DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket 49713; RIN 2105–AB95]

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule; request for comments.

SUMMARY: The Department of Transportation is making a series of minor or technical amendments to its drug and alcohol testing procedures. The most significant of these include revising the initial test cutoff level for marijuana metabolites, changing split specimen collection procedures to be consistent with those of the Department of Health and Human Services, revising the temperature range for urine drug specimens, revising the drug testing custody and control form and modifying the alcohol testing form, clarifying laboratory reporting procedures to consortiums, deleting a requirement for a second "air blank" after alcohol confirmation tests, specifying procedures related to the display of the sequential number for alcohol tests, and clarifying chain of custody requirements. The changes have the purposes of updating the procedures to be consistent with Department of Health and Human Services guidelines and addressing implementation problems of which the Department has become aware.

DATES: This rule is effective September 19, 1994, with the following exceptions:

(1) The amendments to § 40.23(a) are effective February 16, 1995, but compliance with these amendments is authorized on August 19, 1994;

(2) The amendments to §§ 40.25(f)(10)(ii) (B) and (C) and 40.29(b)(1) are effective August 15, 1994;

(3) The amendments to § 40.29 (e) and (f) are effective September 1, 1994; and

(4) The amendments to § 40.25 (c) and (h) are effective on August 19, 1994. Comments should be received by September 19, 1994, except that comments on the amendment to § 40.23 should be received by October 18, 1994. Late-filed comments will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, S.W., Room 10424. 202–366–9306. Information may also be obtained from the Office of Drug Enforcement and Program Compliance, 202–366–3784.

SUPPLEMENTARY INFORMATION: The Department is publishing this final rule to make several minor or technical amendments to its drug and alcohol testing procedures, 49 CFR Part 40. The changes to Part 40 are described below. The changes are intended, among other things, to conform Part 40 to a number of provisions in the recently revised Department of Health and Human Services (DHHS) guidelines (59 FR 29908; June 9, 1994) and to correct a misinterpretation of the Department's chain of custody requirements. The Department is seeking comments on these amendments and will publish a notice in the **Federal Register** responding to comments received including, if appropriate, any changes to the amendments based on the comments.

The Drug Testing Custody and Control Form

As the result of a lengthy process of consultation among the Department of Transportation, the Department of Health and Human Services (DHHS), and other interested parties, the Department has made modifications to the drug testing custody and control form. This form will be used in Federal employee testing as well as testing under DOT rules. The form is reproduced in Appendix A. OMB has approved the form under the Paperwork Reduction Act.

Under the current rule, program participants have had the discretion to modify the drug testing custody and control form, as long as the contents of the form met the requirements of the regulatory text describing the form in § 40.23(a). In the Department's experience, this has led to a proliferation of different forms, with consequent confusion and increased probability of error. In the alcohol testing procedures, we required employers to use the Department's alcohol testing form without modification. Now that we have an improved drug testing custody and control form, we believe that it should be used universally in the program, without exception and without modification. For this reason, we are amending § 40.23 to delete the regulatory text description of the form (which is no longer needed, since everyone would be using exactly the form printed in Appendix A) and to require participants in the program to use the Department's form without modification.

We recognize that participants have stocks of existing forms. To provide participants a reasonable time to exhaust these stocks and begin to obtain new forms, this amendment will not be made effective until February 16, 1995. In addition, we are providing 60 days for interested persons to comment on this amendment (i.e., on the requirement to use the form without modification, not on the content or format of the form itself). Employers and other participants are authorized to use the new form immediately. We believe it would be very useful for those employers who must begin split sample testing on August 15, 1994, to begin using the new form as soon as possible, since we believe the new form is better suited to split sample testing than its predecessors.

We emphasize that seven-part forms must be used in all cases for split samples. Older seven-part split sample forms may continue to be used during the six month transition period (six-part forms may *never* be used in split sample testing). After that, the new seven-part form must be used. RSPA and Coast Guard employers who choose to use *single* sample collection may continue to use old six-part forms during the six month transition period, and thereafter must use the new form, discarding copy three.

The Alcohol Testing Form and Log Book

Currently, Copy 1 of the Alcohol Testing Form (the original) is designated as the breath alcohol technician's (BAT's) copy of the form, for which there is no record retention requirement stated. Copy 3 is designated the employer's copy, which the employer must retain. It makes more sense, in our view, for the original of the form to be retained by the employer, rather than a copy. Consequently, we are switching the form designations, so that Copy 1 will be the employer's copy and Copy 3 will be the BAT's copy. The statement to be signed by the employee in Step 4 of the form is reworded slightly to emphasize the employee's agreement that the test reflected on the form is the test that the employee took and that the result is recorded accurately.

In § 40.59(c), in the context of the discussion of the log book, the rule requires the notation of the "quantified test result." The Department intends that this result be the numerical result displayed by the EBT. The term has the same meaning as the term "result displayed on the EBT" elsewhere in the rule (e.g., § 40.63(d)(1)(i)), and we are changing the term for the sake of consistency.

Clarification of Reference to NHTSA CPL in Definition of "EBT"

The National Highway Traffic Safety Administration (NHTSA) Conforming Products List (CPL) for Evidential Breath Testing Devices (EBTs) includes both devices that meet September 1993 amendments to NHTSA's model specifications and devices that meet only the previous version of the model specifications. Only those devices on the CPL that meet the September 1993 model specifications may be used in the DOT alcohol testing program. Other devices on the CPL (those designated by an asterisk on the published CPL; see for instance 59 FR 18840 (April 20, 1994)) are not authorized for use in DOT-mandated alcohol testing programs. We are adding a reference to the September 1993 model specifications in the definition of "EBT" in § 40.3 to clarify this point.

Split Sample Collection Procedures

The Department's procedures for collecting split samples for drug testing direct the collection site person to pour the urine from a collection container into one or two specimen bottles (depending on the collection method used). Some concern has been raised that this requirement would preclude the use of newer technologies that would subdivide a specimen into a primary and a split specimen without the necessity of a collection site person physically pouring the urine from one vessel into another. The Department does not intend its procedures to preclude the use of such methods or systems, as long as they result in primary and split samples that can be transmitted to laboratories and tested in ways that fully comply with Part 40 requirements. We have added language to this effect. The Department does not endorse drug testing products, and this change should not be construed as an endorsement of any particular product.

In using whichever of the authorized methods of collecting split samples, the Department advises collectors that we believe the preferred practice is to have temperature strips attached to the collection container, which can reduce the time lag in checking the temperature and reduce the likelihood of errors or delays. The temperature should be read, of course, from the collection container itself, rather than from another bottle into which the split specimen may be poured.

Section 40.25(f)(10)(ii)(C) of the Department's current regulation describes one of the alternative split specimen collection procedures. In this procedure, a single specimen bottle is used as the collection container. The collection site person pours 30 ml of the urine from this container into a second specimen bottle, which is then used as the primary specimen. The urine remaining in the collection container becomes the split specimen. When DHHS published its revised drug testing guidelines, however, DHHS provided that, in this situation, the collection site person would pour 15 ml of the urine into the second bottle, to be used as the split specimen, with 30 ml remaining in the collection container, to be used as the primary specimen. In other words, the DHHS procedure was the reverse of the one we issued in February. While there are advantages to the procedure in the current Part 40, we believe, on balance, that it is more important that the DHHS guidelines and Part 40 be consistent on this point. Consequently, we are changing our procedures to conform with those of DHHS.

Change in Temperature Range

The revised DHHS guidelines modify the temperature range within which a specimen must fall in order to avoid creating a reason to believe that a urine specimen has been altered or substituted. The old range is 32.5–37.7C/90.5–99.8F. The new range is 32–38C/90–100F. Part 40 references are being changed to conform with the DHHS revision.

Clarification of Chain of Custody Requirement

Section 40.25 contains a number of references to use of chain of custody documentation in the handling and transportation of urine specimens. Recently, an arbitrator misinterpreted these provisions, determining that a chain of custody was invalid, and that the test must be canceled, because persons involved solely in the transportation of the intact shipping container did not make a chain of custody entry. This interpretation is contrary to Part 40 procedures, wholly unnecessary in order to preserve the integrity of the process, and, if followed, would result in a wholesale disruption of the DOT testing program. As DHHS recently pointed out in its revised drug testing guidelines, "Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the package during transit."

The Department interprets its *existing* regulatory provisions as not requiring couriers, postal employees, and other personnel involved in the transportation of urine specimens to make chain of custody form entries. Likewise, the Department interprets its *existing* rules as not requiring making entries on the chain of custody form when a sealed shipping container is put into or removed from temporary, secure storage. In present § 40.25(c), for example, handling or transportation of a specimen from one "place" to another must be accomplished through chain of custody procedures. The Department interprets this as meaning that as long as there is an entry from an individual authorized to release the specimen from the collection site ("Place" #1) and another from an individual authorized to receive it on behalf of the laboratory ("Place" #2), the persons who perform intervening, ministerial transportation services (e.g., couriers, truck drivers, airplane pilots, postal service employees, mail room employees) need not make such entries.

Present paragraph 40.25(h) authorizes chain of custody documentation to be "enclosed" in the shipping container for shipment to the laboratory. This container is sealed with tamper-evident tape. As a program matter, the Department recommends enclosing chain of custody documentation in the shipping container, as opposed to attaching it to the exterior of the container, since this minimizes the likelihood of loss of or damage to the documents. Interpreting the rule to require persons performing intervening transportation services to make chain of custody entries would nullify this important provision of the rule. In order to make chain of custody entries, intervening transportation personnel would have to break the tamper-evident seal, dig out the documentation, make an entry, reinsert the documentation, and re-seal the container. Of course, a shipping container with a seal that had been broken and re-sealed a number of times would make it unlikely, if not impossible, for a valid test to be conducted of the specimen it contained. The Department could not interpret its regulations to create such an absurd result.

Present § 40.25 (k) directs the use of a chain of custody form "from the point of collection to the final disposition of the specimen." This provision directs that every individual "in the chain" be identified. Unlike authorized collection site and laboratory personnel, who actually handle the specimen, intervening transportation personnel are not, properly speaking, "in the chain" at all, a point which the Department has understood to be consistent with long-standing case law in a variety of

contexts. Consequently, the Department never understood or intended this language to require that intervening transportation personnel make chain of custody entries.

A related issue, raised in the same arbitration decision, concerns temporary secure storage. That is, a collection site person conducts the test, fills out the custody and control form, places the specimen and form in a sealed shipping container, and places the container in secure, temporary storage at the collection site, where a courier picks it up subsequently for transportation to the laboratory. Again, any tampering would be revealed by the tamper-evident seal. Here, too, requiring an entry in the chain of custody for putting the package into and removing it from the temporary secure storage is unnecessary and disruptive. Alternatives, such as not sealing the chain of custody documentation in the shipping container until immediately before pickup, or attaching the chain of custody documentation to the outside of the shipping container when it is ready for pickup, multiply the possibilities for error. We emphasize that the collector should, as a matter of good practice, document in its own records the times at which sealed shipping containers are put into and removed from temporary secure storage.

Notwithstanding the Department's reasonable construction of its existing regulatory language, which has been communicated in the past to persons raising the question, at least one arbitrator did misinterpret these provisions. To prevent the possibility of any such mistakes in the future, the Department it taking this opportunity to clarify its regulations. To this end, we are adding language very similar to that of DHHS to § 40.25 (c), (h), and (k), as well as an additional sentence that strongly emphasizes and underlines that chains of custody need not include entries from such personnel in order to be valid. In addition, the amendments to these paragraphs make clear that the absence of entries in the chain of custody relating to the putting the package into or retrieving it from temporary secure storage of the collection site does not invalidate the chain of custody.

The Department is making this amendment effective immediately, because it is essential to protect DOT drug testing procedures from misinterpretations that, if followed, could invalidate virtually all chains of custody for DOT drug tests, even though they follow Part 40 requirements. This necessity constitutes the good cause required by the Administrative Procedure Act to make a regulation effective without the normal 30-day effective date.

Untestable, Inadequate, or Unavailable Split Specimens

In split sample testing, there could be situations in which the primary specimen reaches the laboratory unscathed, but the split specimen does not. Instead, the split specimen is untestable, inadequate, or unavailable. For example, the split specimen container may have leaked, leaving an inadequate amount of urine for testing. What is a laboratory to do? To answer this question, which the Department has been asked on a number of occasions, we are adding a paragraph to § 40.29. The paragraph directs the laboratory to go ahead and test the primary specimen in the usual way. The laboratory then sends the result of the test of the primary specimen to the MRO in the usual way. If the test result from the laboratory was a confirmed positive, and the MRO verifies the result as positive, then the employee has 72 hours to request a test of the split specimen. If the employee does so, the MRO will pass the request on to the laboratory. It is only at this point, and not before, that the laboratory informs the MRO that the split specimen is untestable, inadequate, or unavailable. The MRO would then cancel the test. This approach is consistent with existing DOT guidance and the DHHS guidelines.

The vast majority of tests of primary specimens have negative results. Of those that test positive, a portion are verified negative by MROs. Of those verified positive by MROs, not all will result in a timely request by the employee for a test of the split specimen. In view of these facts, it would be counterproductive for the laboratory to reject an otherwise testable primary specimen because the split specimen was unavailable, inadequate, or untestable. Nor would it be cost-effective for the laboratory to notify the MRO of the problem with the split specimen at an earlier stage of the process, which could result in the cancellation of tests that may otherwise stand up. There is no loss of protection to the employee, who will be in no worse position than if there was a testable split specimen. As a general matter, employers using split sample collection should not, as a matter of prudence, take irrevocable action (e.g., terminate, as opposed to suspend) against an employee until the result of the split specimen is available.

Split specimens may become unavailable for testing at other stages of the process (e.g., the receiving laboratory mishandles or loses the split specimen in storage, the split specimen is lost in transit between the receiving laboratory and the second laboratory which would analyze the split). In all these cases, the same rule applies. The MRO is not notified of the unavailability, inadequacy, or untestability of the split specimen unless and until there is a verified positive test and the employee has made a timely request for a test of the split specimen.

Reduction of Marijuana Initial Test Level

In its June 9, 1994, revision to its drug testing guidelines, DHHS reduced the initial test level for marijuana metabolites from 100 ng/ml to 50 ng/ml. This rule changes the initial test level for marijuana in Part 40 to conform with the revised DHHS guidelines. This change is consistent with the existing language of § 40.29(e)(2), which states that the initial test levels for drugs are subject to change by DHHS. Since the new DHHS guidelines go into effect September 1, 1994, this provision will be effective on that date, so that DHHS and DOT testing level requirements remain consistent with one another.

Methamphetamine Levels

The Department is also adding to the chart in this section showing confirmation test levels a new footnote 3, stating that, to be confirmed positive, a specimen containing methamphetamine must also contain amphetamine at a concentration equal to or greater than 200 ng/ml. This footnote is also added to be consistent with the revised DHHS guidelines.

Reports to Employers and Consortia

Section 40.29(g)(6), concerning monthly statistical summary reports from laboratories to employers, has been the subject of some confusion since it does not specify the role of consortia in the reporting chain. Laboratories had expressed concern that they were not authorized, by the present language of the paragraph, to provide these reports to a consortium instead of to individual employers. The Department is revising this paragraph to clarify this matter. Suppose a laboratory tests specimens originating with employers 1–100, all of whom are part of Consortium X. The laboratory may send its report summary only to Consortium X, rather than sending 100 single reports to each of the employers. However, the data provided to Consortium X must include employer-specific information for each of the employers and, within 14 days of

receiving the laboratory report, Consortium X is responsible for sending the employer-specific data to each of the 100 employers. When, as provided in the last sentence of § 40.29(g)(6), employer-specific data is withheld because no testing pertinent to the employer was held, or because release of the data would permit inferences about individual employees' identity, the written reports concerning the withholding of the data may also be provided to the employer via the consortium, through the mechanism described above.

MRO Conflicts of Interest

In its revised guidelines, DHHS has added a new provision prohibiting relationships between laboratories and medical review officers (MROs) that could have the reality or create the appearance of a conflict of interest. DHHS added this provision in the belief, with which DOT concurs, that any such relationship that could be construed as a conflict of interest may be sufficient to undermine the integrity of the program. For this reason and to remain consistent with DHHS guidelines on this important issue, the Department is adding the DHHS language to § 40.29(n).

Removal of Requirement for Second Air Blank

The alcohol testing procedures in Subpart C, as originally issued, contained a requirement that the breath alcohol technician conduct an "air blank" (i.e., an internal check of calibration) both before and after every confirmation test. Failure to do so, or a result for an air blank that exceeded 0.00, is a "fatal flaw" that automatically invalidates a test. We have decided, on further reflection, that the air blank after the confirmation test is unnecessary. The main point of an air blank is to ensure that each employee has a testing device that is a "clean slate," unaffected by any alcohol from previous tests or other sources. The pre-test air blank accomplishes this objective fully; the post-test air blank is not necessary for this purpose. Moreover, on some breath testing devices, particularly where a test has shown a high alcohol concentration, it may take several minutes for all alcohol to clear from the device. Under the existing rule, if the breath alcohol technician were to do a post-test air blank under these circumstances too soon, it could result in a reading above 0.00, invalidating an otherwise valid test. Because it is unnecessary, and to avoid problems of this kind, we are deleting the provision requiring a post-test air blank and the provision making the failure to conduct such a test a "fatal flaw."

Display of Sequential Test Numbers

Section 40.53(b)(2) requires that EBTs used for confirmation tests be capable of assigning a unique sequential number to each test, which can be read by the BAT and the employee before the test and printed out on each copy of the test result. Section 40.79(a)(7) makes it a "fatal flaw" if the sequential number displayed on the EBT before the test is not the same as the sequential number printed on the test result. However, the existing regulation leaves a gap between these two points, since the procedures for conducting alcohol tests (§§ 40.63 and 40.65) do not specify the handling of sequential numbers in the testing process.

The Department is adding language to fill this gap. Section 40.65(e) is being revised to require the BAT to ensure that the BAT and the employee read the displayed sequential number before the confirmation test, and § 40.65(h)(3) is revised to direct the BAT to enter in the "Remarks" section of the form any disparity between that number and the sequential test number on the printed result. Such a disparity, per § 40.79, is a fatal flaw. We have made parallel changes to § 40.63 (d)(1) and (e)(2), which apply to situations in which a screening test is conducted with an EBT that has the features specified in § 40.53(b) for EBTs that can be used for confirmation tests.

Record Retention Requirement for BAT Training

The alcohol testing requirements of Part 40 currently call on employers or their agents to keep records of breath alcohol technician (BAT) training and proficiency for two years. The Department is concerned that, for BATs who work as such for longer than two years, this record retention requirement may not be sufficient. The Department requests comment on whether this record retention requirement should be extended (e.g., to require retention of records of the training of a BAT for as long as that BAT works for the employer). Such an extension would not apply, presumably, to BATs who were no longer working for the employer.

Regulatory Analyses and Notices

This is not a significant rule under Executive Order 12866 or under the Department's Regulatory Policies and Procedures. It does not impose costs on regulated parties and may, to a limited extent, reduce regulatory burdens (e.g., the provisions concerning reporting and post-test air blanks). Consequently, a regulatory evaluation has not been prepared.

The Department finds, for purposes of the Administrative Procedure Act, that issuance of a notice of proposed rulemaking on these subjects is unnecessary, impracticable, or contrary to the public interest. This is because the amendments are conforming changes to actions of the Department of Health and Human Services or joint DOT/DHHS actions (the change in the marijuana initial test level, the new Federal drug testing custody and control form), important clarifications the rapid issuance of which is in the public interest (the clarifications to the split sample collection procedures, the chain of custody requirements, and the laboratory reporting procedures regarding consortia), or a correction of what we have come to regard as a mistake in procedures that have not been implemented (removal of the post-test air blank requirement).

The particular effective dates are established for the following reasons. The 180-day effective date for the requirement to use the new drug testing custody and control form is established in order to give participants time to exhaust stocks of existing forms and also to give interested persons a 60-day opportunity to comment on this matter. The August 15 effective date for amendments pertaining to split sample testing procedures was established in view of the August 15 starting date for mandatory split sample testing in the aviation, motor carrier, and railroad industries. The September 1 effective date for the amendments to the initial test level for marijuana is established to be consistent with the September 1 effective date of the revised DHHS guidelines, with which the Department's requirements in this matter should be consistent. The immediate effective date for the amendments to the chain of custody is established because of the necessity of immediately correcting an error that could create potentially serious damage to the program.

List of Subjects in 49 CFR Part 40

Drug testing, Alcohol testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

Issued this 10th day of August 1994, at Washington, DC.

Federico Peña,

Secretary of Transportation.

For the reasons set forth in the preamble, the Department of Transportation amends Title 49, 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; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

§ 40.3 [Amended]

2. In § 40.3, the definition of the term "EBT" is amended by changing the period at the end of the definition to a comma and by adding the following: "and identified on the CPL as conforming with the model specifications available from the National Highway Traffic Safety Administration, Office of Alcohol and State Programs."

3. Section 40.23(a) is revised to read as follows:

§ 40.23 Preparation for testing.

* * * * *

(a) Use of the drug testing custody and control form prescribed under this Part. This form is found in Appendix A to this part. Employers and other participants in the DOT drug testing program may not modify or revise this form, except that the drug testing custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information on the donor (other than the social security number or other employee ID number) may not be provided to the laboratory. Donor medical information may appear only on the copy provided to the donor.

* * * * *

4. § 40.25(c) is revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(c) Chain of Custody. The chain of custody block of the drug testing custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site. Every effort shall be made to minimize the number of persons handling specimens.

5. In § 40.25(e)(2)(i), the words "32°–38° C/90°–100° F" are substituted for the words "32.5°–37.7° C/90.5°–99.8° F".

6. § 40.25(f)(10)(ii)(B) and (C) are revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(f) * * *

(10) * * *

(ii) * * *

(B)(*1*) If a collection container is used, the collection site person, in the presence of the donor, pours the urine into two specimen bottles. Thirty (30) ml shall be poured into one specimen bottle, to be used as the primary specimen. At least 15 ml shall be poured into the other bottle, to be used as the split specimen.

(*2*) If a single specimen bottle is used as a collection container, the collection site person, in the presence of the donor, shall pour 15 ml of urine from the specimen bottle into a second specimen bottle (to be used as the split specimen) and retain the remainder (at least 30 ml) in the collection bottle (to be used as the primary specimen).

(C) Nothing in this section precludes the use of a collection method or system that does not involve the physical pouring of urine from one container or bottle to another by the collection site person, provided that the method or system results in the subdivision of the specimen into a primary (30 ml) and a split (at least 15 ml) specimen that can be transmitted to the laboratory and tested in accordance with the requirements of this Subpart.

* * * * *

7. In § 40.25(f)(13), the words "32°–38° C/90°–100° F" are substituted for the words "32.5°–37.7° C/90.5°–99.8° F".

8. § 40.25(h) is revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(h) Transportation to Laboratory. Collection site personnel shall arrange to ship the collected specimen to the drug testing laboratory. The specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely sealed to eliminate the possibility of undetected tampering with the specimen and/or the form. On the tape sealing the shipping container, the collection site person shall sign and enter the date specimens were sealed in the shipping container for shipment. The collection site person shall ensure that the chain of custody documentation is enclosed in each container sealed for shipment to the drug testing laboratory. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site.

* * * * *

9. § 40.25(k) is revised to read as follows:

§ 40.25 Specimen collection procedures.

* * * * *

(k) *Use of chain of custody form.* A chain of custody form (and a laboratory internal chain of custody document, where applicable), shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the form each time a specimen is handled or transferred

and every individual in the chain of custody shall be identified. Since specimens and documentation are sealed in shipping containers that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is put into or taken out of secure storage at the collection site prior to pickup by such personnel. This means that the chain of custody is not broken, and a test shall not be canceled, because couriers, express carriers, postal service personnel, or similar persons involved solely with the transportation of a specimen to a laboratory, have not documented their participation in the chain of custody documentation or because the chain of custody does not contain entries related to putting the specimen into or removing it from secure temporary storage at the collection site. Every effort shall be made to minimize the number of persons handling specimens.

10. The existing text of § 40.29(b)(1) is redesignated as § 40.29(b)(1)(i), and a new § 40.29(b)(1)(ii) is added, to read as follows:

§ 40.29 Laboratory analysis procedures.

* * * * *

(b) * * *

(1) * * *

(ii) Where the employer has used the split sample method, and the laboratory observes that the split specimen is untestable, inadequate, or unavailable for testing, the laboratory shall nevertheless test the primary specimen. The laboratory does not inform the MRO or the employer of the untestability, inadequacy, or unavailability of the split specimen until and unless the primary specimen is a verified positive test and the MRO has informed the laboratory that the employee has requested a test of the split specimen.

* * * * *

11. In § 40.29(e), the chart is revised to read as follows:

(e) * * *

	Initial test cut-off levels (ng/ml)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	*300
Phencyclidine	25
Amphetamines	1,000

*—25 ng/ml if immunoassay specific for free morphine.

12. In § 40.29(f), the chart is revised to read as follows:

(f) * * *

	Confirmatory test cutoff levels (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine [3]	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.

[2] Benzoylecgonine.

[3] Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/ml.

13. § 40.29(g)(6) is revised to read as follows:

§ 40.29 Laboratory analysis procedures.

* * * * *

(g) * * *

* * * * *

(6) The laboratory shall provide the employer an aggregate quarterly statistical summary of urinalysis testing of the employer's employees. Laboratories may provide the report to a consortium provided that the laboratory provides employer-specific data and the consortium forwards the employer-specific data to the respective employers within 14 days of receipt of the laboratory report. The laboratory shall provide the report to the employer or consortium not more than 14 calendar days after the end of the quarter covered by the summary. Laboratory confirmation data only shall be included from test results reported within that quarter. The summary shall contain only the following information:

(i) Number of specimens received for testing;

(ii) Number of specimens confirmed positive for—

(A) Marijuana metabolite

(B) Cocaine metabolite

(C) Opiates;

(D) Phencyclidine;

(E) Amphetamines;

(iii) Number of specimens for which a test was not performed.

Quarterly reports shall not contain personal identifying information or other data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary, in order to prevent disclosure of such data, the laboratory shall not send such a report until data are sufficiently aggregated to make such an inference unlikely. In any quarter in which a report is withheld for this reason, or because no testing was conducted, the laboratory shall so inform the consortium/employer in writing.

14. A new paragraph (n)(6) is added to § 40.29(n), to read as follows:

§ 40.29 Laboratory analysis procedures.

* * * * *

(n) * * *

* * * * *

(6) The laboratory shall not enter into any relationship with an employer's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an employer use a specific MRO.

15. § 40.59(b) is revised to read as follows:

§ 40.59 The breath alcohol testing form and log book.

* * * * *

(b) The form shall provide triplicate (or three consecutive identical) copies. Copy 1 (white) shall be transmitted to the employer. Copy 2 (green) shall be provided to the employee. Copy 3 (blue) shall be retained by the BAT. Except for a form generated by an EBT, the form shall be 8½ by 11 inches in size.

* * * * *

16. In § 40.59(c), the words "result displayed on the EBT" are substituted for the words "quantified test result".

17. In § 40.63, paragraphs (d)(1), (2), and (3) are redesignated as paragraphs (d)(2), (3), and (4), respectively, and a new paragraph (d)(1) is added to read as follows:

§ 40.63 Procedures for screening tests.

* * * * *

(d)(1) If the EBT does meet the requirements of § 40.53(b)(1) through (3), the BAT shall ensure, before the screening test is administered for each employee, that he or she and the employee read the sequential test number displayed by the EBT.

* * * * *

18. In § 40.63, paragraphs (e)(2), (3), and (4) are respectively redesignated as paragraphs (e)(3), (4), and (2).

19. Redesignated § 40.63(e)(3) is revised to read as follows:

§ 40.63 Procedures for screening tests.

* * * * *

(e) * * *

(3) If a test result printed by the EBT (see paragraph (d)(3) or (d)(4) of this

section) does not match the displayed result, or if a sequential test number printed by the EBT does not match the sequential test number displayed by the EBT prior to the screening test (see paragraph (d)(1) of this section), the BAT shall note the disparity in the "Remarks" section. Both the employee and the BAT shall initial and sign the notation. In accordance with § 40.79, the test is invalid and the employee shall be so advised.

* * * * *

20. § 40.65 (d) and (e) are revised to read as follows:

§ 40.65 Procedures for confirmation tests.

* * * * *

(d) Before the confirmation test is administered for each employee, the BAT shall ensure that the EBT registers 0.00 on an air blank. If the reading is greater than 0.00, the BAT shall conduct one more air blank. If the reading is greater than 0.00, testing shall not proceed using that instrument, which shall be taken out of service. However, testing may proceed on another instrument. Any EBT taken out of service because of failure to perform an air blank accurately shall not be used for testing until a check of external calibration is completed and the EBT is found to be within tolerance limits.

(e) Before the confirmation test is administered for each employee, the BAT shall ensure that he or she and the employee read the sequential test number displayed by the EBT.

* * * * *

21. § 40.65(h) (2) and (3) are revised to read as follows:

§ 40.65 Procedures for confirmation tests.

* * * * *

(h) * * *

* * * * *

(2) If the employee does not sign the certification in Step 4 of the form, it shall not be considered a refusal to be tested. In this event, the BAT shall note the employee's failure to sign in the "Remarks" section.

(3) If a test result printed by the EBT (see paragraph (g)(1) or (g)(2) of this section) does not match the displayed result, or if a sequential test number printed by the EBT does not match the sequential test number displayed by the EBT prior to the confirmation test (see paragraph (e) of this section), the BAT shall note the disparity in the "Remarks" section. Both the employee and the BAT shall initial and sign the notation. In accordance with § 40.79, the test is invalid and the employee shall be so advised.

* * * * *

§ 40.65 [Amended]

22. § 40.65(h)(4) is removed.

23. In § 40.65(i)(2), the comma after the words "in writing" is removed and the words "(the employer copy (Copy 1) of the breath alcohol testing form)," are added at that place.

§ 40.79 [Amended]

24. In § 40.79(a)(3), following the words "0.00 prior to," the words "or after" are removed.

25. Appendix A to part 40 is revised to read as follows:

Appendix A to Part 40—Federal Drug Testing Custody and Control Form

BILLING CODE 4910-62-P

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

▶ **STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE**

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

▶ **STEP 2: TO BE COMPLETED BY COLLECTOR** - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

▶ **STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR** - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

▶ **STEP 4: TO BE COMPLETED BY DONOR** - Go to copy 4 (pink page); STEP 4

▶ **STEP 5: TO BE COMPLETED BY COLLECTOR**

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) X Signature of Collector Date (Mo./Day/Yr.) Time AM PM

▶ **STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER**

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature / Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE INITIAL TEST AND CONFIRMATORY TEST CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ NEGATIVE ☐ POSITIVE, for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE ☐ OPIATES: ☐ codeine ☐ morphine ☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine ☐ OTHER _____ ☐ TEST NOT PERFORMED

REMARKS _____

TEST LAB (if different from above) _____ NAME ADDRESS ( ) PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo. / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 1 - ORIGINAL - MUST ACCOMPANY SPECIMEN TO LABORATORY

SPECIMEN ID NO.

A

PLACE OVER CAP

Donor's Initials

Date (Mo. Day. Yr.)

SPECIMEN ID NO.

B (SPLIT)

PLACE OVER CAP

Donor's Initials

Date (Mo. Day. Yr.)

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information is estimated for each respondent to average: 5 minutes/donor; 4 minutes/collector; 3 minutes/laboratory; and 3 minutes/Medical Review Officer. Federal employees may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to Public Health Service Reports Clearance Officer, Attn: PRA, Hubert H. Humphrey Building, Rm 721-B, 200 Independence Ave. S.W., Washington, D.C. 20201. Individuals from the private sector may send comments/suggestions to: Department of Transportation, Drug Enforcement and Program Compliance, Rm 9404, 400 Seventh St. S.W., Washington, D.C. 20590. In addition, copies of all comments/suggestions may be sent to: Office of Management and Budget, Paperwork Reduction Project, Rm 3001, 725 Seventeenth St. N.W., Washington, D.C. 20503.

Back of Copy 1, 2, 3, 4, and 6.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature / Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE INITIAL TEST AND CONFIRMATORY TEST CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ NEGATIVE ☐ POSITIVE, for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE

☐ TEST NOT PERFORMED ☐ OPIATES: ☐ codeine ☐ morphine ☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine ☐ OTHER _____

REMARKS _____

TEST LAB (if different from above) _____ NAME ADDRESS ( ) PHONE NO.

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo. / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 2 - 2nd ORIGINAL - MUST ACCOMPANY SPECIMEN TO LABORATORY

FEDERAL-DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. -B LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: TO BE COMPLETED BY DONOR - Go to copy 4 (pink page); STEP 4

STEP 5: TO BE COMPLETED BY COLLECTOR

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 7: TO BE COMPLETED BY THE LABORATORY - Specimen Bottle Seal(s) Intact: ☐ YES ☐ NO, Explain in Remarks Below.

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE PROCEDURES ESTABLISHED BY THE HHS MANDATORY *GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS*

☐ RECONFIRMED for the following: ☐ CANNABINOIDS as Carboxy—THC ☐ COCAINE METABOLITES as Benzoylecgonine ☐ PHENCYCLIDINE
☐ FAILED TO RECONFIRM ☐ OPIATES: ☐ codeine ☐ morphine ☐ AMPHETAMINES: ☐ amphetamine ☐ methamphetamine
☐ TEST NOT PERFORMED ☐ OTHER _____

REMARKS _____

TEST LAB (if different from above): _____ NAME ADDRESS ( ) PHONE NO

I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth are for that specimen.

(PRINT) Certifying Scientist's Name (First, MI, Last) Signature of Certifying Scientist Date (Mo / Day / Yr.)

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Reconfirmed ☐ Failed to reconfirm- Both tests cancelled ☐ Test not performed Both tests cancelled REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo / Day / Yr.)

COPY 3 - SPLIT SPECIMEN MUST ACCOMPANY SPLIT SPECIMEN TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

▶ **STEP 4: SEE BELOW**

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

▶ **STEP 4: TO BE COMPLETED BY DONOR**

Daytime Phone No. ( ) Evening Phone No. ( ) Date of Birth / / Mo. Day Yr.

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) X Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 4 - SEND DIRECTLY TO MEDICAL REVIEW OFFICER - DO NOT SEND TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO

LABORATORY ACCESSION NO

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No.

B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No ( ) Evening Phone No ( ) Date of Birth / / Mo Day Yr

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct

(PRINT) Donor's Name (First, MI, Last) X Signature of Donor Date (Mo / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken Therefore, you may want to make a list of those medications as a "memory jogger " THIS LIST IS NOT NECESSARY If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM TAKE COPY 5 WITH YOU

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 5 - GIVE TO DONOR DO NOT SEND TO LABORATORY

Privacy Act Statement: (For Federal Employees Only)

Submission of the information on the attached form is voluntary However incomplete submission of the information, refusal to provide a urine specimen or substitution or adulteration of a specimen may result in delay or denial of your application for employment/appointment or may result in removal from the Federal service or other disciplinary action.

The authority for obtaining the urine specimen and identifying information contained herein is Executive Order 12564 ("Drug-Free Federal Workplace"), 5 U S C § 3301 (2), 5 U S.C § 7301 and Section 503 of Public Law 100-71, 5 U S.C. § 7301 note Under provisions of Executive Order 12564 and 5 U S C 7301, test results may only be disclosed to agency officials on a need-to-know basis. This may include the agency Medical Review Officer, the administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. This information may also be disclosed to a court where necessary to defend against a challenge to an adverse personnel action.

Submission of your SSN is not required by law and is voluntary. Your refusal to furnish your number will not result in the denial of any right, benefit, or privilege provided by law. Your SSN is solicited, pursuant to Executive Order 9397, for purposes of associating information in agency files relating to you and for purposes of identifying the specimen provided for urinalysis testing for illegal drugs If you refuse to indicate your SSN, a substitute number or other identifier will be assigned as required to process the specimen

In the event laboratory analysis determines the presence of one or more illegal drugs in the specimen you provide you will be contacted by an agency Medical Review Officer (MRO) The MRO will determine whether there is a legitimate medical explanation for the drug(s) identified by urinalysis

Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information including the time for reviewing instructions gathering and maintaining the data needed and completing and reviewing the collection of information is estimated for each respondent to average 5 minutes/donor 4 minutes/collector 3 minutes/laboratory and 3 minutes/Medical Review Officer Federal employees may send comments regarding these burden estimates or any other aspect of this collection of information including suggestions for reducing the burden to Public Health Service Reports Clearance Officer Attn PRA Hubert H Humphrey Building, Rm 721 B 200 Independence Ave S W Washington D C 20201 Individuals from the private sector may send comments/suggestions to Department of Transportation Drug Enforcement and Program Compliance Rm 9404 100 Seventh St S W Washington D C 20590 In addition copies of all comments/suggestions may be sent to Office of Management and Budget Paperwork Reduction Project, Rm 3001 725 Seventeenth St N W Washington D C 20503

Back of Copy 5.

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines ☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature / Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	
/ /	Signature / Name	Signature / Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No Evening Phone No Date of Birth ___/___/___ Mo. Day Yr

I certify that I provided my urine specimen to the collector, that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct

(PRINT) Donor's Name (First, MI, Last) Signature of Donor Date (Mo / Day / Yr)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken Therefore, you may want to make a list of those medications as a "memory jogger " THIS LIST IS NOT NECESSARY If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements My determination/verification is.

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 6 COLLECTOR RETAINS DO NOT SEND TO LABORATORY

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. LABORATORY ACCESSION NO.

STEP 1: TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address and I.D. No. B. MRO Name and Address

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident
☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

E. Tests to be Performed: ☐ THC, Cocaine, PCP, Opiates and Amphetamines
☐ Only THC and Cocaine ☐ OTHER (specify) _____

STEP 2: TO BE COMPLETED BY COLLECTOR - Specimen temperature must be read within 4 minutes of collection.

Specimen temperature within range: ☐ Yes, 90° - 100°F/32° - 38°C ☐ No, Record specimen temperature here _____

STEP 3: TO BE COMPLETED BY COLLECTOR AND DONOR - Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s).

STEP 4: SEE BELOW

STEP 5: TO BE COMPLETED BY COLLECTOR - RETURN TO COPY 1

COLLECTION SITE LOCATION:

Collection Facility ( ) Collector's Business Phone No.

SPLIT SPECIMEN COLLECTION ☐ YES ☐ NO

Address City State Zip

REMARKS: _____

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 4 of this form, that it bears the same specimen identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(PRINT) Collector's Name (First, MI, Last) Signature of Collector Date (Mo./Day/Yr.) Time AM PM

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MO. DAY YR.	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
/ /	DONOR - NO SIGNATURE	Signature Name	PROVIDE SPECIMEN FOR TESTING
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	
/ /	Signature Name	Signature Name	

STEP 4: TO BE COMPLETED BY DONOR

Daytime Phone No  Evening Phone No.  Date of Birth ___/___/___ Mo. Day Yr

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; that each specimen bottle used was sealed with a tamper-evident seal in my presence and that the information provided on this form and on the label affixed to each specimen bottle is correct.

(PRINT) Donor's Name (First, MI, Last) Signature of Donor Date (Mo. / Day / Yr.)

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger " THIS LIST IS NOT NECESSARY If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5).—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 8: TO BE COMPLETED BY THE MEDICAL REVIEW OFFICER

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My determination/verification is:

☐ Negative ☐ Positive ☐ Test Not Performed ☐ Test Cancelled

REMARKS _____

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo. / Day / Yr.)

COPY 7 FORWARD TO EMPLOYER - DO NOT SEND TO LABORATORY

INSTRUCTIONS FOR COMPLETING DRUG TESTING CUSTODY AND CONTROL FORM

The following instructions are in accordance with procedures established by the Department of Health and Human Services and the Department of Transportation mandatory guidelines for federal and transportation workplace drug testing programs.

NOTE Use ballpoint pen, press hard, and check all copies for legibility

STEP 1

If the information in STEP 1 has not been completed, collector (not donor) completes STEP 1 (A-E)

NOTE Donor refusal to provide SSN or Employee I.D. number must be annotated in STEP 5, collector's REMARKS section.

STEP 2

Upon receiving specimen from donor check specimen temperature. This must be accomplished within 4 minutes.

Check block marked "Yes" if temperature is within range.

If specimen temperature is not within range, check block marked "No," and record specimen temperature.

STEP 3. FOR SPLIT SPECIMEN COLLECTIONS ONLY

Secure caps on both specimen bottles and affix specimen bottle seal labelled A over the cap and down the sides of the primary specimen (bottle containing at least 30ml of urine).

Affix specimen bottle seal labelled B (split) on the split specimen (bottle containing at least 15ml of urine) in the same manner.

Record date on both specimen bottle seals.

Instruct donor to initial both specimen bottle seals.

FOR SINGLE SPECIMEN COLLECTION ONLY

Secure cap on specimen bottle (containing at least 30ml of urine) and affix specimen bottle seal labelled A over the cap and down the sides of the specimen bottle.

Record date on specimen bottle seal.

Instruct donor to initial the specimen bottle seal.

STEP 4.

Turn to Copy 4 (pink page), STEP 4.

Instruct donor to complete STEP 4.

Ensure donor provides his/her daytime and evening phone number and date of birth.

Instruct donor to read certification statement. Ensure donor prints his/her name and signs and dates the certification statement.

NOTE: Donor refusal to sign must be annotated in STEP 5, collector's remarks section.

Upon completion, check donor entries, return to Copy 1.

STEP 5.

After returning to Copy 1, go to STEP 5.

Complete the name and address of the facility at which the collection is taking place.

List a business telephone number where collector can be reached.

Place a check in the box indicating whether or not a split specimen was collected.

Record any unusual occurrences concerning the collection (e.g. donor refusal to provide information/sign certification statement, specimen collected under direct observation, suspected adulteration) in the remarks section.

Collector completes collection certification section by printing and signing his/her name, recording the date and time of collection. Be sure to circle A.M. or P.M.

STEP 6. CHAIN OF CUSTODY SECTION

NOTE: Each time the specimen is handled, transferred, or placed into storage prior to being packaged for shipment, every individual must be identified (including a direct observer, if required) and the date and purpose of change recorded. The following instructions pertain to a collection in which the donor provides a specimen directly to the collector who seals, packages, and ships the specimen to the laboratory.

Record date of collection.

In the "Specimen Received By" column, sign and print your name indicating that you have received the specimen from the donor.

The "Purpose of Change" entry in the next column is pre-printed (Provide Specimen for Testing) and explains the transfer of the specimen from the donor to the collector.

On the next line, record the date the specimen was released by you.

Complete the "Specimen Released By" block by signing and printing your name.

If you are preparing the specimen for shipment to the laboratory complete the "Specimen Received By" block by printing the carrier or shipment provider name only. (See Example)

Complete the "Purpose of Change" block explaining the transfer of the specimen from the collector to the carrier or shipment provider (e.g. Ship Specimen to Lab)

DATE MO / DAY / YR	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
1 / 12 / 93	DONOR - NO SIGNATURE	Signature: Minnie Mc Donald Name: Minnie McDonald	PROVIDE SPECIMEN FOR TESTING
1 / 12 / 93	Signature: Minnie Mc Donald Name: Minnie McDonald	Signature: Name: ABC Courier Service	SHIP SPECIMEN TO LAB
/ /	Signature: Name:	Signature: Name:	
/ /	Signature: Name:	Signature: Name:	

COMPLETING THE COLLECTION PROCESS

Upon completing Step 6 give donor his/her copy Copy 5, (green page) of the Drug Testing Custody and Control Form.

Donor may leave the collection site at this point.

If a split specimen collection was performed, place both specimen bottles and Copies 1, 2, and 3 of the Drug Testing Custody and Control Form in the shipping container.

If a single collection was performed, place the specimen bottle and Copies 1 and 2 of the Drug Testing Custody and Control Form in the shipping container. Discard Copy 3.

Secure the shipping container. On the shipping container seal, record your initials and the date.

Send Copy 4 (pink page) directly to the Medical Review Officer. Do not send to laboratory.

Retain Copy 6 (yellow page) for your records.

Forward Copy 7 (blue page) to the employer. Do not send to laboratory.

BILLING CODE 4910-62-C

26. Appendix A to Subpart C of Part
is redesignated as Appendix B to Part
and revised to read as follows:

ppendix B to Part 40—The Breath
lcohol Testing Form

.LING CODE 4910-62-P