VA DRUG-FREE WORKPLACE PROGRAM

1. REASON FOR ISSUE: To revise Department of Veterans Affairs (VA) procedures on VA's Drug-Free Workplace Program.

2. SUMMARY OF CONTENTS/MAJOR CHANGES: This handbook contains mandatory procedures on VA's Drug-Free Workplace Program. This revision implements new mandatory guidelines published by the Department of Health and Human Services. The pages in this handbook replace the corresponding page numbers in VA Handbook 5383. Revised text is contained in [brackets]. These changes will be incorporated into the electronic version of VA Handbook 5383 that is maintained on the Office of Human Resources Management Web site. Significant changes include:

a. Revises collection site procedures by itemizing the subject matter used to train collection personnel.

b. Modifies procedures in Appendix II-B by requiring a volume of 45 mL be collected from donors.

c. Clarifies in Appendix II-F that blind samples will be submitted using the same form used for donor specimen.

3. RESPONSIBLE OFFICE: The Employee Relations and Performance Management Service (051), Office of the Deputy Secretary for Human Resources Management.

4. **RELATED DIRECTIVE:** VA Directive 5383, VA Drug-Free Workplace Program.

CERTIFIED BY:

BY DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS

/s/Roger W. Baker Assistant Secretary for Information and Technology /s/Rafael A. Torres Acting Assistant Secretary for Human Resources and Administration

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PART II. URINE DRUG TESTING: COLLECTION AND TRANSPORTATION OF URINE SPECIMENS

1. PURPOSE. This part provides uniform procedures for collection of urine specimens for drug testing, transportation of specimens to the testing laboratory, and submission of blind samples for the purpose of quality control.

2. BACKGROUND. The Mandatory Guidelines for Federal Drug Testing, published by the Department of Health and Human Services (HHS) in the Federal Register on April 11, 1988, established comprehensive standards for laboratory procedures to be used by Federal agencies in implementing a drug testing program as required by Executive Order 12564, Drug-Free Federal Workplace, and Public Law 100-71, Supplemental Appropriations Act of 1987. This part [along with the Mandatory Guidelines for Federal Drug Testing, published by the Department of Health and Human Services (HHS) in the Federal Register on November 25, 2008] is to be used with VA Directive 5383, VA Drug-Free Workplace Program.

3. COLLECTION SITE PROCEDURES

a. Collection Sites

(1) A urine collection site will be identified for each VA facility. Although the collection location for non-medical facilities may be located on-site or at another facility, each medical facility will have a urine collection site. Identification of suitable collection site(s) at medical facilities will be the responsibility of the Chief of Pathology and Laboratory Medicine Service. At non-medical facilities, identification of suitable collection site(s) will be the responsibility of the facility Drug Program Coordinator [(DPC)], with the advice of the Chief of Pathology and Laboratory Medicine Service at the nearest VA medical facility.

(2) The collection site(s) to be [used must be able to be] secured by the collection site personnel before and during collection so that only the materials and supplies necessary for proper urine collection are at the site. The collection site will remain secure throughout the collection process. [The collection site must also provide for:

(a) I]ndividual privacy for the individual during urination. Therefore, the urination area must be partitioned-off from the rest of the collection site. The urination area for the collection site will have only a toilet bowl or a urinal. Facilities for hand washing will be separate from the partitioned-off urination area where the toilet bowl or urinal is located.

(b) [A suitable clean surface area not accessible to the donor, for handling the specimens and completing the required paperwork.

(c) A secure temporary storage capability to maintain a specimen until it is transferred to an HHS-certified laboratory or Instrumented Initial Test Facility.

(d)] Sufficient space [] for temporary storage of materials necessary for a secure collection and for unnecessary outer garments of the individual.

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[(e) The ability to restrict access to collection supplies.]

(3) Designated collection site personnel will be in full control of the collection site as described in paragraph 3b below.

b. Collection Site Personnel

(1) Collection site personnel will be designated by the Director of each VA medical facility based on the recommendation of the Chief of Pathology and Laboratory Medicine Service at that facility. At least one male and one female (and alternates for each) will be appointed based on their experience and demonstrated integrity. Certification in laboratory technology is desirable to ensure familiarity with proper specimen collection procedures. If sufficient certified laboratory technologists or technicians are not available, alternates from other disciplines, such as nursing personnel, may be appointed as long as their qualifications demonstrate experience in specimen collection. Regardless of who are appointed as collectors, these individuals must be capable of complying with strict security measures, following chain of custody procedures and maintaining confidentiality.

(2) Collection personnel will be provided and will become thoroughly familiar with the procedures of this part, the Urinalysis Collection Handbook for Federal Drug Testing Programs published by the National Institute on Drug Abuse, and VA Directive 5383. Particular attention should also be paid to the Mandatory Guidelines for Federal Drug Testing Programs. All field facilities should have copies of these documents. [Collection personnel will receive training from a qualified trainer on the following subjects:

(a) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal Chain of Custody Form (CCF);

(b) Problem collections;

(c) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(d) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.]

(3) The Chief, Pathology and Laboratory Medicine Service, will serve as the collection site supervisor, or with the approval of the facility Director, designate one of the collection site personnel to act in that capacity.

(4) Designated collection site personnel, with the guidance of the Chief of Pathology and Laboratory Medicine Service, will be in control of the collection site, collection kits, CCFs and other required supplies throughout the collection process. Collection supplies should be maintained within the Pathology and Laboratory Medicine Service and protected from tampering. Proper chain of custody and security measures will be followed to fully protect the urine specimen. The collection site personnel will be responsible for shipment of the specimen(s) to a pre-designated certified testing laboratory.

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[(5) Collection personnel will be provided the name and telephone number of the local DPC to contact about problems or issues that may arise during a specimen collection procedure.

(6) Observers must be knowledgeable about the direct observed collection procedure and should be the same gender as the donor (see paragraph 13b of part I).]

c. Services to Non-Medical Facilities. Non-medical VA facilities such as cemeteries, regional offices, data processing centers, [Office of Acquisition, Logistics, and Construction (OALC)] field components, etc., will be provided urine collection services by the nearest VA medical facility. In the event that physical distance precludes easy access to the nearest VA medical center, the medical facility Director, or designee, in consultation with the Director, or designee, of the other facility, will determine whether the individual(s) to be tested will come to the medical center or send collection site personnel to the remote facility.

(1) If collection is done at the other facility, the Chief, Pathology and Laboratory Medicine Service, will ensure that the collection site at the other facility meets the specifications described in paragraph 3a [above]. At the Outpatient Clinics in Anchorage and Honolulu, the Clinic Director will be responsible for designating collection site personnel.

(2) Medical facility Directors, or designees, will contact the Director(s) of the non-medical facilities to be served to make arrangements for the provision of collection services.

(3) The Director, Pathology and Laboratory Medicine Service, in consultation with the Office of Human Resources Management, is delegated the authority to make determinations regarding situations not covered by paragraph 3c [above] or where unique circumstances warrant modification. Such deviations will be kept to a minimum and must be authorized in writing.

d. The designated [DPC] or Human Resources Management Officer will ensure that the designated MRO (Medical Review Officer) receives a copy of this handbook and the related material described in paragraph 2 [above].

APPENDIX B. SPECIMEN COLLECTION – TRANSPORTATION TO THE TESTING LABORATORY

COLLECTION OF SPECIMENS. [Urine is the only specimen that may be collected under the workplace drug testing program.] The following set of procedures will be under the direct control of the collection site personnel.

1. The collector shall ensure that necessary supplies are available in sufficient quantity to complete scheduled collections. All unnecessary material at the site shall be removed and, thereafter, the collector shall have the site under direct observation.

2. The urination area shall be partitioned off, if necessary (existing bathroom stall with door is acceptable).

3. A bluing material shall be placed in the water of the toilet bowl or urinal and any accessible toilet tank for the purpose of preventing dilution of the sample with toilet water.

4. The individual shall arrive at the collection site on time, as designated by the Drug Program Coordinator (DPC). If the individual fails to appear at the pre-designated time, the DPC will be notified by the collection site supervisor. Specific local instructions should be provided on who to contact when an individual fails to report. In such instances, the collector will note on the list of individuals scheduled for collections supplied by the DPC or Human Resources Management Officer, next to the name of the person who failed to report, the date and the notation, "Failed to appear."

5. The collector must verify the identity of the individual to be tested. When an individual arrives at the collection site, the collector shall request the individual to present photo identification. If the individual does not have proper photo identification, the collector will contact the DPC or any other appropriate official, in accordance with locally established policy, who can positively identify the individual. If the individual's identity cannot be established, the collector shall not proceed with the collection.

6. The individual shall be asked to remove unnecessary outer garments (coat, hat, gloves, etc.) and handbags that might conceal items or substances that could be used to tamper with the individual's urine specimen. The collector 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.

7. [The collector must ask the individual to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate or substitute the specimen. If nothing is present that can be used to adulterate or substitute a specimen, the individual may place the items back into the pockets and the collection procedure may continue. If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, a direct observed collection procedure will be used (see paragraph 13b of Part I). If the item appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure. If the individual refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." The collector must stop the collection and report the refusal to test to the Chief, Human Resources Management Service or appropriate management official.]

[8.] Once positive identification has occurred, the collector opens the collection kit and removes the contents in the individual's presence (hereafter, referred to as "donor"). Then the collector completes the following information on the chain of custody form (CCF). (<u>Note</u>: split specimen [collection] procedures will be followed as described in this appendix. Collection site personnel shall prepare two specimen bottles for collection (hereafter referred to as Bottle A [(primary)] and Bottle B [(split)]:

a. Enter the facility name, address and station number of the donor.

b. Enter the name of the Medical Review Officer (MRO) and the facility address where the MRO is employed.

c. Enter the donor's social security number or an alternative to include [the employee's] last name and the [] last four [digits of the employee's] social security number if the employee refuses to provide his or her Social Security Number.

d. Place an "X" in the appropriate box (e.g., "Pre-employment, Random, etc.").

e. Place an "X" next to "THC, Cocaine, PCP, Opiates, and Amphetamines."

[9.] The CCFs are sequentially numbered. They <u>must</u> be used in numerical order and be strictly accounted for.

[10.] The donor shall be instructed to wash and dry hands prior to urination. After washing hands, the donor shall remain in the presence of the collector 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.

[11.] The pre-sealed urine specimen Bottle A shall be given to the donor by the collector. The donor and the collector will inspect the specimen bottle in the presence of each other. If the collector notices that tampering or alteration of the sealed bottle has occurred, a new collection kit will be obtained.

[12.] Unless the collector is instructed otherwise, or as specified in paragraph [22], when there is a reason to believe the donor may alter or substitute the specimen to be provided, the donor may provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The Chief, Pathology and Laboratory Medicine Service, shall review and concur in advance with any decision by a collector to obtain a specimen under the direct observation of a same gender individual based on a reason to believe that the donor may alter or substitute the specimen provided. The reason for collection under observation will be noted in Step 5 of the CCF under the section for remarks. The remarks must be initialed by the Chief, Pathology and Laboratory Medicine Service, indicating concurrence.

[13.] The seal under the cap of the specimen Bottle A will be removed by male donors who will be asked to urinate directly into the specimen bottle. Females will be given the wide mouth container for specimen collection. A specimen of at least 45 mL (approximately 2/3 of full specimen container) will be provided by both the male and female donor. The donor will be <u>instructed not to flush</u> the toilet.

[14.] The collector will remain at the collection site but outside of the stall (or partition) until the urine specimen is collected by the donor and the specimen container is handed to the collector. The donor will hand the specimen container to the collector immediately after voiding. [The collector may set a reasonable time limit for voiding.]

[15.] After the collector has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collector in completing the CCF. Both the individual being tested and the collector shall keep the specimen in view at all times prior to its being sealed and labeled.

[16.] The collector shall determine that at least 45 mL of urine is obtained from the donor. If at least 45 mL is collected, skip paragraphs [17] and [18], and proceed with paragraph [19].

[17.] If the volume is less than [45] mL, the action taken will depend on the temperature of the specimen.

a. If the temperature is within the acceptable range specified in paragraph [19], the specimen shall be discarded and a second specimen collected. The donor may be given a reasonable amount of water to drink [(one 8 ounce glass of water every 30 minutes, not to exceed a maximum of 40 ounces over a period of 3 hours]), and then again attempt to provide a complete sample using a fresh collection container. The collector may use the same CCF for the second specimen. The donor must remain within the area of the collection site during this time. The collector should note in Step 5 of the CCF that the original specimen was discarded due to insufficient volume. [] If the donor fails for any reason to provide at least [45] mL of urine on the second attempt, after drinking at most [40] ounces of [water], the insufficient specimen shall be discarded, testing shall be discontinued and the Chief, Human Resources Management Service or appropriate management official shall be advised.

b. [When the collector reports that the donor did not provide a sufficient amount of urine, the MRO consults with the Chief, Human Resources Management Service or appropriate management official . The Chief, Human Resources Management Service or appropriate management official immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

c.] If the temperature is outside the acceptable range specified in paragraph [19], another specimen shall be collected under direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The donor may be given a reasonable amount of water to drink ([one 8 ounce glass of water every 30 minutes, not to exceed a maximum of 40 ounces over a period of 3 hours]), to provide the second specimen. The collector must use a separate CCF for both specimens. Each specimen shall be inspected in accordance with paragraph [21]. The temperature of both specimens shall be measured in accordance with paragraph [19.] If the donor fails for any reason to provide at least [45] mL of urine on the second attempt, after drinking at most [40] ounces of [water], the insufficient specimen shall be sent to the laboratory with the original specimen, and the Chief, Human Resources Management Service or appropriate management official, shall be advised.

[]

<u>Note</u>: Under no circumstances is the collector permitted to collect and add or combine urine from two separate voids.

[18.] After the specimen has been provided and submitted to the collector, the donor shall be allowed to wash hands.

[19.] Within 4 minutes after urination, the collector will measure the temperature of the urine using the thermometer on collection Bottle A. The temperature is then recorded in Step 2 of the CCF [by placing] an "X" in the appropriate block to indicate whether the temperature was within the acceptable range. If it was not, place an "X" in the "NO" block and record the actual temperature of the specimen. If the temperature is outside the range of $32 - 38^{\circ}$ C/ 90 - 100° F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collector or same gender individual and both specimens shall be forwarded separately to the laboratory for testing.

[20.] A donor may volunteer to have an oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range. If an oral temperature is taken, it should be recorded on the CCF under Step 5 "Remarks."

[21.] Immediately after the specimen is collected, the collector shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted under Step 5 "Remarks" of the CCF. If it is apparent on visual inspection that the donor has adulterated the specimen (e.g., blue dye or other contaminants in the urine), the collector shall collect another specimen under direct observation in accordance with paragraph 22 below.

[22.] Whenever there is a reason to believe that a particular individual has altered or substituted the specimen provided, a second specimen shall be obtained as soon as possible under the direct observation of the same gender collector or individual selected by the Chief, Pathology and Laboratory Medicine Service, and will be recorded on a separate CCF. Both the original specimen and the second observed specimen will be forwarded to the laboratory for testing. All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

[23.] After determining the specimen temperature, the collector, in the presence of the donor, shall retain 30 mL in Bottle A (or pour 30 mL into Bottle A for females) for the primary specimen and pour at least 15 mL into Bottle B for the split specimen.

[24.] The collector shall ensure that the specimen bottle caps are securely screwed on.

[25.] The collection kit contains two red serrated strips that should be placed over the Bottle tops prior to affixing the peel off labels from the form. The red strips should seal the bottles <u>under</u> the peel off labels from the form. The red strips provide an added protection for the donor. The collector shall place the gummed labels from the form securely across the top and down the sides of specimen Bottle A and Bottle B (directly over the red strips) in view of the donor. The collector shall date each label and instruct the donor to initial each label. [If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.]

[26.] The collector shall instruct the donor to complete Copy 4 ("Medical Review Officer" copy) Step 4 of the CCF. The donor shall indicate a daytime and evening phone number, date of birth and after reading the certification statement that the specimen identified as having been collected from the donor is in fact that specimen the donor provided, print his/her name with middle initial, sign, and date the form. [If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.]

[27.] The collector shall complete Step 5 of the CCF, inserting the field facility name, address, collector's phone number, and indicate "yes" for split specimen collection. The collector (after noting any remarks regarding collection, if necessary) must print his/her name, sign and record the date and time of collection.

[28.] The collector shall complete Step 6 of the CCF. The collector will print and sign name and indicate the date the specimen was received and record any transfers of the specimen.

[29.] The collector shall advise the donor of the opportunity to list any prescription and/or over-thecounter medications he or she may have recently taken on the back of the donor copy (Copy 5) of the CCF, but not on any other copy. This information will help the donor remember what medications he or she may have taken if a positive result is reported by the laboratory.

[30.] Both bottles shall be shipped in a single shipping container, together with Copies 1, 2, and 3 of the CCF.

COLLECTION CONTROL

1. While any part of the chain of custody procedures is being performed, it is essential that the urine specimen (Bottles A and B) and chain of custody documents be under the control of the collector. If the collector leaves the work station momentarily, the specimen and custody form shall be taken with the collector or shall be secured in a locker or locked refrigerator with access limited to collection site personnel only. After the collector returns to the work station, the custody process will continue. If the collector is leaving for an extended period of time, the specimen shall be packaged for mailing before the collector leaves the site.

2. To the maximum extent possible, collection site personnel shall keep the donor's specimen bottles within sight both before and after the specimen has been collected. After the specimen is collected, it shall be properly sealed and labeled. The approved CCF is used to identify those individuals who come in contact with the sealed specimen bottles. The date and purpose shall be documented on this form, Step 6, 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.

TRANSPORTATION TO AND FROM THE DESIGNATED DRUG TEST LABORATORY

1. **Packaging.** Only the VA-approved specimen collection kits which include the collection bottles and shipping boxes will be used (see Appendix A to this part). Steps 1 through 6 below will be completed in the donor's presence.

a. The sealed specimen bottles will be placed in the leak proof specimen bag provided and placed in the gray foam insert in the bottom of the shipping box.

b. Peel the Shipping Container Seal off the side of the CCF and set aside. <u>Note</u>: the collection kit contains a separate Kit Shipping Seal. The Kit Shipping Seal should be removed from the box and set aside with the Shipping Container Seal.

c. Then, separate Copy 1, "ORIGINAL," Copy 2, "2nd ORIGINAL" and Copy 3, "SPLIT SPECIMEN," of the CCF. Fold and place all three copies inside the leak proof specimen bag with the urine bottles. <u>Note</u>: if overnight delivery is required, e.g., DHL, express mail, etc., complete appropriate mailing label (self-addressed to the MRO) and place the return label in the box.

d. Close the top of the box. Affix the Kit Shipping Seal in the designated area. Then affix the Shipping Container Seal from the form directly over the Kit Shipping Seal. This provides an added protection for the donor. <u>Note</u>: the same person who last signed the CCF (Step 6) must seal the box.

e. The box will have a pre-printed mailing label affixed and addressed to the screening laboratory.

f. On the Shipping Container Seal now sealing the shipping box containing the specimen, the collection site supervisor shall initial in the area designated "Collector's Initials" and enter the date the specimen was sealed in the container for shipment.

g. Once the box has been sealed in the donor's presence, give the donor Copy 5 and release the individual as instructed by the DPC or Human Resources Management Officer. The donor must remain until the specimen is sealed in the shipping container.

h. Copy 4 of the CCF is to be hand carried to the Medical Review Officer within 2 work days so the MRO may verify that all results have been received from the designated testing laboratory (see Appendix D to this part for a sample memorandum).

i. Copy 6 is to be retained by the collector in a secured file.

j. Copy 7 is to be forwarded to the DPC with the original schedule of donors and kept in a secured file. For pre-employment testing, Copy 7 will be sent to the Human Resources Management Officer.

2. **Delivery.** The sealed box containing the specimen, Copies 1, 2 and 3 of the CCF and the special mailing label if overnight delivery is required, will be delivered to the designated drug testing laboratory by carrying the packaged specimen(s) to the mail room. Packages being sent via regular mail may be directly deposited into an official U.S. mail bag. Overnight deliveries must be given to the mailroom supervisor or designee for special handling. It is not necessary to use registered mail or return receipt mail when mailing specimens.

<u>Note</u>: The same person who sealed the box must place the specimen in the official U.S. mail bag or give it to the mailroom supervisor if overnight mailing is required. Specimens will be mailed from the

collector's facility mail room only. If shipment by overnight courier is desired, remember to complete appropriate mailing label (self-addressed to the MRO) and place the return label in the box.

3. **Expedited Delivery to and from Testing Laboratory.** The screening laboratory will return the testing results by overnight delivery, but will do so <u>only</u> if a self-addressed label is included with each specimen. Failure to include the appropriate label will result in return shipment by regular mail.

RECORDS

The Pathology and Laboratory Medicine Service that collects the specimens is only required to maintain Copy 6 of the CCF. Copy 6 should be stored in a secured file with access only by collection site personnel, the Chief of Pathology and Laboratory Medicine Service, MRO (Medical Review Official), [DPC], and facility Director. <u>Note</u>: the Chief, Pathology and Laboratory Medicine Service is responsible for ensuring that all CCFs are accounted for. CCFs have been sequentially numbered and must be used in that order. If, for any reason a form is voided, it should not be destroyed. Rather, write "VOIDED" across the form (see Appendix E to this part). The Pathology and Laboratory Medicine Service should forward Copy 4 of the "VOIDED" CCF to the MRO and retain all other copies in a secured file to ensure full accountability of all forms.

REPORTS OF DRUG TEST RESULTS

All results shall be reviewed by the MRO. The results will be reported directly to the MRO within an average of 5 working days after receipt of the urine sample by the designated testing laboratory (unless overnight delivery has been arranged). The MRO may also receive a preliminary copy of the results via fax if he or she has completed a form required by the testing laboratory (Minneapolis) indicating he or she has a secured fax line. The official results will be sent via overnight mail or regular mail. The laboratory that collected the specimens will not receive test results. Reports to the MRO will be in printed form only. Telephone reports are not permitted. A copy of the original CCF certified by the laboratory certifying official will also be sent to the MRO. No positive results received will be reported to VA administrative officials unless verified positive by the MRO.

INFORMATION REGARDING TEST RESULTS FOR SPLIT SPECIMENS

1. If the test of Bottle A is verified positive by the MRO, the MRO shall report the result to the Chief, Human Resources Management Service or appropriate management official. The MRO shall then inform the donor of his or her right, in writing, to have Bottle B (split specimen) tested at another laboratory certified by the Department of Health and Human Services (HHS) for the presence of the drug(s) for which a positive result was obtained in the test of Bottle A. The employee [has the opportunity to request through the MRO that the split (Bottle B) specimen be tested at a different (i.e., second) HHS-certified laboratory when the primary (Bottle A) specimen was determined by the MRO to be positive, adulterated, or substituted. A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in his or her records the verbal request from the donor to have the split (Bottle B) specimen tested.] Only the donor may make such a request. The MRO shall honor such a request if it is made within 72 hours of the donor having received notice that he or she tested positive. If such a request is made, the MRO will contact the VAMC Minneapolis laboratory, in writing, and request Bottle B, identified by specimen identification number, be sent to the

HHS-certified laboratory the donor has selected. The result of this test (Bottle B) shall be transmitted to the MRO without regard to the cutoff levels used to test Bottle A.

2. Any action taken as a result of an MRO-verified positive drug test, e.g., removal from performing safety-sensitive duties, may proceed whether or not Bottle B is tested.

3. [If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests that would be conducted on a primary (Bottle A) specimen and report those results to the MRO.]

top and down the sides of specimen Bottles A and B (over the red strips). Do not initial labels at this time. The collection site supervisor will initial labels as described in subparagraph 10.

<u>9</u>. Enter the Specimen Identification No. from the CCF under the space provided for ACCESS# on the ElSohly Control Log.

<u>10</u>. The collection site supervisor will verify that the CCF, the ElSohly Control Log, and that the bottle labels have been completed in accordance with these instructions. It is important to verify the Specimen Identification Number and the fictitious Social Security number from both the ElSohly bottle and the ElSohly Control Log. Following the review, the supervisor will initial in the space marked "Donor Initials" and date both bottle labels. <u>Note</u>: the date on bottle labels must match with the date on of custody form in the space provided for the donor's certification signature. Ensure Copies 1, 2, and 3 of the CCF do not reveal that it is a blind sample.

d. Packaging Samples. The blind PT samples and CCFs are now ready to be packaged and sent to the designated drug testing laboratory. [A blind sample is submitted using the same Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the Federal CCF has been properly completed as well as providing fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature. The samples will be packaged in the same manner as actual donors' specimens.] Packaging instructions are contained in Appendix B to this part.

e. **Submitting Samples to the Testing Laboratory.** The blind PT samples will be sent to the designated testing laboratory and mixed with shipments of bottles of regularly collected urine specimens. If urine specimens are not collected during the time period designated on the ElSohly Control Log, submit the PT samples on the Friday of that designated testing week. Submit all PT samples and annotate on the ElSohly Control Log that no urine specimens were collected for drug testing during that designated submission time period. Check all packages to ensure that they are identical to packages containing actual donors' urine specimens, if applicable.

(1) Note by the ACCESS# on the ElSohly Control Log the date each sample was shipped from the facility to the designated drug testing laboratory.

(2) After the last blind PT sample in each set is submitted, complete and return a copy of the ElSohly Control Log(s) to ElSohly using the mailing label enclosed with the blind PT samples. The collection site supervisor will sign the completed form. A copy of the completed ElSohly Control Log will be retained by the collection laboratory.

f. **Forwarding Forms to Medical Review Officer.** Collection site personnel will advise the Medical Review Officer when blind PT samples are submitted to the designated testing laboratory. The facility Chief of Pathology and Laboratory Medicine Service will provide the Medical Review Officer with Copy 4 of the CCF for each blind PT sample, just as would be provided for each specimen sent to the designated testing laboratory and a copy of the ElSohly Control Log(s) (see the sample memorandum in Appendix D to this part). Next to the Specimen Identification Number on the memorandum, the laboratory will note "Blind PT Sample." <u>Note</u>: collection site personnel will forward an ElSohly mailing label, if available, to the MRO for the MRO's use in submitting test results to ElSohly.