DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket No. 45928 Notice No. 88-17]

RIN 2105-AB42

Procedures for Transportation Workplace Drug Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Interim final rule.

SUMMARY: The Department of Transportation is adopting a modification of the Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Programs." The purpose of the modification is to adapt the procedures and safeguards developed by the Department of Health and Human Services more closely to the circumstances of drug testing programs in industries regulated by the Department of Transportation. Antidrug program rules published by the Department's operating administrations will require employers to conduct drug testing according to these Procedures.

DATES: This rule is effective December 21, 1988. Comments should be received by January 23, 1989. Late-filed comments will be considered to the extent practicable.

ADDRESS: Comments should be sent to Docket Clerk, Docket 45928, Department of Transportation (C-55), 400 7th Street SW., Room 4107, Washington, DC., 20590. In order to expedite handling of comments, commenters are requested to refer to the docket number for this rule and to provide an original and four copies of their comments. Commenters wishing to have their comments acknowledged should include a stamped, self-addressed postcard with their comments. The docket clerk will time and date stamp the card and mail it back to the commenter.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 400 7th Street, SW., Room 10424, Washington DC, 20590. Mr. Ashby's phone number is 202-366-9306.

SUPPLEMENTARY INFORMATION: The Department of Transportation (DOT) believes that a drug-free transportation workplace is essential to transportation safety. For this reason, the Department's operating administrations (the Federal Aviation Administration, Federal Highway Administration, Federal Railroad Administration, United States Coast Guard, Urban Mass Transportation Administration, and Research and Special Programs Administration) are issuing regulations requiring antidrug programs in the aviation, motor carrier, railroad, maritime, mass transit, and pipeline industries, respectively.

The proposed regulations for these operating administration rules proposed that employers conduct drug testing according to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" of the Department of Health and Human Services (DHHS). The "HHS Guidelines," as this document is known, were published in the **Federal Register** on April 11, 1988 (53 FR 11970). They were based on a notice of proposed rulemaking (NPRM) published August 14, 1987 by DHHS, and on comments to that NPRM.

The HHS Guidelines include procedures for collecting urine samples for drug testing, procedures for transmitting the samples to testing laboratories, testing procedures, procedures for evaluating test results, quality control measures applicable to the laboratories, recordkeeping and reporting requirements, and standards and procedures for HHS certification of drug testing laboratories. The intent of the Guidelines is to safeguard the accurancy of test results and the privacy of individuals who are tested.

The Department believes that the basic requirements of the Guidelines must remain a vital component of DOT drug drug testing regulations. However, the Department is aware that the Guidelines, as written by HHS to apply to testing by Federal agencies, do not fit perfectly the circumstances of employers regulated by DOT. There are many references to legal authorities and other matters which are peculiar to Federal agencies (e.g., references to the Privacy Act and to Executive Order 12564). Terminology referring to Federal "agencies" rather than to "employers" may be confusing in the DOT regulated industry context. One purpose of this rule is to make necessary editorial changes to adapt the content of the HHS Guidelines to the context of industries regulated by DOT.

In addition, DHSS drafted the Guidelines to apply to the physical and organizational circumstances of Federal agencies. Obviously, the circumstances of industries regulated by DOT are very different from those of Federal agencies. For this reason, the Department is modifying some provisions of the HHS Guidelines to work better in the implementation of drug testing programs by DOT regulated industries. These revisions are intended to leave intact the safeguards for accuracy and privacy in drug testing established by the HHS Guidelines while ensuring that parties regulated by DOT can practically implement the requirements.

We would call particularly to the attention of commenters the following revisions. This is not an exhaustive list of all modifications to the HHS Guidelines published in this document. The Department seeks comments on all aspects of this interim final rule.

In § 40.2, definitions of "employer" and "employee" have been added. The former definition includes consortia, but points out that individual members of a consortium are not relieved of their responsibilities under the rule by virtue of participation in the consortium. As provided in the operating administration drug rules, the testing rate of 50 percent can relate to the entire employee population covered by a consortium; the definition does not mean that 50 percent of the work force of each consortium member must be tested in a year.

Under the HHS Guidelines, a Federal agency may test a urine sample *only* for certain specified drugs. The Department's Procedures echo this requirement. Under § 40.21(c), an employer may test the sample obtained under a DOT drug rule only for the drugs required or specifically authorized to be tested under the DOT drug rule. That is, an employer must test the sample for the five major drugs listed in each DOT drug regulation. If the DOT agency involved authorizes testing for Drug X under § 40.21(b), the employer may also test the sample for that drug. If the employer wants to test, in addition, for Drug Y, the employer must obtain a second sample from the employee. The obtaining of this second sample is not under the authority of the DOT regulation. The employer must base its request for the second sample on whatever other legal authority is available, since the employer cannot rely on the DOT regulation as the basis for the request.

As alluded to above, an employer may submit to the DOT agency involved a protocol for testing another controlled substance (see § 40.21(b)). DOT agencies have discretion whether or not to entertain such requests; if a DOT agency approves such a request, then the employer can test for the drug as part of its DOT-mandated program.

The HHS Guidelines require Federal agencies to keep a permanent log book at the collection site. This is a requirement that is likely to be difficult for many employers to meet, particularly where there are scattered or remote locations at which testing must take place. Consequently, the DOT

Procedures will not require a permanent log book. Instead, employers would use a custody and control form (described at § 40.21–1(b)(4)), a copy of which would be retained for permanent record purposes. For the sake of flexibility, an employer could use a different but equivalent form, or a permanent log book, with the approval of the DOT agency involved.

The DOT procedures also seek to add flexibility to the choice and use of collection sites, in view of the variety of circumstances in which employers have to conduct tests (especially post-accident and reasonable cause tests). Collection sites are defined to include any suitable facility (e.g., a medical facility or mobile unit could qualify); a facility without all the security safeguards contemplated for collection sites could be used if samples are under the direct control of collection site personnel; and other water sources are permissible in the facility if the other sources are secured or monitored to ensure that they could not be used to dilute a specimen (see §§ 40.22(a); 40.22(b)(3); 40.22(f)(1)).

Based on the experience DOT has gained with its drug testing program for its own employees, the DOT procedures spell out the grounds on which an employee would be directed to give a sample while being observed (§ 40.22(e)(2)). These circumstances, which are the exclusive circumstances under which observation could be ordered, include a discrepancy in the temperature of the sample; a record of the employee having previously given a sample which had a too-low specific gravity or concentration of creatinine; or observation by the collection site person of conduct clearly and unequivocally indicating an attempt to tamper with a sample. In the latter case, the collection site person would have to get authorization from a higher-level supervisor before ordering the providing of a sample under observation (§ 40.22(f)(23)). The Department seeks comment on whether there are circumstances in which obtaining this authorization would be too difficult or would occasion too great a delay, such that this requirement should be modified or eliminated in such circumstances.

An additional circumstance in which a test can be observed is when that test is part of a rehabilitation program or post-positive testing program. The rationale for this provision is that, given recidivism rates among users of some drugs, and the concern that employees would have to avoid a second positive test, employees may have a greater incentive to "cheat" than in other circumstances. The Department seeks comment on this provision and its rationale. Should there be limitations on the authority of employers to conduct observed tests in these situations? For example, should the MRO or other appropriate official have to make a determination that a particular employee is likely to warrant observation during a particular test or series of tests? Should there be a temporal limitation on the period during which tests could be observed (e.g., the first two or three tests, the first or second year of post-positive testing)?

One of the purposes of the Procedures is to ensure that a proper chain of custody is maintained. A number of provisions of the Procedures, particularly in § 40.22, deal with this subject. One such provision (§ 40.22(j)(2)) concerns transfer of the specimen from the collection site person to the laboratory.

It is likely, in some circumstances, that the collection site person will transport or mail the sample directly to the laboratory. For example, the collection site person may put the sample in a mailer and turn it over to a mail room employee, who then sends it to the laboratory. However, the chain of custody form will be sealed in the mailer by the collection site person. This could leave a gap in the chain of custody. The Department seeks comment on whether this would be a significant problem and, if so, how to correct it.

Section 40.24(g)(5) requires a laboratory manager or other employee to sign urine custody and control forms. The Department seeks comment on whether this requirement is needed and whether there are other approaches that would be less burdensome.

The HHS Guidelines do not permit laboratories to subcontract any of their drug testing work. In the interest of flexibility of contracting arrangements for employers, the DOT procedures would permit subcontracting under carefully controlled conditions. These conditions include complete processing of and responsibility for a sample by the subcontract laboratory, which must also be HHS-certified (§ 40.24(j)).

The HHS Guidelines require Federal agencies to inspect laboratories before a testing contract is awarded. Believing that such a requirement would be too burdensome for employers, particularly small employers, the DOT procedures eliminate this requirement. However, DOT, DHSS, or any employer may inspect a laboratory at any time (§ 40.24(1)).

Similarly, the HHS Guidelines require Federal agencies contracting with a particular laboratory to periodically send "blind samples" to the laboratory to test the laboratory's accuracy. Doing so is reasonable for Federal agencies, but it could be very burdensome and costly for small employers. Consequently, the DOT Procedures provide that only large employers (i.e., those with 2,000 or more employees subject to drug testing under the applicable operating administration drug rule) need to follow this practice (§ 40.2(d)(2)(ii)). This relief for small entities is based, in part, on the assumption that most, if not all, HHS-certified laboratories will have contracts with one or more Federal agencies or other large entities, and will therefore be subject to some blind sample testing.

The Department seeks comment on whether this assumption is likely to be correct. If not, what should the Department's response be? The language of the rule would require employers to submit blind samples if the laboratory they work with does not have contracts with entities who would do blind sample testing. Is this reasonable, or would another approach be better? Also, is the 2,000 covered employee cutoff a reasonable one? Should a lower cutoff (e.g., 1,000 covered employees) be used, in order to make it less likely that laboratories would be subject to blind testing from at least some DOT regulated employers? This would also afford employees of more employers the assurance of properly-run drug testing programs which blind sampling provides. Alternatively, should a higher cutoff be used? Another approach that could be taken would be to base the cutoff on the number of specimens submitted by the employer in a year (e.g., 1,000 specimens rather than 2,000 employees, which might include some employers with high numbers of reasonable cause and post-accident tests who might otherwise not have to conduct blind testing.) The Department seeks comment on this approach as well.

Regulatory Process Matters

This is not a major rule under Executive Order 12291. It is a significant rule under the Department's Regulatory Policies and Procedures, since it affects several operating administrations and their regulated industries. A regulatory evaluation has not been prepared, since the costs of conducting drug testing conforming with these Procedures have been analyzed in the regulatory evaluations or regulatory impact analyses for the operating administration drug-free transportation workplace program rules.

This rule will affect small entities in all the industries covered by DOT operating administration drug rules. The basic small entity impacts of each rule have been considered as part of the operating administrations' rulemakings. The Department has taken steps, as described in "Supplementary Information," to reduce small entity impacts in such areas as inspections, submission of blind samples, and permanent log books. Consequently, the Department certifies that 49 CFR Part 40 will not have a significant economic impact on a substantial number of small entities.

The Department has considered the Federalism implications of this rule under Executive Order 12612. The Department has determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. Federalism implications of individual operating administrations' drug rules are discussed in those rulemaking documents.

The reporting and recordkeeping requirements referenced in this regulation have been submitted for Paperwork Reduction Act approval to the Office of Management and Budget by the respective DOT operating administrations in connection with their own drug rules. This is because it is the operating administration rules, rather than this rule, that actually imposes the requirements on regulated parties. However, the Office of the Secretary is seeking OMB approval under the Paperwork Reduction Act for the form described in § 40.21–1(a). A **Federal Register** notice will be published when Paperwork Act approval is obtained.

This rule has been published without prior opportunity for notice and public comment. The Department finds that it would be impracticable, unnecessary, and contrary to the public interest to seek prior public comment for this rule. This finding is made on the basis of the overriding public interest in ensuring a drug-free transportation workplace, in order to ensure transportation safety and as a step toward controlling the nationwide problem of drug abuse. (There have been previous opportunities for public notice and comment on this subject, obtained by DHSS on the HHS Guidelines, which served as the basis for this rule, and on the operating administration drug rules, which proposed use of the HHS Guidelines.) It is necessary to publish final rules on this subject at this time, so that all parties affected by the operating administration drug rules will know what is expected of them with respect to testing procedures as they develop their drug-free workplace programs.

The Department will review comments received on this rule and publish a notice responding to the comments. The Department will also make any appropriate changes to the rule at that time. The operating administrations have received some comments on the HHS Guidelines in the course of their drug rulemakings. These comments will be made a part of the docket for this rulemaking and the Department will respond to them along with the other comments we receive. (Many of the changes in the HHS Guidelines made in this rule appear to be responsive to these comments.)

List of Subjects in 49 CFR Part 40

Controlled substances, Transportation.

Issued this 14th day of November 1988, at Washington, DC.

Jim Burnley,

Secretary of Transportation.

49 CFR Subtitle A is amended by adding Part 40 to read as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG TESTING PROGRAMS

Subpart A—General

Subpart B—Scientific and Technical Requirements

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing

Authority: 49 U.S.C. 102, 301.

Subpart A—General

§ 40.1 Applicability.

This part applies to transportation employers (including self-employed individuals) conducting drug urine testing programs pursuant to regulations issued by agencies of the Department of Transportation and to such transportation employers' officers, employees, agents and contractors, to the extent and in the manner provided in DOT agency regulations.

§ 40.2 Definitions.

For purposes of this part the following definitions apply:

Aliquot. A portion of a specimen used for testing.

Chain of custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody. Two forms of chain of custody documents are utilized under this part. An external chain of custody form or "urine custody and control form" (described in § 40.23) is used to document chain of custody to the laboratory. An internal chain of custody form is utilized to document handling and transfer of the original sample container and aliquots within the laboratory.

Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) A collection is observed or (b) collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

Confirmatory 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. (At this time gas

chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency of the United States Department of Transportation administering regulations requiring compliance with this part, including the United States Coast Guard, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Urban Mass Transportation Administration, and the Research and Special Programs Administration.

Employee. An individual designated in a DOT agency regulation as subject to drug urine testing and the donor of a specimen under this part. As used in this part "employee" includes a final applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, "employer" is inclusive of a industry consortium or joint enterprise comprised of two or more employing entities, but no single employing entity is relieved of its responsibility for compliance with this part by virtue of participation in such a consortium or joint enterprise.

Initial test (also known as screening test). An immunoassay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer. A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Permanent Record Book. A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection. May be used in conjunction with a modified urine custody and control form to document collection.

Reason to believe. Reason to believe that a particular individual may alter or substitute the urine specimen.

Secretary. The Secretary of Transportation or the Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing this part.

Subpart B—Scientific and Technical Requirements

§ 40.21 The drugs.

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval, if testing for those substances is authorized under agency regulations and if the Department of Health and Human Services has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

§ 40.23 Preparation for testing

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a) Utilization of a standard urine custody and control form (carbonless manifold). The form shall be a multiple-part, carbonless record form with an original (part 1) that shall accompany the specimen to the laboratory. Copies shall be provided for the Medical Review Officer (part 2, to go directly to the MRO), the employee (part 3), the collection site (part 4) (if distinct from the employer), and the employer representative (part 5). The form should be a permanent record on which identifying data on the employee and on the specimen collection and transfer process is retained. The form shall be constructed to display, at a minimum, the following elements, which shall appear on its respective parts as indicated:

(1) The following information shall appear on all parts of the form:

(i) A preprinted specimen identification number, which shall be unique to the particular collection.

(ii) The employee's Social Security or employee identification number, which shall be entered by the employee.

(iii) Specification of the type of test conducted (pre-employment, random, etc.), which shall be entered by the employer representative or collector (acting for the employer).

(iv) A block providing that "Collector must note temperature of specimen has been read and record here if not within the range of 32.5—37.7C/90.5—99.8F:" with an area for the required notation.

(v) A chain-of-custody block providing areas to enter the following information for each transfer of possession: purpose of change; released by (signature/print name); received by (signature/print name); date. The words "Provide specimen for testing" and "DONOR" shall be preprinted in the initial spaces.

(vi) Information to be completed by the collection site person, identifying that person and providing the date of collection, the collection site and the telephone number (if any) of the collection site; a space for remarks at which unusual circumstances may be described; and a certification statement as set forth below and a signature block with date which shall be completed by the collection site person:

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have verified that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as required by the instructions provided.

(vii) A block to be completed by the laboratory after analysis of the specimen, providing a space for entry of the laboratory accession number and a certification to read as follows, together with spaces to enter the printed name and signature of the certifying laboratory official and date:

I certify that the specimen identified by this accession number is the same specimen that bears the 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 attached are for that specimen.

(2) Information to be provided by the employee, which shall appear on parts 2 through 5 of the form only: Employee name (printed); duty location; job title; date of birth; and a certification statement as set forth below, together with a signature block with date which shall be completed by the employee:

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

(3) A block to be completed by the employee, which shall appear only on parts 2 and 3 of the form, containing a statement as follows: "If you wish to have prescription or over-the-counter medications you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here:" followed by an adequate writing area to list such substances.

A form meeting the requirements of this paragraph is displayed at Appendix B to this part. The urine 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 (other than the employee identification number) may not be provided to the laboratory and employee medical information may appear only on the copies provided to the employee and to the Medical Review Officer. In lieu of a form meeting the above-described criteria, an employer may choose to use a multiple-sample chain of custody form together with a permanent record book maintained at the site of collection to document collection and transfer of specimens under this part, so long as the data elements set forth above are documented, personal identifying information is not disclosed to the laboratory, and the record system is designed in such a manner as to maintain the confidentiality of medical information.

(b) Use of a tamperproof sealing system designed in a manner such that the specimen bottle top can be sealed against undetected opening, the bottle can be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space has been provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialled to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the employee, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly illustrated written instructions on the collection of specimens in compliance with this part. Employer representatives and employees subject to testing shall also be provided standard written instructions setting forth their responsibilities.

§ 40.25 Specimen collection procedures.

(a) *Designation of collection site.* (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory. An independent medical facility may also be utilized as a collection site provided the other applicable requirements of this part are met.

(2) A designated collection site may be any suitable location where a specimen can be collected under conditions set forth in this part, including a properly equipped mobile facility. A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination (unless a single-use collector is used with sufficient capacity to contain the void), and a suitable clean surface for writing. The site must also have a source of water for washing hands, which, if practicable, should be external to the enclosure where urination occurs.

(b) *Security.* The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen.

(1) Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(2) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the employee or distraction of the collection site person.

(3) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person.

(c) *Chain of custody.* The chain of custody block of the urine 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. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to authorized personnel only.* No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the

conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialled, the urine custody and control form has been executed, and the employee has departed the site.

(e) *Privacy.* (1) Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided, as further described in this paragraph.

(2) For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

(i) The employee has presented a urine specimen that falls outside the normal temperature range, and the employee declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (f)(23) of this part, or the oral temperature does not equal or exceed that of the specimen.

(ii) The last urine specimen provided by the employee (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below .2 g/L.

(iii) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

(iv) The employee has previously been determined to have used a controlled substance without medical authorization and the particular test is being conducted as a part of a rehabilitation program, on return to service after any required rehabilitation, or under a DOT agency regulation providing for follow-up testing after return to service.

(f) *Integrity and identity of specimen.* Employers shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. Where practicable, there shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site, the collection site person shall ensure that the individual is positively identified as the employee selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the urine custody and control form.

(9) In the exceptional event that an employer-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measure is critical and in no case shall exceed 4 minutes.

(13) If the temperature of a specimen is outside the range of 32.5°–37.7° C/90.5°–99.8° F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the urine custody and control form.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual has altered or substituted the specimen as described in paragraph (e)(2)(i) and (iii) of this section, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. As provided below, the specimen shall be sealed (by placement of a tamperproof seal over the bottle cap and down the sides of the bottle) and labeled in the presence of the employee. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19)–(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the employer. If separate form the label, the tamperproof seal shall also be applied.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the urine custody and control form all information identifying the specimen. The collection site person shall sign the urine custody and control form certifying that the collection was accomplished according to the instructions provided.

(22) (i) The individual shall be asked to read and sign a statement on the urine custody and control form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine custody and control form information concerning medications taken or administered in the past 30 days.

(iii) When specified by DOT agency regulation or required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee may not be required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others.

(23) A higher level supervisor of the collection site person, or a designated employer representative, shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based upon the circumstances described paragraph (e)(2) of this section.

(24) The collection site person shall complete the chain of custody portion of the urine custody and control form to indicate receipt from the employee and shall certify proper completion of the collection.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26)(i) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and urine custody and control form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(ii) The collection site person shall not leave the collection site in the interval between presentation of the specimen by the employee and securement of the sample with an identifying label bearing the employee's specimen identification number (shown on the urine custody and control form) and seal initialled by the employee. If it becomes necessary for the collection site person to leave the site during this interval, the collection shall be nullified and (at the election of the employer) a new collection begun.

(g) *Collection control.* To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. The urine custody and control form 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 an approval chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) *Transportation to laboratory.* Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in 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. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site person shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(i) *Failure to cooperate.* If the employee refuses to cooperate with the collection process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen) the collection site person shall inform the employer representative and shall document the non-cooperation on the urine custody and control form.

§ 40.27 Laboratory personnel.

(a) *Day-to-day management.* (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education

in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), and (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

§ 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial

test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) *Initial test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test Level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	* 300
Phencyclidine	25
Amphetamines	1,000

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

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT Agency under that agency's regulations.

(f) *Confirmatory test.* (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

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

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

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT agency as provided in that agency's regulations.

(g) *Reporting results.* (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the employer, and the drug testing laboratory specimen identification number (accession number). The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory *shall report as negative* all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the employer but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the urine custody and control form (part 1), which shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(6) The laboratory shall provide to the employer official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of the employer's employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) *Initial testing*:

(A) Number of specimens received;

(B) Number of specimens reported out; and

(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

(ii) *Confirmatory testing*:

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-term storage.* Long-term frozen storage (−20° C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an employer (or other person designated in a DOT agency regulation) may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part procedures. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor, and other relevant provisions of this part are observed.

(k) *Laboratory facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs must have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserve the right to inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agency) to conduct unannounced inspections.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

§ 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) Laboratory quality control requirements for initial tests. Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory

quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory quality control requirements for confirmation tests. Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Employer blind performance test procedures. (1) Employers shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) (i) During the initial 90-day period of any new drug testing program, each employer shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(ii) These blind performance testing requirements shall not apply to an employer that submits fewer than 1,000 employee specimens per year for analysis under one or more DOT agency regulations requiring compliance with this part, if such employer utilizes a laboratory that is currently subject to blind performance testing under this part or the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs by a Federal agency or by another transportation employer required by this section to perform such blind performance testing for the substances for which the specimen is to be tested

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibited spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(4) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the DOT agency may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

§ 40.33 Reporting and review of results.

(a) *Medical Review Officer shall review results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to employer administrative officials.

(b) *Medical Review Officer—qualifications and responsibilities.* The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of the transportation employer or a private physician retained for this purpose. The role of the Medical Review Officer is to review and interpret positive test results obtained through the employer's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the employer's policy, refer the case to the employer employee assistance or rehabilitation program, if

applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

(d) *Verification for opiates; review for prescription medication.* Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) *Reanalysis authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original sample on timely request of the employee, as provided in applicable DOT agency regulations.

(f) *Result consistent with legal drug use.* If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, the Medical Review Officer shall report the test result to the employer as negative.

(g) *Result scientifically insufficient.* Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in § 40.33(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the DHHS Guidelines.) The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the employer. The employer shall include in its annual report to the DOT agency a summary of any negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

§ 40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations.

§ 40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon written request, have access to any records relating to his or her drug test and any records relatings to the results of any relevant certification, review, or revocation-of-certification proceedings.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing

§ 40.41 Use of DHHS-certified laboratories.

Employers subject to this part shall use only laboratories certified under the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 FR 11970, April 11, 1988, and subsequent amendments thereto. DHHS certification standards are set forth in Appendix A to this part for information and reference. Information concerning the current certification status of laboratories is available from: the Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

Appendix A to Part 40—DHHS Laboratory Certification Standards

Note: Reproduced below is subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs issued by DHHS. Cross-references are to sections of those DHHS Guidelines. Equivalent provisions in this part may be determined by reference to the following table:

	Part 40
DHHS Guidelines:	
Section 1.1	§ 40.1
Section 1.2	§ 40.2
Section 2.1	§ 40.21
Section 2.2	§ 40.25
Section 2.3	§ 40.27
Section 2.4	§ 40.29
Section 2.5	§ 40.31
Section 2.6	
Section 2.7	§ 40.33
Section 2.8	§ 40.35
Section 2.9	§ 40.37

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Section 3.1 Introduction.

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

Section 3.2 Goals and Objectives of Certification.

(a) *Uses of Urine Drug Testing.* Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated is section 2.4 (e) and (f).

(b) *Need to Set Standards; Inspections.* Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus on-site inspection. Maintenace of certification requires participation in an every-other-month performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from must clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen most be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and

advice of a qualified forensic toxicologist, or individual with equivalent qualifications, (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, proper documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

Section 3.3 General Certification Requirements.

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for certification under these standards.

Section 3.4 Capability to Test for Five Classes of Drugs.

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: marijuana, cocaine; opiates, amphetamines, and phencyclidine, using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (section 2.1(a) (1) and (2)) and the methods (section 2.4 (e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of using the methods specified. Certified laboratories must clearly inform non-Federal clients when procedures followed for those clients conform to the standards specified in these Guidelines.

Section 3.5 Initial and Confirmatory Capability at Same Site.

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (section 2.4(e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (section 2.1(a)(1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

Section 3.6 Personnel.

Laboratory personnel shall meet the requirements specified in section 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

Section 3.7 Quality Assurance and Quality Control.

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs as specified in section 2.5 of these Guidelines.

Section 3.8 Security and Chain of Custody.

Laboratories shall meet the security and chain of custody requirements provided in section 2.4(a).

Section 3.9 One-Year Storage for Confirmed Positives.

All confirmed positive specimens shall be retained in accordance with the provisions of section 2.4(h) of these Guideline.

Section 3.10 Documentation.

The Laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in section 2.4(m).

Section 3.11 Reports.

The laboratory shall report test results in accordance with the specifications in section 2.4(g).

Section 3.12 Certification.

(a) *General.* The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified any laboratory that is certified by a DHHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of a DHHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria;

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality assurance/quality control program;

(4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

Section 3.13 Revocation.

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by a DHHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) *Factors to Consider.* The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) *Period and Terms.* The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.14 Suspension.

(a) *Criteria.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by a DHHS-recognized certification program in accordance with these Guidelines.

(b) *Period and Terms.* The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.15 Notice; Opportunity for Review.

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) *Opportunity for Informal Review.* The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date of mailing or service of the notice. The review shall be by a person or persons designated by the Secretary and shall be based on written submissions by the laboratory and the Department of Health and Human Services and, at the Secretary's discretion, may include an opportunity for an oral presentation. Formal rules of evidence and procedures applicable to proceedings in a court of law shall not apply. The decision of the reviewing official shall be final.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) *DHHS-Recognized Certification Program.* The Secretary's responsibility under this section may be carried out by a DHHS-recognized certification program in accordance with these Guidelines.

Section 3.16 Recertification.

Following the termination or expiration of any suspension or revocation, a laboratory may apply for recertification. Upon the submission of evidence satisfactory to the Secretary that the laboratory is in compliance with these Guidelines or any DHHS-recognized certification program in accordance with these Guidelines, and any other conditions imposed as part of the suspension or revocation, the Secretary may recertify the laboratory or accept the recertification of the laboratory by a DHHS-recognized certification program.

Section 3.17 Performance Test Requirement for Certification

(a) *An Initial and Continuing Requirement.* The performance testing program is a part of the initial evaluation of a laboratory seeking certification (both performance testing and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) *Three Initial Cycles Required.* Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for inspection and certification. These initial three cycles (and any required for recertification) can be compressed into a 3-month period (one per month).

(c) *Six Challenges Per Year.* After certification, laboratories shall be challenged every other month with one set of at least 10 specimens—a total of six cycles per year.

(d) *Laboratory Procedures Identical for Performance Test and Routine Employee Specimens.* All procedures associated with the handling and testing of the performance test specimens by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) *Blind Performance Test.* Any certified laboratory shall be subject to blind performance testing (see section 2.5(d)). Performance on blind test specimens shall be at the same level as for the open or non-blind performance testing.

(f) *Reporting—Open Performance Test.* The laboratory shall report results of open performance tests to the certifying organization in the same manner as specified in section 2.4(g)(2) for routine laboratory specimens.

Section 3.18 Performance Test Specimen Composition.

(a) *Description of the Drugs.* Performance test specimens shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analyte by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the specimen composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one specimen container, but generally no more than two drugs will be present in any one specimen in order to imitate the type of specimen which a laboratory normally encounters. For any particular performance testing cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of specimens.

(b) *Concentrations.* Performance test specimens shall be spiked with the drug classes and their metabolites which are required for certification: marijuana, cocaine, opiates, amphetamines, and phencyclidine, with concentration levels set at least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated. Some performance test specimens may be identified for GC/MS assay only. Blanks shall contain less than 2 ng/ml of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

Section 3.19 Evaluation of Performance Testing.

(a) *Initial Certification.* (1) An applicant laboratory shall not report any false postive result during performance testing for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of performance testing required for initial certification, i.e., it must correctly identify and confirm 90 percent of the total drug challenges for each shipment. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total challenges which are ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger). Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

b. *Ongoing Testing of Certified Laboratories. (1) False Positives and Procedures for Dealing with Them.* No false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a classs (e.g., codeine for morphine) are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positve:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurrence of the particular error, in the future and, if there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be a technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for the day-to-day management of the laboratory's urine drug testing. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a retest sample must be corrected because the criteria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred.

However, if the class is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action.

(vi) During the time required to resolve the error, the laboratory shall remain certified, but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* In order to remain certified, laboratories must successfully complete six cycles of performance testing per year. Failure of a certified laboratory to maintain a grade of 90 percent on any required performance test cycle, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges at ±20 Percent or ±2 standard deviations:* Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger).

(4) *Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean.* No quantitative values obtained by a certified laboratory may differ by more than 50 percent from the calculated reference group mean.

(5) *Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug.* For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2), (b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) *Procedures When Requirements in Paragraphs (b)(2)—(b)(5) of this Section Are Not Met.* If a certified laboratory fails to maintain a grade of 90 percent per test cycle after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3), and (b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to successfully quantitate test results and how it failed to successfully quantitate. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) *80 Percent of Participating Laboratories Must Detect Drug.* A laboratory's performance shall be evaluated for all samples for which drugs were spiked at concentrations above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) *Participation Required.* Failure to participate in a performance test or to participate satisfactorily may result in suspension or revocation of certification.

Section 3.20 Inspections.

Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

Section 3.21 Results of Inadequate Performance.

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in sections 3.13 and 3.14 of these guidelines.

Appendix B to Part 40—Urine Custody and Control Form

The urine custody and control form shall meet the requirements of § 40.23. The following is a sample form that meets those requirements:

BILLING CODE 4910-62-M

URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. #_____ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: _____
Social Security No.
or Employee No.

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical

☐ Other(Specify)_____.

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F:_____ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name_____ Date of Collection_____
Print (First, M.I., Last)

Collection Site_____ ( )_____
Facility Name and Location Telephone

Remarks concerning collection: _____

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

_____
Signature of collector

STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. _____

I certify that the specimen identified by this accession number is the same specimen that bears the 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 attached are for that specimen.

_____ _____ _____
Printed Name Signature Date

Copy No. 1: Original

URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. #_____ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: _____
Social Security No.
or Employee No.

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical

☐ Other(Specify)_____.

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F:_____ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name_____ Date of Collection_____
Print (First, M.I., Last)

Collection Site_____ (___)_____
Facility Name and Location Telephone

Remarks concerning collection: _____

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

_____
Signature of collector

STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. _____

I certify that the specimen identified by this accession number is the same specimen that bears the 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 attached are for that specimen.

_____ _____ _____
Printed Name Signature Date

STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name _____ Duty Location _____
Last/First/M.I.

Job Title: _____ Date of Birth _____

If you wish to have prescription or over-the-counter medications that you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here or provide that information separately to your employers' Medical Review Officer:

_____

_____

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

_____ _____
Signature Date

Copy No. 2: Medical Review Officer

URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. #_____ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: _____
Social Security No.
or Employee No.

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical

☐ Other(Specify)_____.

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F:_____ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name_____ Date of Collection_____
Print (First, M.I., Last)

Collection Site_____ ( )_____
Facility Name and Location Telephone

Remarks concerning collection: _____

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

_____
Signature of collector

STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. _____

I certify that the specimen identified by this accession number is the same specimen that bears the 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 attached are for that specimen.

_____ _____ _____
Printed Name Signature Date

STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name _____ Duty Location _____
Last/First/M.I.

Job Title: _____ Date of Birth _____

If you wish to have prescription or over-the-counter medications that you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here or provide that information separately to your employers' Medical Review Officer:

_____

_____

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

_____ _____
Signature Date

Copy No. 3: Employee

URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. #_____ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: _____
Social Security No.
or Employee No.

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical

☐ Other(Specify)_____.

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F:_____ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name_____ Date of Collection_____
Print (First, M.I., Last)

Collection Site_____ ( )_____
Facility Name and Location Telephone

Remarks concerning collection: _____

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

_____
Signature of collector

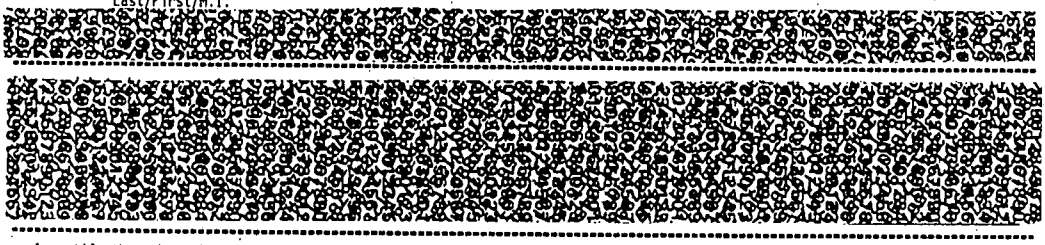
STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. _____

I certify that the specimen identified by this accession number is the same specimen that bears the 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 attached are for that specimen.

_____ _____ _____
Printed Name Signature Date

STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name _____ Duty Location _____
Last/First/M.I.



I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

_____ _____
Signature Date

Copy No. 4: Collector

URINE CUSTODY AND CONTROL FORM

STEP 1 -- TO BE COMPLETED BY EMPLOYEE/APPLICANT

Employee I.D. #_____ [PRE-PRINTED SPECIMEN I.D. #] Employer Name: _____
Social Security No.
or Employee No.

STEP 2 -- TO BE COMPLETED BY EMPLOYER REPRESENTATIVE/OR COLLECTOR Reason for Test (Check One)

☐ Pre-employment ☐ Post Accident ☐ Random ☐ Periodic Medical

☐ Other(Specify)_____.

STEP 3 -- COLLECTOR MUST NOTE THAT TEMPERATURE OF SPECIMEN HAS BEEN READ. RECORD IF NOT WITHIN THE RANGE OF 32.5 - 37.7C/ 90.5 - 99.8 F:_____ ☐ WITHIN RANGE

STEP 4 -- TO BE INITIATED BY THE PERSON COLLECTING SPECIMEN AND COMPLETED AS NECESSARY THEREAFTER:

Purpose of Change	Released By Signature/Print Name	Received By Signature/Print Name	Date
Provide Specimen for Testing	DONOR		

STEP 5 -- (SEE BELOW -- TO BE COMPLETED BY EMPLOYEE)

STEP 6 -- BEFORE COMPLETING THIS STEP HAVE EMPLOYEE COMPLETE STEP 5 BELOW. To be completed by person collecting specimen:

Collector's Name_____ Date of Collection_____
Print (First, M.I., Last)

Collection Site_____ ( )_____
Facility Name and Location Telephone

Remarks concerning collection: _____

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have certified that it bears the same identification number as that set forth above, and that it has been collected, labeled and sealed as required by the instructions provided.

_____
Signature of collector

STEP 7 -- TO BE COMPLETED BY THE LABORATORY: Accession No. _____

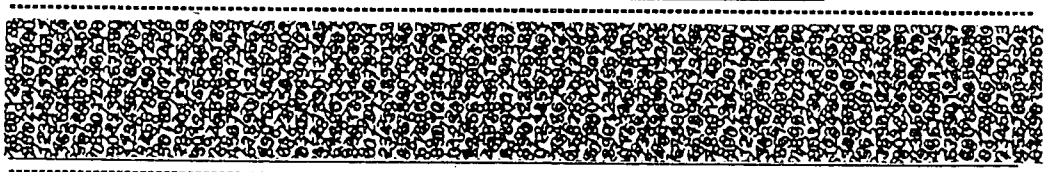
I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that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

_____ _____ _____
Printed Name Signature Date

STEP 5 -- TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN:

Name _____ Duty Location _____
Last/First/M.I.

Job Title: _____ Date of Birth _____



I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

_____ _____
Signature Date

Copy No. 5: Employer

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