

of the CCF (Step 2) and complete the collection process.

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the "Remarks" line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory.

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (e.g., standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or

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deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following "fatal flaws:"

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (g) of this section);

(3) The collector's printed name and signature are omitted from the CCF; and

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(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (g) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3).

(e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of § 40.205(b)(1).

(3) If the flaw is not corrected, report the result as rejected for testing in accordance with § 40.97(a)(3).

(f) If you determine that the specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of § 40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with § 40.97(a).

(g) If you determine that a CCF that fails to meet the requirements of § 40.45(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by following the procedures of § 40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) During the period August 1-October 31, 2001, you are not required to reject a test conducted on an expired Federal CCF because this problem is not corrected. Beginning November 1,

2001, if the problem(s) is not corrected, you must reject the test and report the result in accordance with § 40.97(a)(3).

(h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (*i.e.*, Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the “A” and write “B,” then initial and date the change. A corresponding change shall be made to the other bottle by marking through the “B” and writing “A,” and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test “DOT specimens” for any other drugs.

- (a) Marijuana metabolites.
- (b) Cocaine metabolites.
- (c) Amphetamines.
- (d) Opiate metabolites.
- (e) Phencyclidine (PCP).

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

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmation drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Type of drug or metabolite	Initial test	Confirmation test
(1) Marijuana metabolites	50	
(i) Delta-9-tetrahydrocanna-binol-9-carboxylic acid (THC)		15
(2) Cocaine metabolites (Benzoylcegonine)	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000
(iii) 6-acetylmorphine (6-AM)		10 (Test for 6-AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is

at or above the cutoff concentration, you must conduct a confirmation test.

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(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

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

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you are authorized to conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.91 What validity tests must laboratories conduct on primary specimens?

As a laboratory, when you conduct validity testing under § 40.89, you must conduct it in accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/adulterant that could make a test result invalid, but you are unable to identify it (*e.g.*, a new adulterant), you must, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in

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current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

§ 40.93 What criteria do laboratories use to establish that a specimen is dilute or substituted?

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL and the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL *and* the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

§ 40.95 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

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

(a) As a laboratory, you must report the results for each primary specimen tested as one or more of the following:

(1) Negative;

(2) Negative—dilute;

(3) Rejected for testing, with remark(s);

(4) Positive, with drug(s)/metabolite(s) noted;

(5) Positive, with drug(s)/metabolite(s) noted—dilute;

(6) Adulterated, with remark(s);

(7) Substituted, with remark(s); or

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

(b) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.*, C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.*, computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) Donor's SSN or employee I.D. number, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) Date received at the laboratory;

(J) Date certifying scientist released the results;

(K) Certifying scientist's name;

(L) Results (*e.g.*, positive, adulterated) as listed in paragraph (a) of this section; and

(M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from

unauthorized access or release, both during transmission and in storage.

(2) Non-negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.

(d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(e) You must provide quantitative values for confirmed positive drug, adulterated, and substituted test results to the MRO when the MRO requests you to do so in writing. The MRO's request may either be a general request covering all such results you send to the MRO or a specific case-by-case request.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing

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that you retain a specimen for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

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(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

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

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.*, January-March, April-June, July-September, October-December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab X in Year 1. In this case, you would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab X and 1000 specimens to Lab Y in Year 1. In this case, you would send 20 blind specimens to Lab X and 10 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab Z. In this case, you would send blind specimens to Labs X and Y as in Example 2. You would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you—not the individual employers—send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter "cap" means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be blank (*i.e.*, containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.*, having specific gravity and creatinine meeting the criteria of § 40.93(b)).

(1) The blind specimens that you submit that contain drugs, that are adulterated with a substance cited in HHS guidance, or that are substituted must be validated as to their contents by the supplier using initial and confirmatory tests.

(2) The supplier must provide information regarding the shelf life of the blind specimens.

(3) If the blind specimen is drug positive, the concentration of drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

(4) If the blind specimen is adulterated with nitrite, the concentration of nitrite it contains must be between 1.5 and 2 times the initial validity test cutoff concentration.

(5) If the blind specimen is adulterated by altering pH, the pH must be less than or equal to 2, or greater than or equal to 12.

(6) If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.000.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.*, via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional ini-

tials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202-366-3784) or e-mail (addresses are listed on the ODAPC web site, <http://www.dot.gov/ost/dapc>). ODAPC will notify HHS who will take appropriate action.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing

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that you retain the records for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.

§ 40.13—Prohibition on making specimens available for other purposes.

§ 40.31—Conflicts of interest concerning collectors.

§ 40.47—Laboratory rejections of test for improper form.

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§ 40.125—Conflicts of interest concerning MROs.

§ 40.175—Role of first laboratory in split specimen tests.

§ 40.177—Role of second laboratory in split specimen tests (drugs).

§ 40.179—Role of second laboratory in split specimen tests (adulterants).

§ 40.181—Role of second laboratory in split specimen tests (substitution).

§§ 40.183–40.185—Transmission of split specimen test results to MRO.

§§ 40.201–40.205—Role in correcting errors.

§ 40.329—Release of information to employees.

§ 40.331—Limits on release of information.

§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Credentials.* You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) *Basic knowledge.* You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.