JAN - 1 2004

MEMORANDUM FOR: SEE DISTRIBUTION

SUBJECT: Standard Operating Procedures Manual for Processing and Testing Urine Specimens at Department of Defense Certified Forensic Drug Testing Laboratories

1. The attached Standard Operating Procedures Manual is effective on the date of this memorandum.

2. The Points of Contact are:

Army Drug Testing Program Manager, U.S. Army Medical Command, Phone number (210) 221-7256

Navy Drug Testing Program Manager, Navy Environmental Health Center, Phone number (757) 953-0750

Air Force Drug Testing Program Manager, Office of the Air Force Surgeon General, Phone number (703) 575-5144

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COMMANDER, ARMED FORCES INSTITUTE OF PATHOLOGY, ATTN: CME-T
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COMMANDING OFFICER, NAVY DRUG SCREENING LABORATORY, JACKSONVILLE
COMMANDING OFFICER, NAVY DRUG SCREENING LABORATORY, SAN DIEGO
COMMANDING OFFICER, NAVY ENVIRONMENTAL HEALTH CENTER
COMMANDING OFFICER, NAVY PERSONNEL COMMAND, ATTN: NADAP

LABORATORY CHIEF, AIR FORCE DRUG TESTING LABORATORY

CHIEF, GENERAL LAW DIVISION, OFFICE OF THE JUDGE ADVOCATE GENERAL, UNITED STATES AIR FORCE

COMMANDER, U.S. MILITARY ENTRANCE PROCESSING COMMAND, ATTN: MCDR

DEPARTMENT OF THE ARMY
DEPARTMENT OF THE NAVY
DEPARTMENT OF THE AIR FORCE

STANDARD OPERATING PROCEDURES MANUAL

Processing and Testing Urine Specimens at
Department of Defense Certified Forensic Drug Testing Laboratories

REFERENCES

(a) DoD Directive 1010.1, "Military Personnel Drug Abuse Testing Program", December 9, 1994

(b) DoD Directive 8500.1, "Information Assurance", October 24, 2002

(c) DoD Instruction 1010.16, "Technical Procedures for the Military Personnel Drug Abuse Testing Program", December 9, 1994

(d) AR 600-85, "Alcohol and Drug Abuse Prevention and Control Program", October 1, 2001

(e) OPNAV 5350.4C, "Drug and Alcohol Abuse Prevention and Control", June 29, 1999

(f) MCO P1700.24B, "The Marine Corps Personal Services Manual", December 27, 2001

(g) AFI 44-120, "Drug Testing Program", July 1, 2000

(h) AR 25-1, "Army Information Management", May 31, 2002

(i) AR 380-19, "Information Systems Security", February 27, 1998

1. **Purpose**. This Standard Operating Procedure (SOP) implements and amplifies chain of custody, testing, and reporting requirements set forth in Department of Defense (DoD) Directive 1010.1 and DoD Instruction 1010.16. It provides minimum requirements for standardized forensic drug testing of military personnel and military applicant urine specimens at the DoD Certified Forensic Drug Testing Laboratories (DTLs).

2. **Applicability**.

2.1. All DTLs will at a minimum follow the procedural requirements set forth in this SOP for testing military personnel and military applicant urine specimens collected in the military personnel drug abuse testing program described in reference (a).

2.2. Recommended changes to this SOP shall be submitted to the Biochemical Testing Advisory Board (BTAB) that is composed of the Service drug testing program managers and the Chief Deputy Medical Examiner for Forensic Toxicology (CDMEFT), Armed Forces Institute of Pathology (AFIP), who serves as chair. In coordination with the Office of the Deputy Assistant Secretary of Defense for Counternarcotics (ODASD CN), which has responsibility for program quality assurance, the BTAB may approve minor changes. (See Section 3.4.1 for examples.) The Service approving authorities for this SOP in coordination with ODASD CN shall approve major changes.

2.3. Each DTL will establish a more detailed laboratory SOP; however, local SOPs shall comply with all procedures in this manual. Requirements set forth in this SOP do not preclude implementation of stricter standards by the Services.

2.4. Specimens from military applicants will be processed and tested in accordance with this SOP. The currently approved drug classes for applicant testing are marijuana (cannabinoids) and cocaine and the approved applicant testing form is United States Military Entrance Processing Command () Form 48-8-3-R-E.

3. **Responsibility**.

3.1. Laboratory commander or Laboratory Chief (hereafter laboratory commander)

3.1.1. The laboratory commander is responsible for everything that the laboratory does or fails to do. This includes maintaining the forensic standards of the laboratory. The Commander may delegate in writing his/her authority to subordinate personnel but retains responsibility.

3.1.2. The laboratory commander is responsible for the laboratory SOP and approves it at least annually.

3.1.3. The laboratory commander shall have a plan to address procedures that will be followed in unusual circumstances that stop normal operations in the laboratory (such as power failure, disasters, etc).

3.1.4. The laboratory commander will ensure that the results of each official inspection of the laboratory and any corrective actions are documented.

3.2. Deputy Assistant Secretary of Defense for Counternarcotics (DASD CN), formerly the Coordinator for Drug Enforcement Policy and Support, has overall responsibility for policy and for the quality of the drug demand reduction program that includes the drug testing program.

3.3. Armed Forces Institute of Pathology (AFIP)

3.3.1. The Division of Forensic Toxicology, AFIP, serves as the technical arm of the DASD CN. The CDMEFT is director of the Division of Forensic Toxicology and chair of the BTAB.

3.3.2. AFIP oversees QA inspections and the external proficiency program. AFIP shall conduct three inspections per year for each DTL.

3.3.3. AFIP recommends laboratories for certification and recertification.

3.3.4. AFIP investigates incidents that could impact on the quality of forensic operations as determined by ODASD CN.

3.3.5. AFIP shall maintain the official copy of this SOP. When the official SOP is retired, the AFIP shall keep the historical copy for the same period required for positive drug testing records.

3.4. Biochemical Testing Advisory Board (BTAB): The BTAB is composed of the CDMEFT, who serves as chair, and one member representing the Surgeon General of each Service. The Board advises the DASD CN on technical policy matters.

3.4.1. In coordination with the ODASD CN the BTAB may approve minor changes to this SOP. For example, the BTAB would be permitted to change operating procedures when new tri-service laboratory equipment is purchased under a formal contract and the equipment requires different procedures. In another example, the BTAB could change procedures required by a change in policy from the DASD CN, such as a change in cutoff concentrations or addition of a new drug to the testing menu, since these changes are formally staffed with the Service Secretaries prior to issuance.

3.4.2. Major changes require agreement of the approving authorities for this SOP in coordination with ODASD CN. Each approving authority may waive any provision of this SOP in coordination with ODASD CN.

3.5. Military Service Drug Testing Program Manager: The military service drug testing program manager, a military member in the grade of O5 or above or a civilian employee in the grade of GS12 or above, coordinates and oversees laboratory operations as the representative of the Service Secretary. At a minimum the Drug Testing Program Manager must have a Master's degree in toxicology, biochemistry, or the physical or biological sciences and two years of experience in drug testing.

4. Personnel Qualifications and Training.

4.1. The laboratory commander shall have at least a Master's degree in toxicology, biochemistry, chemistry, the physical sciences or the biological sciences.

4.2. The Director, Technical Services (Laboratory Technical Director) shall have a Ph.D. degree in toxicology, biochemistry, chemistry or the physical or biological sciences and at least one year of forensic toxicology experience or a Master's degree in toxicology, biochemistry, chemistry or the physical or biological sciences and at least two years of laboratory experience in forensic toxicology. The Technical Director will be responsible for the day-to-day technical operations of the laboratory. The laboratory commander shall appoint the Technical Director in writing.

4.3. Either the laboratory commander or the Technical Director shall have a Ph.D.

4.4. An expert witness/consultant shall have at least a Bachelor's degree in a physical science, complete a laboratory training/certification program covering all aspects of forensic drug testing/data review, and demonstrate the ability to clearly communicate information regarding laboratory procedures and forensic toxicology theory and practice. The laboratory is expected to maintain the personnel resources to meet the needs of the military Services for expert witnesses in judicial and administrative proceedings that introduce urinalysis results as evidence. Expert witnesses from other DTLs may be utilized. The laboratory commander shall appoint the expert witnesses in writing.

4.5. A laboratory certifying official (LCO), who authorizes release of test results, shall complete a laboratory training/certification program that demonstrates an understanding of all aspects of the forensic operations in the DTL including data review. The laboratory commander shall appoint the LCOs in writing.

4.6. The Director, Quality Assurance (QA), shall at a minimum have a Bachelor's degree in a physical science. This person shall receive appropriate training in QA and possess an understanding of all aspects of the forensic operations in the DTL. The Director, QA, shall be independent from the testing sections within the laboratory and report directly to the laboratory commander. This direct reporting may not be delegated.

4.7. Civilian personnel in the screening, confirmation, quality assurance, quality control, and results certification sections shall be qualified under the physical science, chemistry, biology, medical technician, medical technologists or equivalent series. Contract employees shall have equivalent qualifications. All personnel hired or assigned to the DTL shall have a background check and not be a security risk. At a minimum they must not have a criminal record or committed a serious act that would call into question their integrity. Civilian and contract employees of the DTL shall be subject to random drug testing as directed by the Services.

4.8. The laboratory commander will ensure that all technical personnel undergo fully documented initial training, certification and periodic recertification for the forensic/analytical procedures they perform. In addition to initial training, DTLs are encouraged to provide and document continuing education and advanced training programs for appropriate DTL personnel.

5. **Security.**

5.1. Security of specimens and their aliquots shall be maintained at all times to ensure that they are not contaminated, adulterated, lost, or tampered with in any way. The number of persons handling or having access to specimens or aliquots will be minimized. Specimens and aliquots will, at all times, be in the possession of an authorized member of the DTL staff, in a secure storage area, or assigned to an instrument on which specimen aliquots are tested.

5.2. Limited access areas shall be designated by the laboratory commander and will include at a minimum the specimen processing section, all temporary and long-term specimen storage areas (to include rooms, freezers, or refrigerators used for such purposes), and the record storage and archive areas for drug testing documents.

5.2.1. The laboratory commander will designate in writing or by electronic means approved by the DASD CN those individuals authorized access to each limited access area. Entry and exit by authorized personnel into limited access areas shall be documented, preferably by a computerized security access system.

5.2.2. Personnel without authorization will not be allowed to enter a limited access area unescorted. They will be escorted at all times by an individual who is authorized access. The access log will reflect name of the visitor and the escort. The escort shall stay with the visitor while in the secure area. The access rosters and logs will be stored in DTL files for the same period of time required for positive drug test records.

5.3. A physical security inspection of the DTL will be conducted annually by an organization authorized by the Service to conduct such security inspections. A copy of the annual security inspection report will be available for review by AFIP inspectors.

6. **Chain of Custody**.

6.1. A complete chain of custody document(s) will account for all specimen and aliquot custody transfers. Chain of custody documents will reflect the date of the transfer, the releaser, the receiver, and the purpose of the transfer. DTL personnel will use similar chain of custody forms to document sample receipt, handling, testing, storage, and disposal. If specimens or aliquots are processed as a batch, a batch custody form may be used if records allow one to associate the individual specimen or aliquot with the batch document.

6.2. The approved specimen custody document (SCD) shall accompany all specimens submitted to the DTL (e.g., DD Form 2624 for military specimens, USMEPCOM Form 48-8-3-R-E for USMEPCOM specimens).

6.2.1. The SCD will document chain of custody of specimens from collection to receipt by the DTL.

6.2.2. The currently approved codes listed in Appendix C shall be used to identify SCDs and specimens submitted but not in accordance with requirements, i.e. with discrepancies.

6.3. The SCD or intra-laboratory chain of custody forms will be used to document all custody transfers for sample processing, storage, and disposal. Custody documentation for aliquots sent to another laboratory is described in section 17.4.

6.4. An intra-laboratory chain of custody form will be used to document custody of a specimen and its aliquots for the screen, rescreen, confirmation testing and any other testing involving aliquots of the specimen. The discarding of negative specimens and/or aliquots will be documented and the document maintained for the time period that negative drug records are kept.

7. **Specimen Receipt & Processing**. Specimens arriving at the laboratory will be immediately transferred, package intact, to the specimen processing room. The specimen processing room will be a limited access area. Specimen processing personnel shall:

7.1. Enter the mode of transportation (i.e., hand-carried, express mail courier, United States Postal Service, etc.) by which the specimens arrived at the laboratory in the "Released By" column on the SCD. (The "Released By" column will reflect how the specimens actually arrived even if different from the annotation made at the collection site in the previous "Received By" column.)

7.2. Sign and date for receipt of the specimens at the laboratory in the "Date" and "Received By" columns.

7.3. Annotate the condition of the box seal.

7.4. Examine package, specimen and SCD to identify and document submission discrepancies. Use the codes in Appendix C to reflect these on the SCD. For any discrepancy each Service operating the DTL will determine if the specimen is testable or untestable.

8. Each DTL SOP will explain the principles of testing procedures.

9. **Initial Screen**. Appendix D lists acceptable screening methodology, minimum testing requirements, and forensic acceptance criteria. The initial test of a specimen will consist of an initial screen and a rescreen. An adjunct screen approved by the DASD CN may also be used following the initial screen to identify negative specimens. The procedures below will be followed for performing the initial screen.

9.1. Specimen processing personnel will obtain the specimen bottle and initiate an intra-laboratory chain of custody form for the specimen batches and subsequent specimen aliquots.

9.2. A unique laboratory accession number (LAN) will be assigned to each specimen. The LAN will be placed on the SCD adjacent to the corresponding specimen social security number (SSN). The LAN will also be placed on the specimen bottle in a manner that precludes it from being disassociated from the urine specimen within the bottle.

9.3. The individual with custody of the specimen bottles for pouring of the specimen aliquot will work with only one open specimen bottle at a time. A LAN label will be transferred

to a clean screening test tube. The individual will pour sufficient urine from the specimen bottle into the labeled test tube. Only the individual with custody of the specimen bottles is permitted to pour an aliquot of the specimen. A pipet or any other sampling device will not be introduced into a single-chambered specimen bottle except by an automated pipeting device approved by the DASD CN.

9.4. Once the specimen aliquots have been dispensed, the specimen bottles will be transferred to a secure temporary storage area. The aliquots will be transferred to a secure temporary storage area or to an individual for initial screening.

9.5. At the completion of the initial testing, documentation (data/results printout and chain of custody documents) will be forwarded through the review process.

10. **Adjunct Screen**. ODASD CN shall authorize adjunct screening tests in writing. It will be used when the initial screening test for a specific drug class identifies a large number of specimens as presumptively positive which would not confirm for a metabolite or parent drug in the drug class of interest.

10.1. This additional screen does not preclude the requirement for rescreen of presumptive positives but specimens that are negative on this screen will be reported as negative for the drug class being tested.

10.2. This test can be conducted on the same specimen aliquot as used for the initial screen or on a newly poured specimen aliquot.

11. **Rescreen**. The rescreen is conducted on those specimens identified as presumptively positive by the first screen and adjunct screen if used. This screen shall be conducted using a new specimen aliquot obtained from the service member's specimen bottle, with fluid blanks inserted between all presumptively positive specimens and blind quality control samples in the rescreening run.

11.1. The individual with custody of the specimen bottles for pouring of the specimen aliquot will work with only one open specimen bottle at a time. The test tubes receiving the aliquot must be labeled with the LAN and the aliquotter must ensure that the LAN on the test tube and bottle are the same.

11.2. Once the specimen aliquots have been poured, the specimen bottles will be transferred to a secure storage area. The aliquots will be transferred to a secure temporary storage area or to an individual for rescreening.

11.3. At the completion of the rescreening, documentation (data/results printout and chain of custody) will be forwarded through the review process.

12. **Automated specimen processing**. In lieu of hand processing and aliquotting for screening described above, DTLs may use an approved automated specimen processing system (APS). The requirements are described in Appendix F.

13. **Confirmation**. Specimens identified as presumptively positive after acceptable initial testing will undergo confirmation testing. The procedures described below will be followed for confirmation tests and any subsequent confirmation tests performed on specimens that were confirmed previously (retests). Appendix E lists the approved confirmation methods, minimum testing requirements, and forensic acceptance criteria.

13.1. The individual with custody of the specimen bottles for pouring of the specimen aliquot will work with only one open specimen bottle at a time. Test tubes for receiving aliquots will be labeled with the LAN and the tube label must be compared to the bottle label at the time of aliquotting to ensure that they match. The preferred method is by comparing bar codes with a scanner or contemporaneously producing the aliquot bar code from a scanner and affixing it to the tube before proceeding to the next specimen bottle. Aliquots must be poured from the original specimen bottle. Do not introduce a pipet into the original bottle to take confirmation aliquots unless ODASD CN has approved the pipeting procedure. When quantitative transfers are made from one aliquot tube into another, the quantitation test tube must be labeled and the label compared to the transit test tube to ensure that they match. When extracts are transferred to another container, the analyst must ensure that the receiving container or extraction column is labeled and the labels correspond to the correct specimen aliquot. Bar code comparison or production with a scanner is once again preferred.

13.2. Once the specimen(s) have been dispensed, the specimen bottles will be returned to a secure temporary storage area. The aliquots will be transferred to a secure temporary storage area or to an individual for confirmation testing.

13.3. The DTL shall introduce procedures to prevent carryover of drug from one sample to the next during the confirmation process. This will be accomplished by introducing check samples within each batch to detect carryover or by validation studies that demonstrate that carryover is negligible using the confirmation procedures.

13.4. At the completion of confirmation testing, documentation (data/results printout and chain of custody documents) will be forwarded through the review process.

14. **Forensic Corrections.**

14.1. Forensic documents are subject to errors like any other documents. However, procedures used to correct errors on forensic documents are different than normal documents. Correction to forensic documents must be clear, concise and consistent. Forensic corrections should document the nature of the correction, not eliminate evidence that an error or omission occurred. To accomplish this, corrections shall be made so that the original entry is preserved,

that the correction and initials of the individual who made the correction are clear and legible. In some cases a memorandum for record (MFR) may be necessary to clarify any uncertainty relating to corrections.

14.2. Memorandum For Record (MFR): A MFR is an official record prepared to document and clarify situations, irregularities or deviations from standard operating procedures that based on the document and corrections alone would not be apparent or explainable. MFRs are written and adopted as true and accurate by the person who signs the MFR. A MFR becomes a permanent part of the original documentation and will be included in any litigation package for affected specimens. MFRs should be clear, concise, typewritten and reflect the same care in preparation that is typically applied to all other activities within the laboratory. Normally the person involved in an incident writes the MFR.

15. **Reporting and Records.** Upon completion of testing, the following procedures will be used to certify and report the results to the submitting unit or medical review officer (MRO). Procedures are also listed for record storage.

15.1. A LCO will review all relevant documents supporting a result and approve the result for release to the submitting command.

15.1.1. Negative Results

15.1.1.1. Any specimen with a valid screen, rescreen, adjunct test or confirmation test that is negative for a drug will be reported as negative for that drug.

15.1.1.2. Before reporting a negative result, a LCO shall ensure that the results were correctly determined. This review includes, at a minimum, ensuring compliance with chain of custody and technical procedures in the laboratory SOP. The LCO who authenticates the results must have reviewed all custody documentation and scientific testing data that supported the negative result.

15.1.2. Positive Results

15.1.2.1. Positive results will be reported only for specimens that are determined to be positive on an initial test (a screen and a rescreen) and a confirmation test. All tests shall meet the scientific, administrative, and forensic requirements described in this SOP prior to being reported as positive.

15.1.2.2. Before reporting a positive result, a LCO shall ensure that results were correctly determined. This review includes, at a minimum, ensuring that proper chain of custody and technical procedures were conducted and that a LCO has verified that the bottle containing the urine matches the SCD.