines that an employee's refusal fell within these parameters and the supporting documentation shows that

the employee can produce such specimens, we will reconsider the employee's original refusal-to-test result.

Section-by-Section NPRM Issues

1. Index Changes—We would modify some existing section headings and added three new section headings in order to reflect regulation text changes. All told, eight section headings have been modified or added.

2. Definition changes—In order to align more closely our definitions section (§ 40.3) with definitions contained in the HHS Mandatory Guidelines, we propose to modify some of our existing definitions and add some new ones. Eleven definitions would be modified or added to harmonize with HHS definitions.

3. SVT Mandatory—We would make SVT mandatory by removing the option to conduct SVT (at § 40.89) and adding text requiring SVT. This text is similar to the wording that had been removed from part 40 in 2001.

4. Adulterant and Invalid Testing Cutoffs—We propose to add two tables (one at the existing § 40.95, the other at a new § 40.96) which will serve to inform MROs and others about the cutoffs and procedures laboratories are directed by HHS to use in reporting adulterants and invalid test results. However, we seek comment on whether this information will be helpful to MROs and other service agents or whether it will prove to be too much information that is too complicated to add value to the testing process.

5. Primary Specimen Laboratory Results—Laboratories are reporting and MROs are reviewing a variety of test results, to include multiple test results for the same testing event. We believe that proposed changes to § 40.97—which highlight categories of primary results—and the sections related to medical review and reporting, especially §§ 40.159(f) and 40.162, will make it easier for laboratories and MROs to understand how to deal with and report multiple test results. Comments from MROs regarding these categories of results will prove especially useful to us.

6. Reporting Invalid Results with No Employee Interview—MROs have informed us of situations in which neither they nor the employers were able to contact employees to complete the interview process for invalid results. These MROs have wondered how they are to close these results. We propose to modify § 40.133 so that invalids will be handled parallel to part 40's directives on positive, adulterated, and substituted

specimens when the employee cannot be interviewed.

7. Closing the Invalid Loops—The NPRM addresses the issues an MRO faces when the employee produces a second invalid result after providing a recollection under direct observation because of an initial invalid result. The NPRM also addresses what an MRO is to do after an invalid test result is cancelled by the MRO because of a legitimate reason and a negative result is required (i.e., because the test type is pre-employment, return-to-duty, or follow-up).

a. Regarding a second invalid result for the same reason, we would amend § 40.159 to require the MRO to report the test result as canceled after confirming with the collector that the collection had been properly observed.

b. Regarding a second invalid result for a different reason, we would amend § 40.159 to require the MRO to report the test result as a refusal after confirming with the collector that the collection had been properly observed. At § 40.191, we would add this to the list of what constitutes a refusal to take a DOT test. This refusal requirement is in alignment with the HHS MRO Manual.

c. Regarding obtaining a negative result when a valid test result cannot be produced and a negative result is needed, we propose to add a new § 40.160 which requires the MRO to determine if there is clinical evidence that the individual is an illicit drug user. The evaluation requirements in this section would be parallel to existing part 40 requirements at § 40.195 when a permanent or long term medical condition is the cause of the inability to provide a sufficient specimen and a negative result is needed. Like § 40.195, the medical procedures would apply only when a negative result is needed for pre-employment, return-to-duty, and follow-up testing. Also, we seek comments about findings of illicit drug use during these medical evaluations. Currently, a finding of illicit drug use during the medical evaluation under § 40.195 causes the test to be cancelled. Should the DOT continue to require that the tests be cancelled or treat them as positives?

8. Split Specimen Results—Because of the myriad of possible test results, perhaps no section of the HHS Mandatory Guidelines is more complex than the one dedicated to split specimens. In the NPRM, we have attempted to categorize the split results—much the same way we did for the primary results—in order to make it easier for MROs to understand their responsibilities should they receive any

of the more complicated split result possibilities. Comments from MROs regarding these categories of results will prove especially useful to us. Also, we seek comments on whether a table in the Appendix would help make the MRO's split specimen requirements easier to understand.

a. We would amend § 40.171 to state that there is no split specimen testing for an invalid result. This is consistent with current part 40 split request procedures and with the HHS MRO Manual.

b. We propose to amend §§ 40.177, 40.179, and 40.181 so that a provision currently contained only in § 40.177 is expanded to the adulterated and substituted split sections. Under the proposal, we would provide authorization for the split laboratory to forward the split specimen or a portion of it to another HHS-certified laboratory if the split fails to reconfirm the presence of validity criteria. We believe the provision fits well into these adulterated and substituted sections. We seek comment on whether providing authorization to the split laboratory would be sufficient, or should the DOT require them to forward the split specimen or portion of it.

c. The NPRM would simplify the many possibilities for split specimen results by placing them into five distinct categories in § 40.187. One category contains MRO actions for split specimens that reconfirm all or some of the primary specimen results. Another contains MRO actions when the split fails to reconfirm all the primary specimen results because drugs were not detected and/or validity criteria were not met. The third category outlines MRO actions when the split fails to reconfirm all the primary specimen results and the split is reported as invalid, adulterated, and/or substituted. A fourth category details actions an MRO is to take when the split fails to confirm some but not all of the primary specimen results and the split is also reported as invalid, adulterated, and/or substituted. The final category delineates MRO responsibility when the split specimen is not available for testing or there is no split laboratory available to test the split specimen.

d. The NPRM would modify § 40.187 so that if a split fails to reconfirm all primary results but is reported as substituted, the MRO will be required to follow medical review procedures for substituted specimens and offer retest of the primary specimen if the MRO verifies the result as a refusal to test. This requirement is the same as the current part 40 procedures for MRO and laboratory actions after the split fails to

reconfirm the primary results but is reported as adulterated.

9. Recollections—In §§ 40.197 and 40.201, we propose to change the regulation to clarify issues related to recollections for dilute specimens, for splits that are reported as invalid, and for a situation in which there is no split laboratory available to test the split specimen.

10. Appendix Items—At Appendix B, we propose to modify the semi-annual laboratory report so that it will have the same information required by the HHS Mandatory Guidelines. The three proposed changes, while not dramatic, will help laboratories avoid needing two different report formats, one for DOT and one for HHS. We would also amend some Appendix F citations so that they will accurately reflect NPRM text changes.

Other NPRM Issues and Questions

1. MROs, TPAs, and collectors have asked the Department to clarify issues of multiple results reporting. Multiple results can be reported by laboratories because of several reasons. For instance, two collections (one unobserved, the other observed) occur during the same testing event because the first collection was out of temperature range or showed signs of tampering; a primary specimen had multiple test results; or a test result was one that required a subsequent collection.

We believe the NPRM clearly delineates our proposals for MRO actions in multiple results situations and would like to have your comment about them. However, we also want to know your thoughts about the relative worth of continuing to have the collector send in two specimens (i.e., a temperature out of range specimen or one that showed signs of tampering and the subsequent observed specimen) instead of sending only the specimen collected under direct observation.

Do the complications caused by linking (or failure to link) the two collections outweigh the possibility that the initial specimen will be non-negative while the observed specimen will be negative or cancelled? What are some of the complications employers and MROs have experienced by having two different results on the two specimens for the same testing event? Can MROs report the verified results for two specimens for the same testing event on the same report? Do we simply need to make it clearer in part 40 that a non-negative result(s) for one specimen takes precedence over a negative or cancelled result for the other specimen?

2. Invalid result rates have risen slightly and adulterated specimen rates decreased slightly since HHS required laboratories to utilize two separate SVT methodologies before they can report results as adulterated. If the laboratory identifies the possible presence of adulterant in a urine specimen using one testing methodology, they will call the specimen invalid. This does not apply to pH testing using a pH meter for both the initial and confirmation tests. Please provide us with your comments on the benefits of requiring all laboratories conducting DOT testing to utilize two methodologies for SVT (except pH) or for directing employers to use only laboratories that employ two methodologies. What will be the associated costs to laboratories and employers for requiring laboratories to utilize two methodologies?

For invalid results, are required recollections under direct observation timely enough to identify drug use? Before laboratories report invalid results, are they contacting MROs (as required by the DOT and HHS) to discuss if sending the specimen to another HHS-certified laboratory will be useful?

3. We propose no change to the 2004 IFR in the treatment of negative-dilute specimens with creatinine in the 2–5 mg/dL range as needing to be recollected under direct observation. The result of the second specimen will continue to be the result of record even if it is again negative-dilute. MROs have informed us that a number of the recollected observed specimens have produced positive results. Some of the reports we have received indicate that while some employees can normally produce specimens with creatinine in the 2–5 mg/dL range, others cannot achieve those results without tampering with their specimens. We are interested in your comments as to whether the DOT should continue to require recollection under direct observation for these negative-dilute results.

Are the negative-dilute recollections under direct observation yielding results that show employee drug use? Given the threat to public safety, what percentage of positive results on these recollections would be considered too low to justify conducting them?

4. Neither DOT nor HHS has required laboratories to report numerical values for creatinine and specific gravity for positive-dilute specimens, like we do for negative-dilute results. When MROs downgrade positive results to negative based upon legitimate medical reasons for these positive-dilute specimens, there is no additional MRO action because the dilute numerical values are

not reported. Therefore, employers are not able to take the additional recollection actions afforded other negative-dilute specimen results.

Should MROs have the same reporting responsibilities for downgraded negative-dilute results as they have for any other negative-dilute result? Should employers have the same responsibilities to recollect under direct observation when the creatinine concentration is in the 2–5 mg/dL range or the same recollection options if creatinine is above 5 mg/dL?

5. Realistic-looking prosthetic devices which hold and heat urine (or water mixed with powdered urine) are available for purchase and are known to have been used during observed collections. They are available in a variety of colors making them difficult to detect. We are interested in your comments as to the appropriateness of having a collector make sure that the employee is not using a prosthetic device during an observed collection.

For example, would it be appropriate to require that collectors and observers, as appropriate, check for these devices by having male employees lower their pants and underwear just before observed collections take place? What should be the consequence if a device is found?

Regulatory Analyses and Notices

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 45101 et seq. and the Department of Transportation Act (49 U.S.C. 322).

This rule is not significant for purposes of Executive Order 12866 or the DOT's regulatory policies and procedures. It proposes modifications to our overall part 40 procedures and is intended to further align our laboratory and MRO procedures with those requirements that are being directed by HHS. Their economic effects will be negligible. Consequently, the DOT certifies, under the Regulatory Flexibility Act, this rule will not have a significant economic impact on a substantial number of small entities.

In the 2000 part 40, we estimated that approximately 80% of industry specimens were being tested for SVT and that the costs associated with making SVT mandatory would be about \$1.4 million annually. Current estimates are that 95% of industry specimens are already undergoing SVT on a voluntary basis. This higher percentage, coupled with the fact that fewer specimens are being collected now than were collected in 2000, leads us to believe the

incremental cost of SVT for those specimens not currently undergoing SVT will be even less than our 2000 cost estimate. There were 6.67 million industry tests conducted in 2005, down from 7 million industry tests in 2000.¹ Therefore, we estimate that the annual cost of new SVT will be about \$1 million.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://dms.dot.gov>.

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.

Dated: October 21, 2005.

Norman Y. Mineta,
Secretary of Transportation.

49 CFR Subtitle A—Authority and Issuance

For reasons discussed in the preamble, the Department of Transportation proposes to amend part 40 of Title 49 Code of Federal Regulations, as follows:

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

1-2. The authority citation for 49 CFR Part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

3. Section 40.3 is proposed to be amended by revising the definitions of "adulterated specimen," "confirmation (or confirmatory) drug test," "confirmation (or confirmatory) validity test," "dilute specimen," "initial drug test," "initial validity test," "invalid result," and "substituted specimen" and adding definitions for "limit of detection," "non-negative specimen," "oxidizing adulterant," and "screening

test" in alphabetical order, all to read as follows:

§ 40.3 What do the terms in this regulation mean?

* * * * *
Adulterated specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.
* * * * *

Confirmatory drug test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine).

Confirmatory validity test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.
* * * * *

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.
* * * * *

Initial drug test (also known as a Screening drug test). An immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Initial validity test. The first test used to determine if a urine specimen is adulterated, diluted, or substituted.

Invalid result. Refers to the result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.
* * * * *

Limit of Detection (LOD). The lowest concentration at which an analyte can be reliably shown to be present under defined conditions.
* * * * *

Non-negative specimen. A urine specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), and/or invalid.
* * * * *

Oxidizing adulterant. A substance that acts alone or in combination with

other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine, halogens, peroxidase, and peroxide.
* * * * *

Screening drug test. See Initial drug test definition above.
* * * * *

Substituted specimen. A specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.
* * * * *

4. Section 40.23 is proposed to be amended by revising paragraph (f) introductory text and adding paragraph (f)(5), to read as follows:

§ 40.23 What actions do employers take after receiving verified test results?

* * * * *
(f) As an employer who receives a drug test result indicating that the employee's specimen was cancelled because it was invalid and that a second collection must take place under direct observation—
* * * * *

(5) You must ensure that the collector conducts the collection under direct observation.
* * * * *

5. Section 40.83 is proposed to be amended by revising paragraph (g)(2) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *
(g) * * *
(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with § 40.97(a)(3).
* * * * *

6-7. Section 40.89 is proposed to be amended by revising paragraph (b) to read as follows:

§ 40.89 What is validity testing, and are laboratories required to conduct it?

* * * * *
(b) As a laboratory, you must conduct validity testing.

8. Section 40.95 and its heading are proposed to be revised to read:

§ 40.95 What are the adulterant cutoff concentrations for initial and confirmation tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for the initial and

¹ The lower number of tests may result from two factors. First, the 2000 number was an estimate, while the 2005 number is based on actual reporting. It is possible that the 2000 number was on the high side. Second, the operating administrations believe that employment and turnover in some industries (e.g., the motor carrier industry) may have declined in recent years, resulting in fewer tests.

confirmation adulterant tests. The table follows:

Adulterant test	Initial test	Confirmation test
(1) pH	Less than 3 or greater than 11	Less than 3 or greater than 11.
(2) Nitrite	Greater than 500 mcg/mL	Greater than 500 mcg/mL.
(3) Presence of Chromium (VI).	Greater than or equal to 50 mcg/mL	Chromium (VI) concentration greater than or equal to the Level of Detection (LOD).
(4) Presence of Halogen	Greater than or equal to 200 mcg/mL nitrite equivalent cutoff or Greater than or equal to 50 mcg/mL Chromium (VI) equivalent cutoff or Halogen concentration greater than or equal to the LOD.	Specific halogen concentration greater than or equal to the LOD.
(5) Presence of Glutaraldehyde.	Aldehyde present or Characteristic immunoassay response on drug test	Glutaraldehyde concentration greater than or equal to the LOD.
(6) Presence of Pyridine	Greater than or equal to 200 mcg/mL nitrite equivalent cutoff or Greater than or equal to 50 mcg/mL Chromium (VI) equivalent cutoff or Greater than or equal to 50 mcg/mL Chromium (VI) concentration.	Pyridine concentration greater than or equal to the LOD.
(7) Presence of Surfactant (dodecylbenzene sulfonate-equivalent).	Greater than or equal to 100 mcg/mL	Greater than or equal to 100 mcg/mL.
(8) Presence of other adulterant.	Greater than or equal to the LOD	Greater than or equal to the LOD.

(b) As a laboratory, you must report results at or above the cutoffs (or for pH, at or above or below the values, as appropriate) as adulterated and provide

the numerical values that support the adulterated result.

9. A new § 40.96 is proposed to be added, to read as follows:

§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria displayed in the following table. The table follows:

Invalid test category	Initial test	Confirmation test
(1) Creatinine & Specific Gravity.	Creatinine less than 2 mg/dL and specific gravity is greater than 1.0010 but less than 1.0200 or Specific gravity is less than or equal to 1.0010 and creatinine is greater than or equal to 2 mg/dL.	Creatinine less than 2 mg/dL and specific gravity is greater than 1.0010 but less than 1.0200 Specific gravity is less than or equal to 1.0010 and creatinine is greater than or equal to 2 mg/dL.
(2) pH	Greater than or equal to 3 and less than 4.5 using a colorimetric pH test or pH meter or Greater than or equal to 9 and less than 11 using a colorimetric pH test or pH meter.	Greater than or equal to 3 and less than 4.5 using a pH meter. Greater than or equal to 9 and less than 11 using a pH meter.
(3) Nitrite	Greater than or equal to 200 mcg/mL using a nitrite colorimetric test or Greater than or equal to the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test or Greater than or equal to the equivalent of 200 mcg/mL using a general oxidant colorimetric test.	Greater than or equal to 200 mcg/mL but less than 500 mcg/ml using a different confirmatory test. Greater than or equal to 200 mcg/mL but less than 500 mcg/mL using the same general oxidant colorimetric test. Greater than or equal to 200 mcg/mL but less than 500 mcg/ml using a different confirmatory test.
(4) Chromium (VI)	Greater than or equal to 50 mcg/mL using a chromium (VI) colorimetric test.	Greater than or equal to 50 mcg/mL using the same chromium (VI) colorimetric test.
(5) Halogen	Greater than or equal to the LOD using a halogen colorimetric test or Odor of the specimen	Greater than or equal to the LOD using the same halogen test colorimetric test. Greater than or equal to the LOD using a halogen colorimetric test.
(6) Glutaraldehyde	Aldehyde present using an aldehyde test or Characteristic immunoassay response on initial drug test.	Aldehyde present using the same aldehyde test. Characteristic immunoassay response on confirmatory drug test.
(7) Oxidizing Adulterant	Greater than or equal to 200 mcg/mL nitrite-equivalent using a general oxidant colorimetric test or Greater than or equal to 50 mcg/mL chromium (VI)-equivalent using a general oxidant colorimetric test or Greater than or equal to the LOD halogen concentration using a general oxidant colorimetric test.	Greater than or equal to 200 mcg/mL nitrite-equivalent using the same general oxidant colorimetric test. Greater than or equal to 50 mcg/mL chromium (VI)-equivalent using the same general oxidant colorimetric test. Greater than or equal to the LOD halogen concentration using the same general oxidant colorimetric test.
(8) Surfactant	Greater than or equal to 100 mcg/ml dodecylbenzene sulfonate-equivalent using a surfactant colorimetric test or	Greater than or equal to 100 mcg/ml dodecylbenzene sulfonate-equivalent using a the same surfactant colorimetric test.

Invalid test category	Initial test	Confirmation test
(9) Interference on immunoassay drug tests. (10) Interference with the GC/MS drug confirmation assay. (11) Physical appearance of the specimen is such that it may damage laboratory equipment.. (12) Physical appearance of Bottles A and B are clearly different and Bottle A result is as stated in 1 through 11, as appropriate, on this table..	Foam/shake test	Greater than or equal to 100 mcg/ml dodecylbenzene sulfonate-equivalent using a surfactant colorimetric test.
	Valid drug test cannot be obtained	Valid drug test cannot be obtained.
	No interfering substance can be identified	No interfering substance can be identified.

(b) To obtain one of the invalid results outlined at 1 through 10 of this table, as a laboratory, you must use two separate aliquots—one for the initial test and another for the confirmation test.

(c) For a specimen having an invalid result for one of the reasons outlined at 4 through 12 of this table, as a laboratory, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(d) As a laboratory, you must report the reason a test result is invalid.

10. Section 40.97 is proposed to be amended by adding the words, “and Rejected for Testing” between “Non-negative” and “results” at paragraph (b)(2) and by revising paragraph (a) to read as follows:

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of three categories. They are as follows:

(1) *Category 1: Negative Results.* When a specimen is found to be negative, as a laboratory, you must report the test result as being one of the following, as appropriate:

- (i) Negative, or
- (ii) Negative-dilute, with numerical values for creatinine and specific gravity.

(2) *Category 2: Non-negative Results.* When a specimen is found to be non-negative, as a laboratory, you must report the test result as being *one or more* of the following, as appropriate:

- (i) Positive, with drug(s)/metabolite(s) noted;
- (ii) Positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for creatinine and specific gravity;

(iii) Adulterated, with adulterant(s) noted, with numerical values (when applicable), and with remark(s);

(iv) Substituted, with numerical values for creatinine and specific gravity; or

(v) Invalid result, with remark(s).

(3) *Category 3: Rejected for Testing.* When a specimen is rejected for testing, as a laboratory you must report the result as being Rejected for Testing, with remark(s).

* * * * *

11. Section 40.103 is proposed to be amended by removing the word “blank” and adding in its place the word “negative” in paragraph (c) introductory text, by revising paragraphs (c)(1) through (5), and removing paragraphs (c)(6) to read as follows:

§ 40.103 What are the requirements for submitting blind specimens to a laboratory?

* * * * *

(c) * * *

(1) All negative, positive, adulterated, and substituted blind specimens you submit must be certified by the supplier and must have supplier-provided expiration dates.

(2) Negative specimens must be certified by immunoassay and GC/MS to contain no drugs.

(3) Drug positive blind specimens must be certified by immunoassay and GC/MS to contain a drug(s)/metabolite(s) between 1.5 and 2 times the initial drug test cutoff concentration.

(4) Adulterated blind specimens must be certified to be adulterated with a specific adulterant using appropriate confirmatory validity test(s).

(5) Substituted blind specimens must be certified for creatinine concentration and specific gravity to satisfy the criteria for a substituted specimen using

confirmatory creatinine and specific gravity tests, respectively.

* * * * *

§ 40.105 [Amended]

12. Section 40.105 is proposed to be amended by adding in paragraph (c) the words “adulterated, or substituted result” after the word “positive,” and before the word “you’.

13. Section 40.129 is proposed to be amended by revising the section heading and paragraph (a)(5) to read as follows:

§ 40.129 What are the MRO’s functions in reviewing laboratory confirmed non-negative drug test results?

(a) * * *

(5) Verify the test result, consistent with the requirements of §§ 40.135–40.145, 40.159, and 40.160, as:

- (i) Negative; or
- (ii) Cancelled; or
- (iii) Positive, and/or refusal to test because of adulteration or substitution.

* * * * *

14. Section 40.131 is proposed to be amended by revising the section heading to read as follows:

§ 40.131 How does the MRO or DER notify an employee of the verification process after laboratory confirmed non-negative drug test results?

* * * * *

15. Section 40.133 is proposed to be amended by revising the section heading, redesignating paragraphs (b) and (c) as (c) and (d), respectively, revising them, and adding paragraph (b) to read as follows:

§ 40.133 Under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled-invalid, without interviewing the employee?

* * * * *

(b) As the MRO, you may verify a test result as cancelled-invalid (with instructions to recollect immediately under direct observation) without interviewing the employee, as provided at § 40.159, if:

(1) The employee expressly declines the opportunity to discuss the test with you;

(2) If the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee; or

(3) If neither you nor the DER, after making all reasonable efforts, has been able to contact the employee within ten days of the date on which you received the confirmed invalid test result from the laboratory.

(c) As the MRO, after you verify a test result as a positive or refusal to test or as a cancelled-invalid result under this section, you must document the date and time and reason, following the instructions in § 40.163, and, for a cancelled-invalid result, at § 40.159(a)(5)(i).

(d) As the MRO, after you have verified a test result under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation of the confirmed test result.

16. Section 40.149 is proposed to be amended by revising the section heading, removing the words "positive or refusal to test" in paragraph (a), and removing, in paragraph (a)(1), the reference to "§ 40.133(c)" and adding in its place "§ 40.133(d)" to read as follows:

§ 40.149 May the MRO change a verified drug test result?

* * * * *

17. Section 40.155 is proposed to be amended by adding paragraph (d) to read as follows:

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

* * * * *

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Obtain verification from the collector that the recollection was directly observed.

(2) If the recollection was directly observed, report this result to the DER as a negative-dilute result.

(3) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

18. Section 40.159 is proposed to be amended by revising paragraphs (a)(1) through (3), adding paragraphs (a)(4)(iii), and (d) through (f) to read as follows:

§ 40.159 What does the MRO do when a drug test is invalid?

(a) * * *

(1) Discuss the laboratory results with the certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not carried out its requirements to contact you at §§ 40.91(e) and 40.96(c), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You should inquire about the medications the employee may have taken.

(4) * * *

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term physiological or anatomic abnormality that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

* * * * *

(d) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason reported for the first specimen, as the MRO, you must:

(1) Obtain verification from the collector that the recollection was directly observed.

(2) If the recollection was directly observed, document that the employee had another specimen with an invalid result.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (*i.e.*, pre-employment, return-to-duty, or follow-up tests), follow the procedures at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason reported for the first specimen, as the MRO, you must report the test result as being a refusal.

(f) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any of those results as being a positive and/or refusal to test, you do not report the cancelled-invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.

19. Section 40.160 is proposed to be added to read as follows:

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(4)(iii) and (d)(4)), as the MRO, you must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician (if appropriate).

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (*e.g.*, blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding the medical examination. The report must also state why the medical examination was required (*i.e.*, either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

(1) Check "Negative" (Step 6) on the CCF.

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted another invalid result for the same reason, as appropriate) and for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).

20. Section 40.162 is proposed to be added to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

(a) If the testing event is one in which there was one specimen collection with multiple verified non-negative results, as the MRO, you must report them all to the DER. For example, if you verified the specimen as being positive for marijuana and cocaine and as being a refusal to test because the specimen was also adulterated, as the MRO, you would report the positives and the refusal to the DER.

(b) If the testing event was one in which two separate specimen collections (e.g., a specimen out of temperature range and the subsequent observed collection) were sent to the laboratory, as the MRO, you must:

(1) If both specimens were verified negative, report the result as negative.

(2) If either of the specimens was verified negative and the other was verified non-negative(s), report the non-negative result(s). For example, if you verified one specimen as negative and other as a refusal to test because the specimen was substituted, as the MRO you would report the only the refusal to the DER.

(3) If both specimens were verified non-negative, report all of the non-negative results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, as the MRO you would report the positive and the refusal results to the DER.

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO you must follow procedures at

§ 40.159(f) when any verified non-negative result is also invalid.

21. Section 40.171 is proposed to be amended by revising paragraph (a) to read as follows:

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

* * * * *

22. Section 40.177 is proposed to be amended by revising paragraph (d) to read as follows:

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

* * * * *

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/ drug metabolite(s) that were reported in the primary specimen, you may transmit the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

23. Section 40.179 is proposed to be amended by revising the section to read as follows:

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the criteria of § 40.95, just as you would do for a primary specimen.

(b) In addition, if the test fails to reconfirm validity criteria reported in the primary specimen, you may transmit the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

24. Section 40.181 is proposed to be amended by revising the section to read as follows:

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

(a) As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.93(b),

just as you would do for a primary specimen.

(b) In addition, if the test fails to reconfirm validity criteria reported in the primary specimen, you may transmit the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

25. Section 40.183 is proposed to be amended by revising paragraph (a), removing paragraph (b), and redesignating paragraph (c) as paragraph (b), to be read as follows:

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box and/or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

* * * * *

26. Section 40.187 is proposed to be amended by revising the section to read as follows:

§ 40.187 What does the MRO do with split specimen laboratory results?

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) *Category 1:* The laboratory reconfirmed all or some of the primary specimen results.

(1) As the MRO, you must report to the DER and employee which result(s) was/were reconfirmed.

(2) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(3) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(4) In the case of combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) *Category 2:* The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/ drug metabolite(s) were not detected; adulteration criteria were not met; and/ or substitution criteria were not met.

(1) As the MRO, you must report to the DER and the employee that the test must be cancelled.

(2) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(3) In a case where the split failed to reconfirm because the substitution

criteria were not met because the split specimen creatinine concentration was greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to steps at (b)(1) and (2) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) *Category 3*: The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen also is present in the primary specimen and/or

to determine if the primary specimen meets appropriate substitution criteria.

(B) Except that the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(3) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) *Category 4*: The laboratory failed to reconfirm some but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory reconfirmed one or more of the primary specimen result(s), as the MRO, you must follow procedures in paragraph (a) of this section and:

(2) Report that the split was reported also as being invalid, adulterated, and/or substituted (as appropriate).

(3) Inform the DER to take action only on the reconfirmed result(s).

(e) *Category 5*: The split specimen was not available for testing or there was no split laboratory available to test the specimen.

(1) As the MRO, you must report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(2) As the MRO, you must also direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) As the MRO, you must notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must:

(1) Enter your name, sign and date (Step 7) of Copy 2 of the CCF.

(2) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter,

see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

27. Section 40.191 is proposed to be amended by redesignating paragraphs (c) through (e) as (d) through (f), respectively, and adding paragraph (c) to read as follows:

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

* * * * *

(c) As an employee, if you have a recollection under direct observation because of an invalid test result and the MRO reports the result of the observed specimen as being invalid for a different reason than the first specimen, you have refused to take a drug test.

* * * * *

28. Section 40.197 is proposed to be amended by revising paragraph (c)(3), redesignating paragraph (c)(4) as (c)(5), and adding paragraph (c)(4) to read as follows:

§ 40.197 What happens when an employer receives a report of a dilute specimen?

* * * * *

(c) * * *

(3) If the result of the test you directed the employee to take under paragraph (b)(1) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute.

(4) If the result of the test you directed the employee to take under paragraph (b)(2) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.

* * * * *

29. Section 40.201 is proposed to be amended by revising paragraphs (c), (d), and (e) to read as follows:

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

* * * * *

(c) The split specimen failed to reconfirm all of the primary specimen results because drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. You must follow the applicable procedures in 40.187(b) (no recollection is required in this case, unless the specimen creatinine concentration for a substituted specimen was greater than 2mg/dL but less than or equal to 5mg/dL—which requires recollection under direct observation).

(d) The split specimen failed to reconfirm all of the primary specimen results, and reported that the split specimen was invalid. You must follow the procedures in 40.187(c)(1) (recollection under direct observation is required in this case).

(e) The split specimen failed to reconfirm all of the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must follow applicable procedures in 40.187(e) (recollection under direct observation is required in this case).

* * * * *

§ 40.207 [Amended]

30. Section 40.207 is proposed to be amended by removing, in paragraph (a)(3), the reference to “40.187(b)” and adding in its place “40.187(b)(3), (c)(1), and (e)”.

31. Appendix B to Part 40 is proposed to be amended by revising it to read as follows:

Appendix B to Part 40—DOT Drug Testing Semi-Annual Laboratory Report

The summary report shall contain the following information:

Reporting Period: (inclusive dates)

Laboratory Identification: (name and address)

Employer Identification: (name; may include Billing Code or ID code)

C/TPA Identification: (where applicable; name and address)

1. Specimen Results Reported (total number)
By Type of Test

- (a) Pre-employment (number)
- (b) Post-Accident (number)
- (c) Random (number)
- (d) Reasonable Suspicion/Cause (number)
- (e) Return-to-Duty (number)
- (f) Follow-up (number)
- (g) Type of Test Not Noted on CCF (number)

2. Specimens Reported

- (a) Negative (number)
- (b) Negative and Dilute (number)

3. Specimens Reported as Rejected for Testing (total number)

By Reason

- (a) Fatal flaw (number)
- (b) Uncorrected Flaw (number)

4. Specimens Reported as Positive (total number)

By Drug

- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opiates (number)
- (1) Codeine (number)
- (2) Morphine (number)
- (3) 6-AM (number)
- (d) Phencyclidine (number)
- (e) Amphetamines (number)
- (1) Amphetamine (number)
- (2) Methamphetamine (number)

5. Adulterated (number)

6. Substituted (number)

7. Invalid Result (number)

Appendix F to Part 40—[Amended]

32. Appendix F to Part 40 is proposed to be amended by removing the references to § 40.187(a)–(f) and § 40.191(d) and adding in their place § 40.187(a)–(e) and § 40.191(e), respectively.

[FR Doc. 05–21488 Filed 10–28–05; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 71

[OST Docket No. 2005–22114]

RIN 2105–AD53

Standard Time Zone Boundary in the State of Indiana

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: DOT tentatively proposes to relocate the time zone boundary in Indiana to move St. Joseph, Starke, Knox, Pike, and Perry Counties from the eastern time zone to the central time zone at the request of the County Commissioners. We are tentatively not proposing to change the time zone boundary to move Marshall, Pulaski, Fulton, Benton, White, Carroll, Cass, Vermillion, Sullivan, Daviess, Dubois, Martin, and Lawrence Counties from the eastern time zone to the central time zone based on the petitions from the commissioners in these counties. If additional information is provided that indicates that the time zone boundary should be drawn differently, either to include counties currently excluded or to exclude counties that are currently included in this proposal, we will make the change at the final rule stage of this proceeding.

DATES: Any County Commissioners from the counties that have submitted petitions who wish to provide additional data to justify a change from the eastern time zone to the central time zone should do so by November 10, 2005. Other comments should be received by November 30, 2005 to be assured of consideration. Comments received after that date will be considered to the extent practicable. If the time zone boundary is changed as a result of this rulemaking, the effective date would be no earlier than 2 a.m. EST Sunday, April 2, 2006, which is the changeover from standard time to daylight saving time.

ADDRESSES: You may submit comments by any of the following methods:

- Web Site: <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1–202–493–2251.

• Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.

• Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

• Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number (OST Docket Number 2005–22114) or Regulatory Identification Number (RIN) (2105–AD53) for this rulemaking. Note that all comments received will be posted without change to <http://dms.dot.gov> including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Public Hearings: In addition to the submission of written comments, an opportunity for oral comments will be provided at four public hearings in Jasper, Logansport, South Bend, and Terre Haute. These hearings will be chaired by a representative of DOT in November. We will publish the date and time in a separate document that will be posted in the docket and published in the **Federal Register**.

The hearings will be informal and will be tape-recorded for inclusion in the docket. The DOT representative will provide an opportunity to speak for all those wishing to do so, to the greatest extent possible. The hearing locations will be accessible for persons with disabilities. If you need a sign language interpreter, please let us know no later than one week before the hearing.

FOR FURTHER INFORMATION CONTACT: Joanne Petrie, Office of the Assistant General Counsel for Regulation and Enforcement, U.S. Department of Transportation, Room 10424, 400