



Department of Defense INSTRUCTION

NUMBER 1010.16

October 10, 2012

Incorporating Change 1, Effective February 27, 2017

USD(P&R)

SUBJECT: Technical Procedures for the Military Personnel Drug Abuse Testing Program
(MPDATP)

References: See Enclosure 1

1. PURPOSE. This Instruction:

a. Pursuant to DoD Directive (DoDD) 5124.02 (Reference (a)) reissues DoD Instruction (DoDI) 1010.16 (Reference (b)) to update the policies, requirements and procedures for the MPDATP pursuant to DoDI 1010.01 (Reference (c)).

b. Incorporates and cancels Standard Operating Procedures Manual (Reference (d)).

c. Promotes standardization and joint service operations among all Service Forensic Toxicology Drug Testing Laboratories (FTDTL).

2. APPLICABILITY. This Instruction:

a. Applies to:

(1) OSD, the Military Departments (including the Coast Guard when operating as a service in the Navy), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (hereinafter referred to collectively as the "DoD Components"). The term "Military Services" as used herein, refers to the Army, Navy, Air Force, Marine Corps, Active and Reserve Components.

(2) Tests conducted under the MPDATP on specimens received by the military FTDTLs.

(3) Foreign nationals employed by DoD or attending U.S. military training schools only as authorized by intergovernmental agreements negotiated on a country-by-country basis.

b. Does not apply to testing by the Armed Forces Medical Examiner System (AFMES) ~~pursuant to the DoD Executive Agency of the Secretary of the Army, and DoDD 5136.01 (Reference (e)); or forensic pathology analysis pursuant to DoDD 5124.24 (Reference (e)) and the Department of the Army, Office of the Surgeon General Memorandum (Reference (g)) or forensic pathology analysis pursuant to DoDI 5154.30 (Reference (e)).~~

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. Pursuant to Reference (c), drug testing will be conducted to deter Military Service members, including those members on initial entry and on active duty after enlistment or appointment, from abusing drugs (including illegal drugs, other illicit substances, and prescription medications).

b. Drug testing is used to permit commanders to assess the security, military fitness, readiness, good order, and discipline of their commands and allow commanders to take disciplinary or administrative action as appropriate.

c. Urine specimens tested as part of the MPDATP shall be tested by a DoD laboratory certified pursuant to sections 23-24 of Enclosure 4 of this Instruction or by a laboratory approved by the ~~Deputy~~ Assistant Secretary of Defense for Readiness ~~(DASD(R))(ASD(R))~~.

d. Urine specimens, collected as part of the drug abuse testing program, shall be controlled by a stringent chain of custody (CoC) procedure at the collection site and during all analytical procedures conducted at the FTDTLs.

e. Testing of foreign nationals employed by DoD or attending U.S. military training schools may be conducted pursuant to this Instruction only as authorized by intergovernmental agreements negotiated on a country-by country basis.

f. All FTDTL personnel hired or assigned to the FTDTL, including contract personnel, shall have a satisfactory background check, verification of education credentials and prior employment history. Indications of drug/alcohol abuse, workplace violence, harassment, unprofessional, or unethical behavior are grounds for denial or termination of employment *consistent with civilian personnel laws, regulations, and policies.*

5. RESPONSIBILITIES. See Enclosures 2 and 3.

6. PROCEDURES. Procedural guidance for this Instruction is found in Enclosure 4.

7. RELEASIBILITY. ~~UNLIMITED~~. *Cleared for public release*. This Instruction is ~~approved for public release and is~~ available on the ~~Internet from the~~ DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. *This Instruction is effective October 10, 2012.*

~~— a. This Instruction is effective October 10, 2012.~~

~~— b. This Instruction must be reissued, cancelled, or certified current within 5 years of its publication in accordance with DoD Instruction 5025.01 (Reference (h)). If not, this ISSUANCE will expire effective October 10, 2022 and be removed from the DoD Issuances Website.~~



Erin C. Conaton
Under Secretary of Defense
Personnel and Readiness

Enclosures

1. References
2. Responsibilities
3. Organization Within the MPDATP – Technical Qualifications and Responsibilities
4. Technical Procedures for the MPDATP
5. DoD BTAB
6. MS/MS Instrument Standards
7. Procedures for Substance Abuse Testing and the Administrative Processing of Applicants and New Entrants to the Military Services and Their Reserve Components
8. Special Drug Testing

Glossary

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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R)), June 23, 2008
- (b) DoD Instruction 1010.16, "Technical Procedures for the Military Personnel Drug Abuse Testing Program," December 9, 1994 (hereby cancelled)
- (c) DoD Instruction 1010.01, "Military Personnel Drug Abuse Testing Program," ~~December 9, 1994~~ *September 13, 2012*
- (d) Service Surgeon General, "Standard Operating Procedures Manual for Processing and Testing Urine Samples at Department of Defense Certified Forensic Drug Testing Laboratories," January 1, 2004 (hereby cancelled)
- ~~(e) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," June 4, 2008~~ *September 30, 2013*
- ~~(f) DoD Directive 5154.24, "Armed Forces Institute of Pathology (AFIP)," October 3, 2001~~
- ~~(g) Memorandum, Department of the Army, Office of the Surgeon General, "Command and Control (C2) for the Armed Forces Medical Examiner's Office (AFME) and the National Museum of Health and Medicine (NMHM)," July 29, 2010~~
- ~~(h) DoD Instruction 5025.01, "DoD Directives Program," October 28, 2007~~
- ~~(e) DoD Instruction 5154.30, "Armed Forces Medical Examiner System (AFMES) Operations," December 29, 2015~~
- ~~(i)(f)~~ U.S. Postal Service, "Domestic Mail Manual," section 600, ~~October 11, 2007~~ *current edition*
- ~~(j)(g)~~ Section 219.102(e) of Title 32, Code of Federal Regulations
- ~~(k) DoD Directive 8500.01E, "Information Assurance (IA)," October 24, 2002~~
- ~~(h) DoD Instruction 8500.01, "Cybersecurity," March 14, 2014~~
- ~~(i)(i)~~ Section 521 of Public Law 100-456, "The National Defense Authorization Act for Fiscal Year 1989," September 29, 1988
- ~~(m)(j)~~ DoD Instruction 1332.14, "Enlisted Administrative Separations," ~~August 28, 2008~~ *January 27, 2014, as amended*
- ~~(n)(k)~~ DoD Instruction 1332.30, "Separation of Regular and Reserve Commissioned Officers," ~~December 11, 2008~~ *November 25, 2013*
- ~~(l) DoD Instruction 1215.08, "Senior Reserve Officers' Training Corps (ROTC) Programs," June 26, 2006~~

ENCLOSURE 2

RESPONSIBILITIES

1. ~~DASD(R) ASD(R)~~. The ~~DASD(R)-ASD(R)~~, under the authority, direction, and control of the ~~Assistant Secretary of Defense for Readiness and Force Management (ASD(R&FM)) Under Secretary of Defense for Personnel and Readiness (USD(P&R))~~, ~~shall~~ will:

- a. Establish the procedures and standards for the technical aspects of the MPDATP.
- b. Provide oversight of the certification program and ensure quality and accuracy of the analyses performed at each FTDTL.
- c. Provide oversight for an external quality assurance (QA) program for the DoD-certified FTDTLs.
- d. Establish a DoD Drug Testing Laboratory Biochemical Testing Advisory Board (BTAB) to provide technical consultation to the Director, DoD Drug Testing and Program Policy (DDT&PP) on technical matters related to the MPDATP.

2. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments shall:

- a. Assign a Military Service drug testing program manager with technical responsibility for oversight of the procedures used within the FTDTLs under the respective Military Department's cognizance to ensure that the minimum guidelines promulgated in this Instruction are met.
- b. Ensure that personnel involved in the collection, handling, and testing of specimens, and review and interpretation of drug test results receive appropriate training.
- c. Ensure that procedures used in the FTDTLs are described in an operating procedures (OP) manual that meets, at a minimum, the requirements of this Instruction. The OP manual shall include, at a minimum, standards for the following: specimen receipt and laboratory CoC procedures; procedures for conducting initial screen, adjunct screen, and confirmatory tests; retest procedures; internal quality control (QC) and QA programs, privacy and confidentiality standards, and administrative procedures, to include a continuity of operations plan (COOP) as detailed in paragraph 5.a. of Enclosure 4.
- d. Ensure their respective Military Department uses legally supportable CoC procedures and, at a minimum, conform to the requirements of Enclosure 4 of this Instruction, to confirm the presence of either the parent drug or their metabolites in urine specimens.
- e. Ensure that any forensic urine specimens, collected in military treatment facilities or clinics, are submitted to the FTDTLs using the procedures described in Enclosure 4 of this

Instruction. Specimens collected prior to confinement and in military rehabilitation programs, solely for the purpose of monitoring abuse of drugs, may be submitted to the FTDTLs. Specimens collected solely for clinical diagnosis are not forensic specimens and are not submitted to the FTDTLs.

f. Develop and manage a medical review process (MRP) to review all drug positive results that could be the result of licit or illicit prescription drug use. The MRP ensures that no adverse disciplinary action will be administered to those who possess a valid medical prescription for the drug for which the member tested positive. The Military Departments must have a procedure for transmitting the results of the MRP to the Defense Manpower Data Center (DMDC) within 90 days of the original FTDTL result report.

ENCLOSURE 3

ORGANIZATION WITHIN THE MPDATP – TECHNICAL QUALIFICATIONS AND RESPONSIBILITIES

1. DIRECTOR, DDT&PP. The Director, DDT&PP, under the authority, direction, and control of the ~~DASD(R)~~ *ASD(R)*, shall:

a. Be a member of the Armed Forces in the grade of O-5 or O-6, have a PhD degree in toxicology, biochemistry or physical or biological sciences from an accredited university, and possess a minimum of 4 years of leadership or managerial experience in an FTDTL.

b. Develop, staff, and provide execution oversight for policy related to the technical aspects of the MPDATP.

c. Coordinate the activities of the Military Service drug testing program managers to assure efficient inter-laboratory cooperation between the Services to support best business practices through standardization, common analytical methodologies, and purchasing contracts.

d. Be responsible for the overall forensic integrity of the DoD forensic drug testing system. Ensure that QA incidents that significantly impact the forensic integrity of the testing process are investigated and appropriate corrective actions are completed.

2. CHIEF DEPUTY MEDICAL EXAMINER, DIVISION OF FORENSIC TOXICOLOGY (CDME-FORTOX). The CDME-FORTOX, under the authority, direction, and control of the Secretary of the Army, shall:

a. Provide technical expertise to the ~~DASD(R)~~ *ASD(R)* through the Director, DDT&PP.

b. Provide for external QC and proficiency testing programs for the FTDTLs.

c. Coordinate the external QA program consisting of three annual inspections at each FTDTL.

d. Coordinate FTDTL certification and recertification actions, for the drugs listed on the DoD drug testing panel, and forward recommendations to the Director, DDT&PP.

e. Evaluate, through on-site investigation or document review, all significant non-conforming events (NCEs) that impact the quality of forensic operations, and forward recommendations to the Director, DDT&PP.

f. Serve as the chair of the BTAB. The BTAB functions are outlined in Enclosure 5 of this Instruction.

3. COMMANDER, U.S. MILITARY ENTRANCE PROCESSING COMMAND (USMEPCOM). The Commander, USMEPCOM, under the authority, direction, and control of Deputy Assistant Secretary of Defense for Military Personnel Policy, shall ensure that all applicant testing is conducted at a DoD approved testing laboratory and will coordinate with that laboratory to maximize efficiency of testing pursuant to Enclosure 7. The Commander, USMEPCOM, will notify applicants of positive results and encourage the applicant to seek treatment and provide them with a list of appropriate resources.

4. MILITARY SERVICE DRUG TESTING PROGRAM MANAGER. The Military Service Drug Testing Program Manager shall:

a. Be a member of the Military Service in grade of O-5 or above or a civilian employee in the grade of GS-14 or above, have, at a minimum, a PhD degree in toxicology, biochemistry or the physical or biological sciences from an accredited university, and at least 3 years of experience as an FTDTL Commander.

b. Serve as a voting member of the BTAB.

c. Serve as the representative of the Service Secretary, coordinate and oversee FTDTL operations, and ensure compliance of senior FTDTL staff assignments pursuant to this Instruction.

5. FTDTL COMMANDERS. The FTDTL Commanders, under the authority, direction, and control of their respective chains of command, shall:

a. Be a member of the Armed Forces, in the grade of O-4 or above and have, at a minimum, a PhD degree in toxicology, biochemistry or the physical or biological sciences from an accredited university, and at least 3 years of experience in one of the DoD FTDTLs.

b. Be responsible for the forensic integrity of the FTDTL operations. While the Commander may delegate in writing his or her authority to subordinate personnel for various FTDTL functions, the Commander retains ultimate responsibility for ensuring all operations of the FTDTL are held to the quality and forensic standards set forth in this Instruction and further defined in their individual OP manual.

c. Be responsible for ensuring their individual FTDTL OP manuals are current and reflect the standards defined in this Instruction and their individual OP manual. All changes to FTDTL OP manuals must be approved by the Commander. All FTDTL OP manuals must be reviewed, at a minimum, annually by the FTDTL Commander.

d. Establish plans that address procedures to be followed in unusual circumstances that impede normal operations in the FTDTL.

e. Ensure all results from scheduled QA inspections and QA incident inspections are documented and any required corrective actions are completed and documented in a timely manner.

6. DIRECTORS, TECHNICAL SERVICES (TECHNICAL DIRECTORS) OR PRODUCTION SERVICE MANAGERS. The Directors, Technical Services or Production Service Managers, under the authority, direction, and control of their respective chains of command, shall:

a. Be appointed in writing by the FTDTL Commander.

b. Have as a minimum requirement either a PhD degree in toxicology, biochemistry or the physical or biological sciences from an accredited university and at least 3 years experience in forensic toxicology; or, have a Masters degree in toxicology, biochemistry, chemistry or the physical or biological sciences from an accredited university and at least 4 years experience in forensic toxicology.

c. Maintain technical expertise in the science of forensic toxicology by regular review of publications in peer reviewed scientific journals.

7. EXPERT WITNESSES. Expert witnesses shall:

a. Be appointed in writing by the FTDTL Commander.

b. Have as a minimum requirement a Bachelor's degree in toxicology, biochemistry, chemistry, or the physical or biological sciences from an accredited university.

c. Complete a comprehensive training program, which includes but is not limited to, certification as a laboratory certifying official (LCO), expert witness training, and certification requirements of the FTDTL and MPDATP.

d. Demonstrate the ability to clearly communicate information regarding laboratory procedures, forensic toxicology theory and practice, and the physiologic effects of drugs.

e. Maintain technical expertise in the science of forensic toxicology by regular review of publications in peer reviewed scientific journals.

8. FTDTL-LCOs. The FTDTL-LCOs, under the authority, direction, and control of their respective chains of command, shall:

a. Be appointed in writing by the FTDTL Commander.

b. Have as a minimum requirement a Bachelor's degree in toxicology, biochemistry, chemistry, or the physical or biological sciences from an accredited university.

c. Complete a comprehensive training program that documents technical understanding of the methodologies and forensic regulations used to process and analyze specimens, review data and report results.

d. Demonstrate proficiency and technical competency to perform testing procedures within the FTDTL and complete certification in all technical areas of the FTDTL.

ENCLOSURE 4

TECHNICAL PROCEDURES FOR THE MPDATP

1. GENERAL

a. Procedures for collection of specimens shall be established by the Military Departments and incorporate the basic requirements as stated throughout this enclosure.

b. Specimen collection, custody transfer, and transport to the FTDTL shall be pursuant to Service instructions and shall be documented on the approved CoC form, DoD Form 2624, "Specimen Custody Document – Drug Testing" or USMEPCOM Form 40-8-3-R-E, "Urine Sample Custody Document."

2. PREPARATION FOR SPECIMEN COLLECTION. Service procedures shall ensure that approved bottles are used for specimen collection. Each bottle must be properly labeled with specific Service-required information to include the member's full *social security number (SSN): DoD identification number (DoD ID). Acceptable DoD ID is the Electronic Data Interchange – Personal Identifier (EDI-PI) or social security number (SSN)*. However, the member's name must not be part of the information on the specimen bottle, CoC, or other documentation submitted to the FTDTL. Other information regarding collection may be included (e.g., base area code, unit identifiers, and date of collection).

3. COLLECTION OF SPECIMENS. Military Department procedures shall ensure that:

a. The volume of urine collected exceeds 30 milliliters. Volumes less than 30 milliliters will be screened but may limit the extent of testing conducted on polydrug positive specimens. A specimen with volumes less than 30 milliliters will be reported as a non-fatal discrepancy (specimen is testable) to the submitting command. If the specimen volume is insufficient for testing, a fatal discrepancy will be reported to the submitting command. *Urine is the only acceptable specimen tested at the FTDTL.*

b. Specimens are collected under the direct observation of a designated individual ~~of the same sex~~ *with the same gender marker in the Defense Enrollment Eligibility Reporting System* as the Service member providing the specimen. *Commanders have discretion to take additional steps to promote privacy, provided those steps do not undermine the integrity of the program. However, all collections must be directly observed.* CoC procedures are designed to ensure the security of and accountability for specimens during all aspects of collection, storage, and transportation to the FTDTL. Service requirements for testing policy (e.g., quotas, scheduling, observation, storage, and transportation) are established by the Military Departments.

c. Each individual to be tested shall present proof of identity. The Service member submitting the specimen will provide an unadulterated specimen, verify that the SSN is

accurately recorded on the CoC form and bottle label, initial the bottle label, and sign the corresponding entry in the collection record. Authorized tamper-evident tape is placed over the lid of the specimen bottle in the presence of the member and attached securely to the bottle label. The tape shall contact the label at both ends. Other types of tape shall not be used for this purpose.

d. The appropriate CoC form is properly completed and the collection record is properly documented with Service required information including the name and signature of the Service member and the name of the observer.

4. TRANSPORTATION OF SPECIMENS. Service procedures shall comply with the requirements of section 600 of the U.S. Postal Service domestic Mail Manual (Reference ~~(i)~~(f)), and ensure that:

a. The lids of all specimen bottles forwarded for testing are securely tightened, properly sealed and the bottles are enclosed in a leak-proof secondary container. The secondary container(s) must contain sufficient absorbent material to absorb the entire specimen contents in case of leakage.

b. The original CoC form or photocopy of the original CoC form is shipped with the specimens. Each shipping package must be sealed. Except for Military Entrance Processing Station (MEPS) collections, the signature or initials of the collection coordinator, or appropriate individual must be annotated across the seal to ensure integrity of specimens. This requirement applies to all methods of transportation including specimens hand-carried to the FTDTLs.

c. Packages are transported to the FTDTL using either U.S. Postal Service, commercial air freight, air express, or surface transportation, Air Mobility Command, United States Transportation Command, or hand delivery.

5. OP DURING CATASTROPHIC INCIDENTS

a. Each FTDTL shall have documented a COOP in the event of a catastrophic incident (e.g., hurricane, tornado, flood, fire, earthquake) during which FTDTL operations are temporarily suspended. Other events, such as personnel shortages, extreme number of sample submissions, laboratory relocations, computer hardware and software failure, may also adversely impact the FTDTL network and FTDTL operations. The laboratory must anticipate such events and establish an emergency notification, shelter, and recovery plan that is detailed in the FTDTL COOP. The FTDTL COOP shall be tested periodically by conducting evacuation and shelter drills, personnel recall, and other exercises.

b. When FTDTL operations cannot be restored within a few days, the Military Service drug program manager will coordinate with the Director, DDT&PP, and the other Military Service drug program managers, to coordinate redistribution of specimen submissions to other FTDTL

facilities. Each incident will be assessed to determine the proper utilization of manpower and resources in order to resume FTDTL operations, when feasible, as quickly as possible.

6. LABORATORY SECURITY

a. The security of urine specimen submissions and aliquots used in testing shall be maintained at all times to ensure that the urine is not subject to possible contamination, adulteration, loss, or tampering. Access to and the number of individuals in the processing of specimens or aliquots will be kept to a minimum. All individuals involved in the processing of specimens or aliquots shall be documented in a CoC. Specimens and aliquots must always be either in the possession of an authorized member of the FTDTL staff, in a secured storage area, or assigned to an instrument on which specimens are tested.

b. The FTDTL Commander will delineate in writing or by electronic means the individuals with authorized entry to each limited access area of the laboratory. For each of the limited access areas, the entry and exit of authorized personnel shall be documented, preferably by an electronic security access system. Limited access areas shall be designated by the FTDTL Commander and will include at a minimum the areas of specimen processing or accessioning sections, all testing areas, all temporary and long-term specimen storage areas (to include rooms, freezer, or refrigerators used for such purposes), and record archive areas for drug testing documents. Visitors must be escorted at all times by an individual who is authorized access. The access logs or memorandum for record (MFR) will reflect the date, time, names of visitors and the FTDTL escort, and purpose of the visit.

c. The FTDTL shall have physical security measures, to include, but not limited to, intrusion alarm systems, camera monitors and recording devices, motion detectors, card access, and card entry tracking. A physical security inspection of the FTDTL will be conducted annually by an organization authorized by the Service to conduct such inspections and a copy of the annual security inspection report will be available for review by DoD certification inspection teams.

7. INTERNAL LABORATORY CoC

a. Internal laboratory CoC forms will be used to document all specimen and aliquot custody transfers during processing, storage, and disposal. CoC forms will reflect the date of the transfer, the releaser, the receiver, and the purpose of the transfer.

b. Individual specimens are tracked using the unique laboratory accession number (LAN) originally assigned to the specimen on the original DoD Form 2624 upon receipt at the labs. A batch CoC form will be used to accompany a batch of specimens throughout the testing process to document and track the progress of individual specimens or aliquots.

c. Specimens are considered to be in the custody of the laboratory technician, as long as the technician remains in the same secured, limited access area of the laboratory as the specimens. If the technician leaves this area, custody of the specimens must be transferred to another

technician, secure temporary storage, or to the appropriate laboratory instrumentation. If the secured area contains multiple rooms, once the technician leaves one room in the section, the custody of the specimens must be transferred to another technician, secure temporary storage, or to the appropriate laboratory instrumentation. Custody of the specimens must always be transferred to the screening analyzer, mass spectrometer or other instruments during processing and analysis.

d. Custody documentation for aliquots sent to another laboratory is described in paragraph 16.e. of this enclosure.

8. SPECIMEN RECEIPT AND PROCESSING. Specimens arriving at the FTDTL will be transferred, with the original packing intact, to the specimen processing area. Specimen processing personnel shall:

a. Examine the package, specimen, and CoC to identify and document submission discrepancies, and sign and date the sample submission CoC form for receipt of the specimens at the FTDTL. Each Service shall comply with the list of fatal and nonfatal discrepancy codes established by the Director, DDT&PP, to determine the acceptability of a specimen for testing received at the FTDTL.

b. Assign a unique LAN to each specimen. A LAN label shall be placed on the CoC adjacent to the corresponding specimen, on the specimen bottle, and on the bottle lid.

9. DRUG TESTING

a. The DoD authorized panel of drugs to be tested at the FTDTLs and their associated initial screen and confirmation cutoff concentrations (Tables 1 and 2, respectively) are in the Appendix to this enclosure.

b. All FTDTLs will screen 100 percent of the testable specimens that they receive for the marijuana acid metabolite, cocaine metabolite, heroin metabolite and amphetamines (including designer amphetamines).

c. The FTDTL will “pulse test” (screen 20-100 percent of specimens received) for the other drugs listed in Table 1 of the Appendix in this enclosure. Changes to the drug testing panel and cutoff concentrations listed in Tables 1 and 2 of the Appendix to this enclosure, as well as pulse testing rates are defined by ~~the DASD(R)-ASD(R)~~.

d. The MPDATP will conduct prevalence testing to monitor the use of illicit drugs that are not on the current drug testing panel. As determined by subject matter experts of the BTAB and AFMES to address emergent drug threats, negative urine samples slated for destruction will periodically be retained and screened for additional illicit drugs. Results of the prevalence studies along with recommendations will be forwarded through the BTAB to the Director, DDT&PP, to support policy changes by the ~~DASD(R)-ASD(R)~~.

e. Testing of specimens for drugs or drug metabolites other than those listed in Tables 1 and 2 of the Appendix to this enclosure shall be collected pursuant to the procedures in section 3 of this enclosure. The FTDTL may forward aliquots of these special tests specimens to another DoD certified drug testing laboratory pursuant to Enclosure 8. The recipient laboratory must have demonstrated expertise in conducting urine drug testing and use certified and validated reference standards in the analytical assays. The recipient laboratory must employ 2 independent methodologies, based on different scientific principles to test the specimens. If 2 methodologies are not available, positive results using only DoD-approved separation techniques with mass spectrometry detection is permitted. Duplicate analysis must be completed, going back to the original specimen to begin analysis for each replicate. Since administrative cutoff concentration testing levels are not established for drugs other than those in Tables 1 and 2 of the Appendix to this enclosure, the DoD certified laboratory may report a specimen as positive when the concentration of the drug or metabolite exceeds the limit of quantification (LOQ).

f. All specimens arriving at the FTDTL shall be tested, except for those specimens with discrepancies determined to be fatal according to the receiving FTDTL OP manual. All submission discrepancies will be coded using the Military Department's approved list of discrepancies. During specimen processing and testing, fatal discrepancies shall be documented and will be reported to the submitting unit.

10. INITIAL SCREEN TEST

a. The purpose of the initial screen test is to identify those specimens that are "presumptively positive" and will require continued testing. The initial screen will eliminate negative specimens to focus efforts and resources on those specimens most likely to contain drugs of abuse. All immunoassay (IA) test kits used for the initial screen test must be authorized by the Director, DDT&PP, and, unless otherwise authorized, all IA test kits must be approved for commercial sale and distribution by the Food and Drug Administration. All IA procedures must be validated prior to implementation. Method validation will be described in the FTDTL OP manual and must include, at a minimum:

(1) Determination of the IAs precision at 0 percent, 50-75 percent, 100 percent, and 125-150 percent of the screening cutoff concentration.

(2) Determination that no data overlap occurs between the 0 percent cutoff concentration and the 100 percent cutoff concentration.

(3) Demonstration of the IAs ability to discriminate between positive and negative specimens near the 100 percent cutoff concentration.

(4) Demonstration of the IAs ability to differentiate between known positive and known negative specimens.

(5) Performance of a statistically acceptable parallel or “side-by-side” study of the current and new or revised IA.

(6) Determination of interferences from similar or related compounds.

b. To process specimens for the initial screen test, the technician will complete the appropriate intra-laboratory bottle and aliquot CoC documents. The technician will work with only one specimen bottle at a time in applying the duplicate LAN label from the specimen bottle onto a test tube and contemporaneously pour a sufficient volume from the specimen bottle for the initial screen test. A pipette or any other sampling device will not be used to transfer an aliquot from the original specimen bottle except via an automated device approved by the Director, DDT&PP. Once the aliquots have been prepared, the specimen bottles will be transferred to a secure temporary storage area. Aliquots will be transferred to a secure temporary storage area or to the technician conducting the initial screen testing.

c. All IAs performed at the FTDTL will consist of specimens contained within discrete identifiable batches. Each batch will contain a minimum of 5 percent open controls. The instrument used in screening analysis will be calibrated at least daily. Calibration acceptance criteria include a negative (drug-free) control which must test lower than the low control, low controls (50-75 percent cutoff concentration which shall test negative) and high controls (125-150 percent cutoff concentration which shall test positive).

(1) Each batch of aliquot samples for the initial screen test will contain a minimum of one blind positive and one blind negative (target analyte-free control). The blind controls will be placed randomly in the batch pursuant to the FTDTL OP manual. Blind positives must test positive. Blind negatives must test negative with values below those for the low control. The FTDTL OP manual will provide guidance for partial batch acceptance criteria when these criteria are not met.

(2) At the completion of the initial screen, the test results and other documentation will be forwarded for QC and LCO review. The FTDTL OP manual will provide guidance for repeat testing whenever the open or blind control criteria are not met.

(3) The FTDTL Commander has the right to repeat or terminate testing for any specimen when it is determined that the validity of the result is forensically or scientifically questionable.

11. ADJUNCT SCREENING TEST. Pursuant to recommendations from the BTAB, the Director, DDT&PP, shall authorize adjunct screen tests. Adjunct testing will be used when the initial screen test for a specific drug class identifies a large number of specimens as presumptive positive that would not test positive in the confirmatory test for the target analyte in the drug class of interest. An adjunct screen test may be conducted on the same specimen aliquot used for the initial screen or a separate aliquot. Negative results can be used to eliminate specimens from further testing and positive results can be used to determine that a specimen requires further testing and may be used to complete the requirement for the initial test.

12. CONFIRMATORY TEST

a. The purpose of the confirmatory test is to specifically identify and quantify drug presence in specimens identified by IA screening as presumptive positive for a drug or drug metabolite at or above the administrative cutoff concentration, established by the ~~DASD(R)~~ ASD(R).

b. Specimens that screen presumptive positive will be confirmed by chromatography/mass spectrometry (C/MS). Different analytical methodologies may be approved by the ~~DASD(R)~~ ASD(R) pursuant to recommendations from the BTAB.

c. The general guidelines for all confirmatory extraction procedures and confirmatory C/MS analyses performed at the FTDTLs include:

(1) All specimen aliquot transfers within the confirmatory testing batch must ensure positive identification of aliquots by use of forensically supportable procedures of one-to-one extract transfer during extraction procedures and transfer to C/MS instrumentation.

(2) Each batch of specimen aliquots shall contain a minimum of 5 percent standards and controls relative to the number of actual specimen aliquots in the batch. The batch must contain an extracted urine calibrator with a concentration equal to the confirmatory administrative cutoff concentration; a target analyte-free blind negative control; an open low control with a concentration 40-50 percent of the cutoff concentration; a blind positive control with a concentration at least 120-200 percent of the cutoff concentration. If a hydrolysis step is included in the extraction procedure; a hydrolysis control will be included in the batch, if available. All standards, controls, and specimens, in the batch, must be processed and analyzed as part of the batch using the same procedures. For direct injection on liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS), all standards, controls, and specimens, in the batch must be prepared simultaneously using the same procedures.

(3) Internal standard (IS) will be added to all calibrator, controls, and specimens analyzed. The IS will be a deuterated analog of the analyte, if available. Procedures that do not use deuterated analogs must be recommended by the BTAB and approved by the Director, DDT&PP, as an exception to policy.

d. The general guidelines for all mass spectrometry (MS) analyses performed at the FTDTLs are listed in paragraphs 12.d.(1) through (17) of this enclosure. Additional specific MS/MS guidelines are detailed in Enclosure 6 of this Instruction.

(1) An instrument that is used to analyze a batch must have an acceptable autotune for analysis by gas chromatography/mass spectrometry (GC/MS) or a system verification sample injection for analysis by MS/MS performed within 24 hours prior to the injection of the calibration standard.

(2) All calibrators, controls, and specimens in a batch will be analyzed simultaneously and under the same conditions.

(3) The calibrator will be injected as a drift control at the end of each batch run. This control must be within ± 10 percent of its theoretical value. For in-line extraction instrumentation, the end of batch control will be the re-extraction of the calibrator. Since the calibrator must be re-extracted, the control must be within ± 20 percent of its theoretical value.

(4) A minimum of three mass ions for the analyte and two mass ions for the IS must be presented in the data printout for all GC/MS analyses. For MS/MS analyses, the data printout must include at least two transition fragmentation ions for the analyte and two transition fragmentation ions for the internal standard.

(5) The mass ion ratios (MIRs) or multiple reaction monitoring ratios (MRMs) of all unextracted standards and controls must have values that are within ± 20 percent of the MIRs or MRMs of the extracted calibrator.

(6) The retention time (RT) of all unextracted standards and controls must be within 2 percent of the RT of the extracted calibrator.

(7) The quantification of controls must be within ± 20 percent of the target values. The open and blind negative must not quantify above the established limit of detection (LOD).

(8) A minimum of 8 MS scans are required for each peak.

(9) Each FTDTL must set minimum criteria for mass ion abundance to ensure valid drug concentration determinations.

(10) Batch analyses interrupted by power failure must be restarted with a new autotune or a reinjection of the system verification sample and re-injection of the controls prior to continuing with the batch. Batch analyses may be continued the next business day, if the autotune or system verification specimen is validated and the re-injection of the calibrator meets established criterion.

(11) All mass ions for each drug must include part of the primary structure of the drug molecule. The use of isotopic ions is allowed, if no other quality ion fragments are produced.

(12) Negative specimens in a failed batch may be reported as negative for the analyte being tested. A diluted specimen may not be reported as positive if the on-column amount of the drug is less than the low control in the batch.

(13) Altering instrument conditions to separate co-eluting peaks is allowed. However, all calibrators, unextracted standards, controls, and affected specimens must be analyzed under the new conditions and all acceptance criteria must be met.

(14) An appropriate negative control specimen or solvent blank as described in the FTDTLs' OP manual will be injected prior to each positive member specimen to demonstrate that the positive result was not impacted by the previous specimen injection.

(15) The FTDTL Commander may cancel testing of member specimens that fail to meet acceptance criteria twice for the same reason.

(16) Disposal of excess urine aliquots will be documented in the CoC.

(17) All ion chromatograms must meet the following minimum acceptance criteria:

(a) Peak resolution for all quantifying and qualifying ions must be such that the measurement from the valley to the baseline is less than 10 percent of the measurement from the peak to the baseline.

(b) The Peak asymmetry (As) factor for all quantifying and qualifying ions must be within 0.5-2.0. The (As) factor is determined by drawing a perpendicular line from the apex of the peak to the base. The (As) factor = A/B, where A is equal to the width of the left half of the peak at 10 percent peak height, and B is equal to the width of the right half of the peak at 10 percent peak height.

e. At the completion of the confirmatory test, documentation will be forwarded for appropriate forensic laboratory review.

(1) The confirmatory test is positive when all criteria of this section are met and the specimen quantifies at or above the approved administrative cutoff concentration.

(2) The FTDTL Commander has the right to repeat or terminate testing for any specimen when it is determined that the validity of the result is forensically or scientifically questionable.

(3) All lots of reagents, negative (target analyte-free) urine, calibrators, standards, and controls will be certified as free of interferences and, where applicable, will be verified to contain the analyte(s) of interest at stated values prior to their use. The methods for certification and verification will be described in the FTDTL OP manual.

(4) All confirmatory procedures must be validated prior to implementation. Method validation will be described in the FTDTL OP manual and must include, at a minimum:

(a) Determination of the LOD.

(b) Determination of the LOQ.

(c) Determination of the limits of linearity (LOL).

(d) Evaluation of precision at the cutoff concentration.

(e) Documentation of the carryover potential.

(f) Determination of interferences from similar and related compounds.

f. New instruments must be validated prior to being placed into service and will be verified annually or within each run on each instrument certified for that particular method. If there is a major change in a method extraction or derivatization procedure, the method must be validated on each instrument used.

g. All documents related to method validation will be maintained in the FTDTL's historical data archived according to the Service's records disposition schedule.

13. QC AND QA PROGRAMS

a. Each FTDTL shall maintain an internal QC program that includes at least 5 percent open and blind control specimens as part of the total number of urine specimens analyzed in a batch.

(1) QC specimens intended to ensure the operation and specificity of the assay shall be identified as controls. Analyte-free specimens (unless incorporated into a standard curve) shall be identified as negative controls. Controls that are used to calibrate an instrument or establish an actual concentration shall be classified as 'calibration' standards.

(2) The FTDTL shall use separate sources of QC stock material in the preparation of controls and standards. If separate sources of stock material are unavailable, material from separate lots from the same manufacturer or two separately prepared solutions are acceptable. All primary standards must have a certificate of analysis and drug purity provided by the commercial vendor. The certificates must be maintained on file by the FTDTL.

(3) All calibrators, standards and QC controls must be certified prior to use. The FTDTL OP manual will describe the certification requirements.

b. Each FTDTL shall maintain a comprehensive QA program with the minimum criteria in paragraphs 13.b.(1) through 13.b.(3) of this enclosure:

(1) The internal QA program must monitor all QC processes, not limited to, internal methods development, instrument and drug certification, personnel certification, overall data review, instrument and equipment calibrations, open and blind external proficiency performance, and internal/external audits of testing processes according to the FTDTL OP manual.

(2) The FTDTL must have an OP manual that describes the QA program and defines the documentation used by the FTDTL to manage the program. FTDTL documentation must include the use and tracking of MFRs for any occurrence that does not follow the strict guidelines of the FTDTL OP manual.

(3) A QA Chief or QA officer (QAO) will be designated in writing by the FTDTL Commander. The QAO is responsible for overall management of the QA program. The QAO is responsible for ensuring the investigation of all NCEs. The QAO organizes supporting documentation related to the NCE, publishes an MFR that clearly defines the issue, and makes

recommendations for corrective actions to the FTDTL Commander. The Commander must document by signature and date completion of their review of all NCE supporting material, QAO recommendations, and the corrective actions taken.

c. The FTDTL will participate in the AFMES QA inspection and proficiency programs. The FTDTL OP manual will describe how the FTDTL will comply with the requirements of these programs. After results of the monthly open proficiency program are reported by the AFMES, the AFMES proficiency material may be used as internal controls and reference material.

d. The AFMES and BTAB will establish acceptance criteria for the blind QC proficiency program. If the quarterly percentage of false negative results exceeds 5 percent, the FTDTL must take immediate action to correct the deficiency.

e. If an apparent false positive result on a military member specimen is reported, the FTDTL Commander must notify the service program manager as soon as practical. The service program manager must immediately notify the Director, DDT&PP, and the AFMES. The FTDTL will suspend all results reporting until notified otherwise by the service program manager. An investigation and any corrective actions implemented must be documented.

14. REPORTING AND RECORDS

a. Any specimen that fails to meet required quantity or quality criteria for determination as positive, for the initial, adjunct, or confirmatory tests, shall be reported as negative. The FTDTL Commander has the right to repeat any analysis when it is determined that the validity of the positive or negative result is forensically or scientifically questionable.

b. All results must be reviewed and certified by at least two LCOs. Certification of results consists of the review of all scientific testing data and relevant supporting documentation (e.g., CoC documents, MFRs) to ensure compliance with technical procedures and CoC requirements in the FTDTL OP manual. All reviews and results will be documented in the FTDTL information management system (LIMS). LCOs will annotate test results on reporting forms required by the Military Departments.

c. If a specimen is submitted with a fatal (specimen is not testable) discrepancy, the appropriate discrepancy code will be documented on the original CoC or submission form. Non-fatal discrepancies identified on drug positive specimens will be annotated on the original CoC or submission form and reported to the submitting command.

d. The report to the submitting unit shall only specify which specimens were positive, negative, or not tested. The reporting of specimen results shall not identify or indicate a member's specimen that screened positive but failed to confirm positive. No analytical information on negative specimens shall be reported to the submitting unit, unless there are exceptions as stated in Reference (c), or when:

(1) A request for further information on the results of a negative test is made by a Service member or the defense counsel for use in defending against an accusation of drug use.

(2) A Service member who, facing disciplinary or administrative proceedings of suspected drug use, offers or is expected to offer as proof of innocence prior negative urinalysis results; then, the Command's legal representative may request further information on the reported negative results for rebuttal or impeachment purposes.

(3) As authorized by the Secretary of the Military Department concerned or as otherwise ordered by a competent judicial authority.

e. Negative results.

(1) Negative test results should be reported within 4 working days (monthly average) after specimens are received at the FTDTL.

(2) Any specimen with a valid initial screen, adjunct test or confirmation test that is negative for a drug will be reported as negative for that drug. The FTDTL Commander has the right to repeat any analysis when it is determined that the validity of the positive or negative result is forensically or scientifically questionable.

(3) Before reporting a negative test result, a final LCO shall ensure that the results have been reviewed and certified as required in paragraphs 14.a. and 14.b. of this enclosure.

(4) All testing and CoC documentation for specimens that tested negative will be maintained for 1 year.

f. Positive results.

(1) Positive test results should be reported within 6 working days (monthly average) after specimens are received at the FTDTL.

(2) Positive test results will be reported only for specimens that are determined to be positive on the initial screen and, if applicable, the adjunct screen, and the confirmation tests. All tests will meet the scientific and forensic requirements described in the FTDTL OP manual prior to being reported as positive.

(3) Before reporting a positive test result, a final LCO will ensure that the results have been reviewed and certified as required in paragraph 14.b. of this enclosure, that an LCO has verified the information on the specimen bottle and original CoC form, and that this information is accurately reflected in the LIMS.

(4) As soon as practical after LCO review, positive specimens will be placed in a secured freezer designated for long-term storage.

(5) The original CoC documents for positive specimens, along with their associated testing documents, will be archived in a secure storage area for a minimum of 3 years.

15. DISPOSITION OF SPECIMENS

a. Negative specimens.

(1) Negative specimens may be discarded after transmission of the negative report. The discard date must be documented into the LIMS computer database.

(2) Negative specimens may be retained without consent from the service member for use in developmental work, prevalence studies, and special projects according to section 219.102(e) of title 32, Code of Federal Regulations (Reference (j)(g)). The transfer of the specimen to special projects must be documented. No further CoC documentation is required for these specimens. Specimens or screen aliquots designated for destruction may be used for research, if all specimen identifiers, which could be used to trace a specimen back to an individual, are removed or redacted.

b. Positive specimens.

(1) All positive specimens will be placed in long-term secure frozen storage for a minimum of 1 year. CoC will be maintained on all specimens in long-term storage.

(2) During the initial 1 year frozen storage period, the submitting unit or legal representative may request, in writing, that the FTDTL retain the specimen for an additional year, unless a longer retention period is required. The request must also explain the reason for the longer retention period. The FTDTL will document the extended period in the LIMS and notify the requestor of the new disposal date.

(3) Upon expiration of the retention period, positive specimens may be discarded. Disposal of the specimen at the end of the retention period must be documented in the LIMS. Upon expiration of the retention period, positive specimens may be retained for use in developmental work, prevalence studies, and special projects as long as all specimen identifiers, which could be used to trace a specimen, back to an individual, are removed or redacted. Transfer of the specimens to special projects must be documented in the FTDTL file system. No further CoC documentation is required for these specimens.

(4) Specimens suspected of adulteration will be retained as described for positive specimens in paragraph 15.b.(1) of this enclosure.

16. RETESTING OF SPECIMENS

a. After receiving a test result, the member, the member's legal representative, the submitting unit commander, a military judge or an attorney representing the submitting unit, may

request a retest. All requests must be forwarded through the submitting unit or trial counsel to the FTDTL that reported the result. A specimen retest requires a C-MS procedure to confirm the presence of the reported drug or drug metabolite. On a retest, the drug does not need to quantify above the DoD confirmation cutoff concentration. The retest only requires the drug to quantify by C-MS at or above the FTDTL's established LOD.

b. The FTDTL Commander has the right to retest any specimen when in his or her opinion retesting will enhance the forensic results or clarify unusual information. The reason for a retest must be documented by an MFR.

c. A specimen may be retested at the FTDTL that confirmed and reported the positive result or the specimen may be sent to another DoD-certified FTDTL or AFMES for retesting.

d. The FTDTL must obtain authorization from the Military Service Drug Testing Program Manager, submitting unit commander, or military judge if sending a specimen for retest would result in less than 10 milliliters remaining for any additional retest purposes.

e. The FTDTL will document specimen handling on the original CoC or supplemental CoC form. A new CoC form will be prepared to document handling of the aliquot and will be mailed with the aliquot to the designated FTDTL. The original specimen bottle with remaining urine, the original CoC and any supplemental CoC forms will be retained by the FTDTL. The FTDTL will transmit a document to the receiving FTDTL that explains the testing to be performed or a copy of the requestor's letter that contains this explanation.

f. A specimen may be sent to a Department of Health and Humans Services certified commercial laboratory for retest, if the requirements in paragraphs 16.a., b., d., and e. of this enclosure are met. The request must also include the complete address of the laboratory where the specimen is to be sent along with a point of contact, documentation that arrangements have been made to pay for any tests, a statement relieving the FTDTL of any monetary charges associated with the testing, and the commercial courier account number to pay for shipping the aliquot to the designated laboratory.

17. BOTTLE REQUESTS. A request for the original specimen bottle for a court-martial or administrative board by the trial counsel, judge, administrative board president, or submitting unit commander will be honored if the request is in writing and contains sufficient information to identify the specific specimen, the name and phone number of the point of contact, and a return mailing address. The original CoC or supplemental CoC form shall be annotated to document the transfer of the remaining specimen urine to a new bottle. The new bottle must be labeled with duplicate identifying information from the original bottle label and the date and location of subsequent storage of the new bottle. A new custody document will be produced or an affidavit will be generated to document the movement of the original specimen bottle to the court.

18. DOCUMENT AND INFORMATION REQUESTS

a. Request for documentation and additional information must be submitted in writing through the submitting unit or an attorney representing the submitting unit. Requests will include sufficient information to identify the specific specimen, trial date (if known), and the name, address, and phone number of the point of contact.

b. When a complete laboratory records packet is requested, the FTDTL will provide, at a minimum, copies of all CoC forms for assays attempted and performed, all accepted instrument printouts that directly involved the specimen, and analysis of all calibrators, standards and controls associated with the specimen. The packet will include a statement of business records certification. A LCO will authenticate the packet attesting that they reviewed the documents and that the business record certification statement is accurate. A copy of each laboratory records packet will be maintained for a minimum of 1 year.

c. The FTDTL may also provide a summary packet upon request. This packet will be an abbreviated laboratory records packet. The summary packet will include, at a minimum, a summary sheet that includes the tests performed, dates of the tests, and test results.

d. The FTDTL will comply with all reasonable requests for laboratory documentation and records. A request for laboratory records or documents generated 3-6 months before and after a specimen was reported is considered as reasonable. A records request exceeding this time period may be considered unreasonable and not granted unless specifically required by a judicial order.

19. EXPERT WITNESS REQUESTS. The FTDTL shall comply with judicial orders to produce an expert witness and will attempt to accommodate reasonable requests for expert witnesses in accordance with the FTDTL OP manual. When funding is provided by the requesting command, the FTDTL will require receipts of accounting information or travel orders, from the requesting unit, at least 10 working days in advance of the witness travel date or as soon as practical in order to comply with a judicial order. Requesting commands will coordinate scheduling of expert testimony with the FTDTL. The requesting command is responsible for all travel, per diem, lodging, expenses to include a rental car or other personal local transportation and will ensure that adequate dining accommodations are made available.

20. CUTOFF CONCENTRATIONS AND REPORTING REQUIREMENTS

a. The cutoff concentrations for IA screening and confirmation analysis are shown in Tables 1 and 2, respectively, in the Appendix of this enclosure. The authorized panel of tested drugs may be updated by memorandum from ~~DASD(R)~~-ASD(R), to include drug panel additions and deletions, changes to cutoff concentrations, and pulse testing rates to address current drug threats. A specimen with forensically acceptable documentation and valid screening and confirmation results, equal to or greater than the cutoff concentration, will be reported as positive for that analyte.

b. To report a heroin positive result, the FTDTL may use a 6-acetylmorphine (6AM) specific IA kit for initial screening followed by 6AM C-MS analysis or an opiate IA kit followed by a 6AM C-MS analysis. Specimens that initially screen positive using the 6AM kit will have an adjunct screen with both the 6AM and the opiate IA kits. Specimens on the adjunct screen that are positive only for opiates will be sent for codeine and morphine confirmation analysis. Specimens that on the adjunct screen are positive for both 6 AM and opiates, and confirm only for codeine, morphine, or both will be reported positive for codeine, morphine, or both. Specimens that confirm positive for morphine, codeine, and 6AM will be reported as positive for the respective drugs.

c. All FTDTL drug test results will be downloaded to a secure, password protected, encrypted web results portal (iFTDTL) for retrieval by authorized users.

21. COMPUTER REQUIREMENTS

a. System security of the FTDTL LIMS shall comply with ~~DoDD 8500.01E~~ *DoDI 8500.01* (Reference (~~kh~~)). The FTDTL COOP shall be prepared and reviewed by the Military Service Drug Testing Program Manager or designee pursuant to the appropriate Service regulation. The COOP must include a section that deals with events that may affect the LIMS operation.

b. Each specimen received by the FTDTL will be tracked within the LIMS using specific identifiers, *including DoD ID*, LAN, submitting unit code, and dates of specimen receipt and reporting of results. The LIMS will maintain a forensic record of each action taken on an individual specimen. The LIMS will be capable of verifying that the SSN on the CoC matches the SSN on the bottle. The LIMS will maintain an audit trail of changes to the records, which will include the original information, the new information, the date and time of the change, and the individual who made the change.

c. LCOs who reviewed and approved the screening, QC, and confirmation results will be identified and this information will be retrievable from the LIMS. The LIMS will also be able to verify that these steps have been completed before results are reported, manually or electronically.

d. Negative and cancelled specimen test data will be purged from the LIMS on a 5 year cycle at each FTDTL. This does not apply to data on the iFTDTL.

22. LABORATORY EQUIPMENT. Major equipment utilized for IA screening and confirmation analysis at the FTDTLs must be recommended by the BTAB, authorized by the Director, DDT&PP, and maintained and inspected at least semi-annually by the original equipment manufacturer (OEM). Maintenance service of major equipment must be done by OEM trained technicians who must certify the conduct of services performed by signing and dating the laboratory instrument maintenance documents. Centrifuges must be certified annually and after major repair. Minor equipment, such as analytical balances, automated aliquoting devices, pipettes, and any other equipment used to make measurements for forensic purposes,

will be certified for accuracy, at least annually. Weights used to certify analytical balances must be National Institutes of Standards and Technology certification traceable. Maintenance records, documenting all certification and repair, must be retained for a minimum of 3 years.

23. LABORATORY CERTIFICATION

a. To be certified by the DoD, an FTDTL shall:

(1) Maintain an OP manual as described in paragraph 2.c. of Enclosure 2 and paragraph 5.a. of this enclosure.

(2) Maintain and document specimen and aliquot CoC from receipt to disposal.

(3) Maintain training and certification records of laboratory personnel.

(4) Maintain records for equipment maintenance and repair.

(5) Maintain records for validation of all analytical methods for each analyte.

(6) Participate, satisfactorily, in a certification round of AFMES proficiency specimen analyses for each drug group being tested.

(7) Participate, satisfactorily, in ongoing AFMES proficiency (open and blind) programs.

(8) Maintain an internal QC program consisting of at least 5 percent controls and standards in each specimen testing batch.

(9) Participate, satisfactorily, in the ongoing AFMES QA inspection process.

(10) Maintain an internal QA program to verify and document the quality and accuracy of test results.

b. Request for certification specimens and participation in the blind QC program will be made, in writing to AFMES via the Military Service Drug Testing Program Manager.

c. After the FTDTL has satisfied the requirements in section 23.a. of this enclosure and performed successfully during certification analysis in paragraph 24.b. of this enclosure, the AFMES shall submit a written request for DoD laboratory certification to the Director, DDT&PP. A laboratory may not report test results to submitting units until certified in writing by the Director, DDT&PP. The QA inspections shall assess the performance of the FTDTL and its adherence to the requirements in section 23.a. of this enclosure. A copy of each inspection report shall be forwarded to the Director, DDT&PP.

24. DRUG ANALYSIS CERTIFICATION

- a. The FTDTL shall participate in the AFMES proficiency testing program for drug groups that are approved by the ~~DASD(R)~~ ASD(R) in the DoD Drug Testing Panel (Tables 1-2 of the Appendix to this enclosure) for which they are certified.
- b. A certification set consists of negative (target analyte-free) urine specimens and urine containing the parent drug and drug metabolite at various concentrations surrounding the DoD cutoff. The specific contents of the certification set are determined by the drug(s) requested and will include 5 urine specimens prepared at each drug concentration.
- c. When an FTDTL is being certified for more than one drug, the proficiency specimens may be formulated with multiple drugs, as necessary. The FTDTL shall be instructed as to which specimens are to be tested for which drugs.
- d. The FTDTL shall summarize the results by listing quantitative values for each specimen, calculated from the confirmation test results, and indicate whether specimens are positive or negative by the initial test. The summary sheet, along with initial screen and confirmation test data will be sent to the AFMES's QA Laboratory. All confirmatory tracings are to include retention times, peak areas, peak height, ion monitored, and specimen identification. Repeat extraction analyses to bring outlier quantitative results into agreement with other specimens are not permitted.
- e. MS criteria include:
 - (1) For analyte-free specimens, the quantitative values from MS may not exceed the LOD. The LOD for each drug tested must be listed on the data sheet provided and returned to the AFMES.
 - (2) No more than one quantitative value in the drug class may be more than ± 20 percent from the Laboratory mean for each positive level.
 - (3) No more than one quantitative value in the drug class may be more than ± 20 percent from the group mean. The groups mean values are derived from the AFMES QA laboratory and at least one reference laboratory.
- f. Chromatographic tracings criteria. See paragraphs 12.d.(1)-(9) and 12.d.(17) of this enclosure.
- g. Continuous participation in the AFMES open and blind proficiency testing program.
 - (1) If an FTDTL does not report the required data analyses for the monthly open proficiency specimens for drug(s) it is certified for testing, all 5 analyte(s) data points will be considered incorrect.

(2) For the AFMES blind proficiency specimens, an analysis is considered correct if negative specimen(s) are reported negative and positive specimen(s) are reported positive. At least 95 percent of specimens received during the quarter must be correctly reported. This ensures that the number of false negative results is less than 5 percent for the quarter. When an FTDTL is not in compliance with the 95 percent reporting requirement:

(a) The AFMES shall immediately contact the FTDTL, the Military Service Drug Testing Program Manager and the Director, DDT&PP. The Director, DDT&PP, in conjunction with AFMES, shall assess the information available and specify corrective action(s) based on the circumstances surrounding the error(s).

(b) The Military Service Drug Testing Program Manager shall ensure that corrective action is taken or the FTDTL shall be decertified. Once the FTDTL has completed the prescribed corrective actions, the AFMES shall use the procedures for certifying a new drug analysis to ensure that the FTDTL can correctly analyze for the drug class(es) affected.

(c) The Director, DDT&PP, may require an on-site inspection or may recertify the FTDTL for the particular drug analyses based upon the recommendation of the AFMES and the Military Service Drug Testing Program Manager.

(d) The FTDTL, in conjunction with the Military Service Drug Testing Program Manager, shall provide a written summary of the corrective actions taken to AFMES and the Director, DDT&PP.

(3) For the AFMES open proficiency specimens, an analysis is considered unacceptable whenever two analyte results quantify greater than ± 2 standard deviations or ± 20 percent from the group mean, whichever is greater, in each of two consecutive monthly sets of specimens. When an FTDTL is not in compliance with this requirement:

(a) The AFMES shall immediately contact the FTDTL, the Military Service Drug Testing Program Manager, and the Director, DDT&PP.

(b) The FTDTL shall immediately stop testing and reporting results for the specific drug class; and, conduct a review and inventory of any actual member specimen(s) that may have been incorrectly reported as drug positive. If a member specimen(s) is deemed to have been incorrectly reported as drug positive, the FTDTL shall proceed to paragraph 25.c. of this enclosure.

(c) If, upon review, no member specimens were incorrectly reported as drug positive, the Director, DDT&PP, shall seek ~~DASD(R)-ASD(R)~~ decertification of the FTDTL for the drug class.

(d) After the FTDTL has determined the cause of the error and has implemented corrective action, the Military Service Drug Testing Program Manager shall provide a written summary of the corrective actions taken and notify the AFMES that the FTDTL is ready to analyze a set of certification specimens for the drug category in question.

(e) Based upon successful completion of recertification analysis of specimens, the Director, DDT&PP, shall recommend that the ~~DASD(R)~~-ASD(R) recertify the FTDTL for the drug analysis based upon AFMES recommendations. The Director, DDT&PP, may direct retesting of any military personnel specimens previously reported positive for the drug analyte in question.

(4) For the AFMES open proficiency specimens, an analysis is considered unacceptable for a specific analyte whenever three or more analyte results quantify greater than ± 2 standard deviations or ± 20 percent from the group mean, whichever is greater, in any one month's open proficiency specimens. When an FTDL is not in compliance with this requirement:

(a) AFMES shall immediately contact the FTDTL, the Military Service Drug Testing Program Manager, and Director, DDT&PP.

(b) The FTDTL must immediately suspend reporting results for the drug class in question. The FTDTL must investigate the cause of the problem, implement a plan to correct the issue, and send a memorandum to the Military Service Drug Testing Program Manager, AFMES and Director, DDT&PP, stating the cause of the testing error and the corrective actions implemented.

(c) The FTDTL must retest the set of failed open proficiency specimens for the drug class in question and attain at least 4 data points that are within ± 20 percent of the group mean for that month. If successful, the FTDTL can resume reporting of the drug class. If the retest is unsuccessful, the FTDTL will be decertified for the drug class and must follow the steps for certification as described in paragraphs 24.b.-f. of this enclosure.

(5) An FTDTL that reports a false positive on an AFMES blind proficiency specimen will be decertified by the Director, DDT&PP, pursuant to paragraphs 25.a.-25.b., of this enclosure.

25. FTDTL DECERTIFICATION AND RECERTIFICATION PROCESSES

a. Decertification of an FTDTL may occur upon the erroneous reporting of drug presence due to a technical false positive or an administrative false positive result. Administrative review of an FTDTL's reporting procedures may occur upon failure to correctly report an AFMES blind positive proficiency specimen due to a technical false negative or administrative false negative basis. Errors in non-critical information in a message report (e.g., date of collection, base area code, testing premise) will not impugn the forensic correctness of drug presence reported for a drug positive specimen.

b. When an FTDTL reports a false negative or false positive result for an AFMES blind proficiency specimen, the AFMES shall contact the FTDTL, the Military Service Drug Testing Program Manager, and the Director, DDT&PP.

(1) When the AFMES notifies an FTDTL that it has reported a false negative result on a blind proficiency specimen, the FTDTL shall immediately review the reported testing data to ascertain whether the error was of an administrative or technical nature. The FTDTL shall immediately retest the specimen, if available, and send an aliquot to the AFMES for retesting. The FTDTL shall maintain telephonic communication with AFMES, the Military Service Drug Program Manager and the Director, DDT&PP, on the status of review and investigation and shall report in writing the basis of the error, corrective actions taken, and any additional reviews conducted. The report shall be submitted to the Military Service Drug Testing Program Manager and AFMES who shall determine whether any additional action is warranted.

(2) When the AFMES notifies the FTDTL that it has reported a false positive result on a blind proficiency specimen, the FTDTL shall:

(a) Immediately suspend reporting results for all drugs and conduct a review of testing data to ascertain whether the false positive result was of an administrative or technical nature.

(b) Immediately retest the specimen, if available, and send an aliquot to the AFMES for retesting. The FTDTL shall maintain telephonic communication with AFMES, the Military Service Drug Program Manager and the Director, DDT&PP, on the status of the review and investigation. The Director, DDT&PP, shall notify the ~~DASD(R)-ASD(R)~~ and may seek decertification of the FTDTL.

(c) Report, in writing, the basis of the error, corrective actions taken, any additional reviews, and submit the report to the Military Service Drug Testing Program Manager, AFMES and Director, DDT&PP. Based upon the status updates and the written report, the AFMES, in conjunction with the Director, DDT&PP, shall determine whether any additional action is warranted, to include possible on-site inspection and recertification for the affected analyte. If AFMES believes that the actions taken by the FTDTL are adequate, in consultation with the Military Service Program Manager and Director, DDT&PP, the Director, DDT&PP, shall recommend to the ~~DASD(R)-ASD(R)~~ to recertify the FTDTL for reporting of results.

c. When the FTDTL discovers that it has erroneously reported an actual military member's specimen as positive for drug presence, the FTDTL shall:

(1) Immediately suspend reporting results for all drugs.

(2) Immediately contact the Military Service Drug Testing Program Manager. The Service Drug Testing Program Manager will immediately notify the submitting Command of the nature of the error and maintain communication throughout the subsequent investigation.

(3) Notify AFMES, and the Director, DDT&PP. The Director, DDT&PP, will immediately notify the ~~DASD(R)-ASD(R)~~ of the situation and request FTDTL decertification. The Director, DDT&PP, may direct the AFMES to send a technical team to the FTDTL for on-site assistance and QA monitoring.

(a) When the false positive result is due to a technical false positive error, the following actions will be completed:

1. The FTDTL shall consider itself to be decertified on all affected drug analyses pending formal notification of decertification by the ~~DASD(R)~~-*ASD(R)*.

2. The FTDTL shall immediately investigate the circumstances surrounding the false positive report and implement corrective actions to the analytical procedures to correct the problem. The FTDTL may retest the specimen as necessary. Retesting of other specimens, including other previously reported positive specimens, may be required as part of the investigation.

3. After implementing the required corrective measures, the AFMES shall review and approve the technical changes. Once approved, the AFMES shall provide the FTDTL with a validation set of specimens for recertification analysis.

4. Following AFMES approval of the recertification analysis and notification of results to the Director, DDT&PP, the Director, DDT&PP, shall recommend to the ~~DASD(R)~~-*ASD(R)* recertification of the FTDTL to resume drug analysis and reporting. The Director, DDT&PP, may specify additional requirements for personnel retraining, or retesting of additional member specimens previously reported over specified testing periods.

5. The FTDTL shall provide the submitting unit with a summary report and the corrected copy of the testing report.

6. The FTDTL, in conjunction with the Military Service Drug Testing Program Manager, shall enter into the files of affected command specimen folders a written summary of the incident, corrective actions taken, results of the retesting of member specimens, copies of notifications to affected commands, and summary of corrective actions taken against any member whose results may have been incorrectly reported.

(b) When the false positive result is due to an administrative false positive error, the following actions will be completed:

1. Following completion of notifications by an FTDTL and other investigative requirements cited in section 25.c. (1)-(3) of this enclosure, if the Service Drug Testing Program Manager, AFMES, and the Director, DDT&PP, is satisfied that the corrective action(s) is adequate to prevent a recurrence of the error for all drugs tested and reported by the FTDTL, the Director, DDT&PP, will notify the ~~DASD(R)~~-*ASD(R)* of the Director, DDT&PP, intent to authorize the FTDTL to resume testing and reporting of results.

2. The Director, DDT&PP, may specify any additional requirements for retesting of member specimens, retraining, or a follow-on inspection by a technical team from AFMES.

APPENDIXDoD ILLICIT DRUG TESTING PANELTable 1. Initial Screen Test Cutoff Concentrations

Drug Class	Cutoff Concentration nanograms/milliliter (ng/mL)
Amphetamines	500
Cannabinoids	50
Cocaine Metabolites	150
Designer Amphetamines	500
Opiates (Codeine/Morphine/Hydrocodone/Hydromorphone)	300
Heroin (6-monacetylmorphine (6AM))	10
Opioids (Oxycodone/Oxymorphone)	100

Table 2. Confirmation Cutoff Concentrations

Initial Presumptive Positive Test	Confirmation Drug/ Metabolite	Cutoff (ng/mL)	Reported Drug Use
Amphetamines	d-amphetamine	100	d-amphetamine
	d-methamphetamine	100	d-methamphetamine
Designer Amphetamines	Methylenedioxymethamphetamine	500	MDMA
	Methylenedioxyamphetamine	500	MDA
Cannabinoids	Tetrahydrocannabinol-carboxylic acid	15	THC
Cocaine Metabolite	Benzoylcegonine	100	Cocaine
Opiates —(Opioids)	Morphine	4,000	Morphine
	Codeine	2,000	Codeine
	6-monoacetylmorphine	10	Heroin
	Oxycodone	100	Oxycodone
	Oxymorphone	100	Oxymorphone
	Hydrocodone	100	Hydrocodone
	Hydromorphone	100	Hydromorphone

Table 1. Initial Screen Test Cutoff Concentrations

Drug Class	Cutoff Concentration (ng/mL)
<i>Amphetamines</i>	500
<i>Benzodiazapines</i>	200
<i>Cannabinoids (Marijuana)</i>	50
<i>Synthetic Cannabinoids</i>	10
<i>Cocaine Metabolites</i>	150
<i>Designer Amphetamines</i>	500
<i>Opiates (Morphine/Codeine)</i>	2,000
<i>Opioid (6-monoacetylmorphine)</i>	10
<i>Opioid (Oxycodone / Oxymorphone)</i>	100
<i>Opioid (Hydrocodone / Hydromorphone)</i>	300

Table 2. Confirmation Cutoff Concentrations

Initial Presumptive Positive Test	Confirmation Drug/Metabolite	Cutoff (ng/mL)	Reported Drug Use
<i>Amphetamines</i>	<i>Amphetamine</i>	100	<i>d-Amphetamine</i>
	<i>Methamphetamine</i>	100	<i>d-Methamphetamine</i>
<i>Designer Amphetamines</i>	<i>Methylenedioxyamphetamine</i>	500	<i>MDMA</i>
	<i>Methylenedioxymphetamine</i>	500	<i>MDA</i>
<i>Benzodiazepines</i>	<i>Lorazepam</i>	100	<i>Lorazepam</i>
	<i>Nordiazepam</i>	100	<i>Nordiazepam</i>
	<i>Oxazepam</i>	100	<i>Oxazepam</i>
	<i>Temazepam</i>	100	<i>Temazepam</i>
	<i>α - hydroxy-alprazolam</i>	100	<i>α - hydroxy-alprazolam</i>
<i>Cannabinoids</i>	<i>Tetrahydrocannabinol-carboxylic acid</i>	15	<i>THC</i>
<i>Synthetic Cannabinoids</i>	<i>Synthetic Cannabinoid Compounds resulting in excretion of:</i>		
	<i>JWH-018-N-pentanoic acid</i>	1.0	<i>SYCAN</i>
	<i>JWH-073-N-butanoic acid</i>	1.0	<i>SYCAN</i>
	<i>UR-144-N-pentanoic acid</i>	1.0	<i>SYCAN</i>
	<i>5-fluoro-PB22-3-carboxyindole</i>	1.0	<i>SYCAN</i>
	<i>MAM-2201-N-pentanoic acid</i>	1.0	<i>SYCAN</i>
	<i>AB-Chminaca metabolite</i>	1.0	<i>SYCAN</i>
	<i>AB-Fubinaca metabolite</i>	1.0	<i>SYCAN</i>
<i>AB-Pinaca metabolite</i>	1.0	<i>SYCAN</i>	

Table 2. Confirmation Cutoff Concentrations, Continued

<i>Initial Presumptive Positive Test</i>	<i>Confirmation Drug/Metabolite</i>	<i>Cutoff (ng/mL)</i>	<i>Reported Drug Use</i>
<i>Cocaine Metabolites</i>	<i>Benzoyllecgonine</i>	<i>100</i>	<i>Cocaine</i>
<i>Opiates</i>	<i>Morphine</i>	<i>4,000</i>	<i>Morphine</i>
<i>Codeine/Morphine</i>	<i>Codeine</i>	<i>2,000</i>	<i>Codeine</i>
<i>Heroin</i>			
<i>6-monacetylmorphine</i>	<i>6-monacetylmorphine</i>	<i>10</i>	<i>Heroin</i>
<i>Opioid</i>			
<i>Oxycodone/</i>	<i>Oxycodone</i>	<i>100</i>	<i>Oxycodone</i>
<i>Oxymorphone</i>	<i>Oxymorphone</i>	<i>100</i>	<i>Oxymorphone</i>
<i>Hydrocodone/</i>	<i>Hydrocodone</i>	<i>100</i>	<i>Hydrocodone</i>
<i>Hydromorphone</i>	<i>Hydromorphone</i>	<i>100</i>	<i>Hydromorphone</i>

ENCLOSURE 5

DoD BTAB

1. ORGANIZATION AND MANAGEMENT

a. The DoD BTAB shall advise the Director, DDT&PP, on technical and policy issues related to the MPDATP.

b. The BTAB for technical issues shall be composed of one member from the AFMES (who serves as the non-voting board chair), the 3 Military Department Drug Testing Program Managers, and any other non-voting subject matter experts as designated by the board chair. Members shall be active duty military members or full-time civilian employees of the United States Government.

c. The BTAB for policy issues shall be composed of the Director, DDT&PP (who serves as the non-voting board chair), one voting representative from the Army, Navy, Air Force, Marine Corps, and National Guard Military Personnel Offices, and any other non-voting subject matter experts as designated by the board chair. Members shall be active duty military members or full-time civilian employees of the United States Government.

2. FUNCTIONS. The BTAB shall make recommendations to the Director, DDT&PP, on:

a. Methodologies and new technologies for FTDTL drugs of abuse testing.

b. Procedures for evaluating changes in testing methodologies and technologies to ensure that such changes are applicable for the DoD-certified FTDTL.

c. External proficiency testing and QA procedures for evaluating the performance of the DoD-certified FTDTLs.

d. Procedures for the certification, decertification, and recertification of the DoD-certified FTDTLs.

e. Recommendations for the additions or deletions of testable drugs on DoD Drug Panel.

f. Applied research projects to improve the effectiveness of the MPDATP.

g. A policy issue requiring a change to this Instruction to standardize or update MPDATP processes among the Services.

3. MEETINGS

a. The BTAB shall meet a minimum of twice annually, and as required by the Director, DDT&PP, or AMFES.

b. The board chair is responsible for issuing minutes of each meeting and forwarding the minutes with any recommendations to the Director, DDT&PP.

ENCLOSURE 6

MS/MS INSTRUMENT STANDARDS

1. MS/MS AUTOTUNE CRITERIA. A full autotune shall be performed on a quarterly basis, using an appropriate tuning compound as recommended by the instrument manufacturer. The full autotune report shall be retained for a minimum of 3 years (including any failed tunes). The full autotune shall pass the manufacturer's specifications. A full autotune shall be performed after any maintenance that required the venting of the MS.

2. VERIFICATION OF INSTRUMENT PERFORMANCE

a. LC/MS/MS equipment will be tuned as a response to a failure or other maintenance but not as a verification of instrument performance.

b. Instrument performance shall be evaluated on a daily basis when analyses are to be performed by injecting a system verification sample. The system verification sample shall be analyzed prior to the analysis of member specimens. The criteria for evaluating the system verification sample and the corrective action shall be documented in maintenance files by the FTDTL. Criteria must include:

(1) Retention times within ± 2 percent of the expected retention time for the compound.

(2) Area counts for the quantitative transition shall be similar to or above a lower limit established by the FTDTL based upon historical values for the transition.

(3) MRM transition ratios shall be similar to historical values for the compound.

(4) Mass assignment for the transition should be within ± 0.1 amu. If the area counts have fallen below acceptable criteria or MRM ratios are unacceptable, the atmospheric pressure ionization source may require cleaning.

c. If source cleaning does not return the system verification sample within acceptable ranges, a full autotune shall be performed.

3. MOLECULAR IDENTIFICATION AND CONCENTRATION DETERMINATIONS. For tandem mass spectral methods, the FTDTLs analyze specimens using MRM methods to optimize sensitivity and molecular identification. The DoD FTDTL shall monitor at least one transition that is used for quantification, one transition that is used as a qualifier, and evaluate the ratio of the abundance of these two transitions for the target analyte. The same applies to the internal standard. The selection of these transitions shall be for transitions relatively free of interferences and matrix effects and shall be a relevant to the target analyte (i.e., shall be a transition from the target analyte or minimally be a justifiable structure relative to the target analyte). For tandem

mass spectral methods, the mass resolution of the first sector must be at least one unit mass resolution or the narrowest setting allowed by the instrument. The MRM transition ratios shall be ± 20 percent based upon the calibration sample.

ENCLOSURE 7

PROCEDURES FOR SUBSTANCE ABUSE TESTING AND THE ADMINISTRATIVE
PROCESSING OF APPLICANTS AND NEW ENTRANTS TO THE MILITARY SERVICES
AND THEIR RESERVE COMPONENTS

1. TESTING PROCEDURES. In compliance with section 521 of Public Law 100-456 (Reference ~~(H)(i)~~), testing for drug and alcohol use and evaluation for dependency shall occur within 72 hours after the member's initial entry on active duty following enlistment or appointment. For Reserve Component members not entering extended active duty, the tests shall be administered no later than 72 hours after the beginning of the first scheduled annual training or initial active duty training.

2. REQUIRED TESTING. Individuals required to be tested and evaluated are:

a. New enlisted entrants in the Military Services, including officer candidates undergoing initial training in an enlisted status.

b. Appointees to Service Academies will be tested within 72 hours of reporting to an Academy. Reserve Officer Training Corps (ROTC) Cadets and Midshipmen shall be tested pursuant to individual Service policy and as a component of their commissioning physical examination.

c. Other individuals to whom a commission may be offered following completion of a Service commissioning program (e.g., advanced training under the ROTC program).

d. Regular and Reserve officers appointed from the civilian community.

e. Prior Service applicants for enlistment in the Active component with a break in service of more than 6 months.

f. Prior Service applicants for enlistment in the Selected Reserve who have a break in service in the Selected Reserve or Active component of more than 6 months are to be tested as facilities and resources permit. The Services shall fund appropriate resources and facilities to ensure all such applicants are tested.

3. TIMING OF TESTING AND EVALUATIONS

a. Individuals covered by paragraph 2.a. or 2.d. of this enclosure shall undergo testing and be evaluated within 72 hours after initial entry on active duty (IEAD). The IEAD is the member's first period of full-time duty in the active Military Service of the United States following enlistment or appointment.

b. Officers not covered by paragraph 2.b. or 2.c. of this enclosure shall undergo testing and be evaluated during the officer basic courses. If an officer's IEAD shall not occur at a basic course, alternative testing and evaluation arrangements must be made by the appointing authority.

c. Individuals covered by paragraph 2.b. of this enclosure shall undergo testing and be evaluated during the physical examination given to the applicants before appointment as cadets or midshipmen at a Service Academy or for an ROTC scholarship.

d. Individuals covered by paragraph 2.c. of this enclosure shall undergo testing and be evaluated during the pre-commissioning physical.

e. Individuals covered by paragraph 2.e. or 2.f. of this enclosure shall be tested and evaluated in conjunction with a reentry physical (if conducted), or within 72 hours following reentry at accession locations specified by the Military Service concerned (e.g., first duty station).

4. TESTING PANEL AND PROCEDURES

~~a. All samples shall be tested for marijuana (THC), cocaine, and amphetamines (including methamphetamine and designer amphetamines (MDMA and MDA) using the cutoff concentrations described in the Appendix to Enclosure 4 of this Instruction. The analysis shall be conducted in a DoD-certified FTDTL following the requirements of Enclosure 4 of this Instruction. Testing results shall be obtained as soon as practicable. All samples shall be collected under direct observation and be submitted to a DoD-certified FTDTL using the chain of custody form, DD Form 2624 (or successor) or if processed through MEPS then USMEPCOM Form 40-8-3 R-E (or successor). Testing outside the DoD-certified FTDTL is strictly prohibited.~~

a. All urine samples will be tested for the same panel of drugs as the military population. The analysis will be conducted in a DoD-certified FTDTL following the testing requirements of Enclosure 4 of this instruction. All samples will be collected under direct observation and be submitted to a DoD-certified FTDTL using the chain of custody form, DD Form 2624 (or successor) or, if processed through MEPS, USMEPCOM Custody Form 40-8-3, "Urine Sample Custody Document" (or successor). Testing results will be obtained as soon as practicable. Testing outside the DoD-certified FTDTL is strictly prohibited.

b. All persons covered by section 2 of this enclosure, with the exception of paragraph 2.e., shall be tested for alcohol use using a National Highway Traffic Safety Administration-approved breath alcohol test. A DoD approved blood alcohol test may be used in place of a breath alcohol test provided forensic CoC is maintained from specimen collection until results of analysis are determined. *Alcohol testing is not conducted at the DoD FTDTLs.*

c. Individuals covered by section 2 of this enclosure shall be medically evaluated for dependency using appropriate medical and psychiatric criteria.

5. SEPARATION FOR DRUG OR ALCOHOL DEPENDENCY

a. Voided enlistment or appointment. The enlistment or appointment of any person determined to have been dependent on drugs or alcohol at the time of such enlistment or appointment shall be voided as a release from custody or control of the Military Service as provided by DoDI 1332.14 (Reference ~~(m)(j)~~) and DoDI 1332.30 (Reference ~~(m)(k)~~). A person whose enlistment or appointment is voided shall be referred to a civilian treatment facility.

b. Enlisted Members. The basis for discharge of enlisted members pursuant to the policies established by this Instruction shall normally be erroneous enlistment (uncharacterized) as provided by Reference ~~(m)(j)~~. The Military Services are not precluded in appropriate cases from taking disciplinary action against a member or processing a member for discharge, with or without a characterization, under an alternative basis. The counseling requirement in Reference ~~(m)(j)~~ for separation based on entry level performance and conduct is waived for the purposes of discharge resulting from initial entry drug and alcohol testing pursuant to this Instruction.

~~(1) Enlisted personnel who refuse to consent to testing or evaluation during IEAD or who are confirmed positive for cocaine shall be discharged.~~

~~(2) Enlisted personnel confirmed positive for THC alone shall be discharged unless the Secretary of the Military Department concerned, or his or her designee, grants a waiver following an individual assessment of the particular case.~~

~~(1) Enlisted personnel who refuse to consent to drug or alcohol testing or evaluation during IEAD will be discharged.~~

~~(2) Enlisted personnel confirmed positive for any drug on the testing panel will be discharged and permanently disqualified from military service unless the Secretary of the Military Department concerned, or his or her designee, grants a waiver following an individual assessment of the particular case.~~

(3) Enlisted personnel confirmed positive at a 0.05 percent blood alcohol level and who are not alcohol dependent shall be discharged unless the Secretary of the Military Department concerned, ~~or his or her designee,~~ grants a waiver following an individual assessment of the particular case.

(4) During national emergencies when conscription is authorized, Secretaries of the Military Departments may retain inductees who test positive for drugs or alcohol if deemed appropriate considering all relevant factors at the time.

c. Officer Policy

~~(1) Application for appointment as cadets or midshipmen shall be disapproved if the applicant refuses to consent to drug or alcohol testing or evaluation, are confirmed positive for~~

~~THC, cocaine, amphetamine, methamphetamine, MDMA, or MDA, uses or are dependent on drugs or alcohol.~~

~~(2) Appropriate disenrollment action shall be taken against an ROTC member upon refusal to consent to testing or evaluation, a positive test for THC, cocaine, amphetamine, methamphetamine, MDMA, or MDA, or diagnosis of dependency. No offer of appointment shall be made to such individuals. Positive drug test results or refusal to consent to testing or evaluation may be treated as evidence of misconduct on the part of the ROTC member for purposes of recoupment or ordering to active duty in an enlisted status. During national emergencies when conscription is authorized, Secretaries of the Military Departments may retain Cadets who test positive only for THC and who receive a waiver, if deemed appropriate considering all relevant factors at the time.~~

~~(3) Officers who are tested after appointment and are found positive for THC, cocaine, amphetamine, methamphetamine, MDMA, or MDA or who refuse to consent to testing or evaluation shall be given an honorable or general discharge under honorable conditions unless the separating authority determines, pursuant to Service regulations, that a discharge under other than honorable conditions is more appropriate based upon other misconduct.~~

(1) Applications for appointments as cadets or midshipmen will be disapproved if the applicant refuses to consent to drug or alcohol testing or evaluation during IEAD.

(2) ROTC members will be disenrolled in accordance with Reference (1) if they refuse to consent to testing or evaluation, are diagnosed with a drug dependency, or test positive, unless the member possesses a valid prescription to account for the positive drug test result. Positive drug test results or refusal to consent to testing or evaluation may be treated as evidence of misconduct for purposes of recoupment or ordering to active duty in an enlisted status. During national emergencies when conscription is authorized, Secretaries of the Military Departments may retain cadets and midshipmen who test positive and who receive a waiver, if deemed appropriate considering all relevant factors at the time.

(3) Officers testing positive after appointment without possessing a valid prescription, or who refuse to consent to testing or evaluation, will be given an honorable or general discharge under honorable conditions, unless the separating authority determines, pursuant to applicable Service regulations, that a discharge under other than honorable conditions is more appropriate based upon other misconduct.

(4) Individuals covered under paragraph 5.b.(2), (3), or (4) of this enclosure and who are confirmed positive at a 0.05 percent blood alcohol level and who are not alcohol dependent shall be denied appointment or discharged, as appropriate, unless the Secretary of the Military Department concerned ~~or his or her designee~~ grants a waiver following an individual assessment of the particular case.

d. Notification of Discharge. Members separated as a result of testing positive under new entrant drug or alcohol testing must be properly identified during screening of applicants by the MEPS and recruitment centers in the event the member applies for reentry (or entry to another

Service or component). Therefore, the individual's name, *DoD ID number*, reentry code, and other appropriate data shall be furnished to the DMDC by the separation authority within 2 duty days following separation.

6. QUALIFICATION AND DISQUALIFICATION

a. Applicants for military service participating in drug or alcohol testing including such testing at MEPS must test negative for drugs and alcohol prior to entering active duty, the Reserve Component, or the National Guard. A positive drug test constitutes use.

~~b. When applicants test positive for either marijuana, alcohol, or both, the following disqualification periods apply:~~

~~(1) Disqualification Period (First Positive Test). Applicants testing positive for the first time are not eligible for military service for a period of 45 days from the date of the test. Applicants may, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 46th day following the date of the first positive test.~~

~~(2) Disqualification Period (Second Positive Test). Applicants testing positive on a subsequent test are not eligible for military service for a period of 24 months (730 days) from the date of the second positive test. Applicants may, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 731st day following the date of the second positive test.~~

~~(3) Disqualification Period (Third Positive Test). Applicants testing positive on a third drug test will be permanently disqualified for military service.~~

b. When applicants test positive for alcohol, the following disqualification periods apply:

(1) Disqualification Period (First Positive Test). Applicants testing positive for the first time for alcohol are not eligible for military service for a period of 45 days from the date of the test. Applicants may, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 46th day following the date of the first positive test.

(2) Disqualification Period (Second Positive Test). Applicants testing positive on a subsequent test are not eligible for military service for a period of 24 months (730 days) from the date of the second positive test. Applicants may, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 731st day following the date of the second positive test.

(3) Disqualification Period (Third Positive Test). Applicants testing positive on a third alcohol test will be permanently disqualified for military service.

(4) Use of Alcohol. The Military Services may implement more restrictive standards of applicant qualification and disqualification for use of alcohol. If an applicant tests positive for

both alcohol and drugs on the same processing day (date of test), this will be counted as one positive test. An applicant testing positive for alcohol on one day and positive for drugs on a subsequent day (or vice versa), will be counted as two positive tests.

(5) Combined Use of Alcohol and Drugs. The Military Services may implement more restrictive standards of applicant qualification and disqualification for use of drugs or alcohol. If an applicant tests positive for both alcohol and drug(s) on the same day, this will be counted as one positive test. An applicant testing positive for alcohol on one day and positive for drug(s) on a subsequent day (or vice versa), will be counted as two positive tests.

~~e. When applicants test positive for cocaine, amphetamines, methamphetamine, MDMA or MDA, the following disqualification periods apply:~~

~~(1) Disqualification Period (First Positive Test). Applicants testing positive for the first time are not eligible for military service for a period of 12 months (365 days) from the date of the initial positive test. Applicant may or may not, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 366th day following the date of the first positive test.~~

~~(2) Disqualification Period (Second Positive Test). Applicants testing positive on a subsequent test shall be permanently disqualified for military service.~~

~~(3) The Services may implement more restrictive standards of applicant qualification and disqualification for cocaine, amphetamine, methamphetamine, MDMA or MDA.~~

c. When applicants test positive for any drug on the testing panel, the following disqualification periods apply:

(1) Disqualification Period (First Test). Applicants testing positive for the first time for any drug on the testing panel are not eligible for military service for a period of 90 days from the date of the test. Applicants may, at Service discretion, return for subsequent testing and MEPS processing, if appropriate, on the 91st day following the date of the first positive test.

(2) Disqualification Period (Second Test). Applicants testing positive for any drug on the testing panel on the second test are permanently disqualified for military service.

*d. Applicants testing positive for a combination of testable drugs *or alcohol and testable drugs* are processed as follows:*

~~(1) An applicant testing positive for THC in combination with cocaine or any amphetamine(s) on one specimen will be counted as one positive test and processed pursuant to the cocaine and amphetamine(s) standard.~~

~~(2) An applicant testing positive for alcohol and THC on one specimen (at any time) and who subsequently tests positive for cocaine or selected amphetamine(s) or both will be disqualified for 24 months (730 days). If the applicant provides a third positive specimen,~~

~~whether alcohol and THC, or cocaine and amphetamines, the applicant will be permanently disqualified for military service.~~

~~(3) An applicant who tested positive for alcohol or THC or both on two specimens (at any time) and subsequently test positive for any tested drug on a third specimen (at any time) will be permanently disqualified.~~

(1) An applicant testing positive for a combination of drugs on one specimen will be counted as one positive test and processed pursuant to the drug positive standard in Paragraph 6.c.(1).

(2) An applicant testing positive for alcohol or drugs on one specimen (at any time) and who subsequently tests positive for drugs will be permanently disqualified from military service.

(3) An applicant testing positive for alcohol and drugs on one specimen (at any time) and who subsequently tests positive for alcohol will be processed pursuant to Paragraph 6.b.(2).

(4) If the applicant provides a third positive specimen for alcohol, the applicant will be permanently disqualified for military service pursuant to Paragraph 6.b.(3).

e. The Military Services may implement more restrictive standards of applicant qualification and disqualification.

ENCLOSURE 8

SPECIAL DRUG TESTING

1. SPECIAL DRUG TESTING

a. The wrongful use of anabolic steroids, controlled substances, other products such as inhalants, cleaning agents, or other substances outside their intended purpose, and the wrongful use or misuse of prescription drugs, and over-the-counter medications by members of the military is an offense under the Uniform Code of Military Justice.

b. Commanders must be aware of the potential harm that abuse and misuse of drugs and other products have on the health, well being, safety, and morale of the individual and their unit. Commanders must be attuned to incidents of drug and product misuse not covered by testing conducted with the MPDATP. Specialty testing is available for many of these products and requests for such testing require coordination with the Service Drug Testing Program Managers or the Service FTDTL.

2. STEROID (ANABOLIC STEROIDS) TESTING

a. Steroid testing is considered when substantial indications exist to suspect wrongful steroid use pursuant to a probable cause, command directed or medical basis. Random testing or unit sweeps for steroid misuse is not authorized.

b. Prior to the submission of specimen(s) for steroid testing, a written, signed request must be submitted to the Service Drug Testing Program Manager or Service designee describing the basis for submission. Failure to coordinate prior submissions may result in the specimen not being tested or a delay in the submission of the specimen to the civilian steroid testing laboratory.

c. Specimens only for steroid testing must contain a minimum of 60 milliliter of urine and must be collected using the same CoC, observation and security procedures described in this Instruction. Specimens only for steroid testing must not be placed in the same shipping container as other specimens for routine drug testing being submitted to the Service FTDTL.

d. If routine drug testing is requested in addition to steroid testing on a single individual, two separate specimen bottle submissions are required unless the FTDTL OP manual allows single bottle submission with sufficient urine volume to complete both testing events. A minimum of 60 milliliter must be collected for steroid testing and a separate specimen containing a minimum of 30 milliliter must be collected for routine drug testing. Separate CoC documentation must be completed for each specimen container collected from the individual. The two specimen containers and CoC documentation on the single individual may be submitted in the same shipping container, but must not be comingled with other specimen bottles submitted for testing.

3. OTHER SPECIAL DRUG TESTING REQUESTS. Testing for drugs, chemicals, compounds, or their metabolites other than those routinely tested pursuant to this Instruction may be requested with prior consultation with the Service FTDTL Commander or the CDME-FORTOX. Specific guidance regarding approval and specimen collection requirements for special drug testing is contained at the AFMES Forensic Toxicology web-site, www.afmes.mil. Failure to coordinate with the FTDTL or CDME-FORTOX prior to specimen submission(s) may result in the specimen(s) not being tested or a delay in testing. Specimens may be collected using the AFMES Toxicology submission form (AFMES Form 1323, 'AFMES/Division of Forensic Toxicology-Toxicology Request Form') located at www.afmes.mil. Specimen(s), with prior coordination for special drug testing, and their accompanying CoC form can be mailed directly to the Division of Forensic Toxicology, AFMES at the address provided in the web site.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

6-AM	6-monacetyl morphine
AFMES	Armed Forces Medical Examiner System
AMU	atomic mass unit
<i>ASD(R)</i>	<i>Assistant Secretary of Defense for Readiness</i>
A _s	asymmetry factor
ASD(R&FM)	Assistant Secretary of Defense for Readiness and Force Management
BTAB	Biochemical Testing Advisory Board
CDME- FORTOX	Chief Deputy Medical Examiner, Division of Forensic Toxicology
C.F.R	Code of Federal Regulations
C/MS	chromatography/mass spectrometry
CoC	chain of custody
COOP	continuity of operations plan
DASD(R)	Deputy Assistant Secretary of Defense for Readiness
DMDC	Defense Manpower Data Center
DDT&PP	DoD Drug Testing Policy and Programs
DoDD	DoD Directive
DoDI	DoD Instruction
DoD ID	DoD Identification Number
FTDTL	Forensic Toxicology Drug Testing Laboratory
EDI-PI	Electronic Data Interchange – Personal Identifier
GC/MS	gas chromatography/mass spectrometry

IA	immunoassay
IEAD	initial entry on active duty
iFTDTL	FTDTL posted results web portal
IS	internal standard
LAN	laboratory accession number
LC/MS/MS	liquid chromatography/mass spectrometry/mass spectrometry
LCO	laboratory certifying official
LIMS	laboratory information management system
LOD	limit of detection
LOL	limit of linearity
LOQ	limit of quantification
MDA	methylenedioxyamphetamine
MDMA	methylenedioxymethamphetamine
MEPS	Military Entrance Processing Station
MFR	memorandum for record
MIR	mass ion ratio
MPDATP	Military Personnel Drug Abuse Testing Program
MRM	multiple reaction monitoring
MRP	medical review process
MS	mass spectrometry
NCE	non-conforming event
NG/ML	nanogram/milliliter
OEM	original equipment manufacturer
OP	operating procedures
QA	quality assurance
QAO	Quality Assurance Officer
QC	quality control
ROTC	Reserve Officer Training Corps
RT	retention time

SSN	social security number
THC	tetrahydrocannabinol-carboxylic acid
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USMEPCOM	United States Military Entrance Processing Command

PART II. DEFINITIONS

These terms and their definition are for the purposes of this Instruction.

aliquot. A portion of a specimen used in drug analysis.

analyte. A drug or drug metabolite to be analyzed by IA or C-MS.

autotune. An adjustment of MS conditions that ensures the ability of the MS to accurately measure ion mass resolution.

batch. A set of specimens consisting of open and blind control, and actual military member specimens. A certification batch consists of controls only.

certification set. A series of specimens prepared by AFMES for purposes of certifying an FTDTL to conduct testing and reporting of selected drugs.

controls. Specimens prepared to exact specifications and analyzed to ensure the reliable performance of an analytical procedure. Methods include:

blind control. A control included in a batch, where the location and composition is unknown to the technician involved in the analytical procedure.

calibration control. A control used to establish a standard concentration in an analytical procedure. The calibration control is also referred to as a calibration standard.

negative control. A control that is absent the drug(s) of interest in an assay procedure.

open control. A control, included in a batch, where the location and composition is known to the technician involved in the analytical procedure.

discrepancy. A deviation in the proper submission of a specimen or accompanying documentation to an FTDTL.

fatal discrepancy. A discrepancy that prohibits testing of the specimen at an FTDTL.

non-fatal discrepancy. A discrepancy that does not preclude testing of the specimen at an FTDTL.

error in reporting. A report issued by an FTDTL in which there is an inconsistency in the report of non-critical member identity information between the FTDTL report and DoD Form 2624 (e.g., error in date of collection, base area code, testing premise).

false negative. An erroneous negative reporting of a specimen for drug presence when drug is actually present in the specimen.

administrative false negative. An AFMES blind proficiency specimen sent to an FTDTL in which drug(s) is present by AFMES C/MS analysis that is reported by the FTDTL as negative for the presence of drug(s) due to a failure to meet either the administrative or analytical requirements to permit reporting the specimen positive for the drug(s).

technical false negative. An AFMES blind proficiency specimen sent to an FTDTL in which drug(s) is present by AFMES C/MS analysis that is reported by the FTDTL as negative for the presence of drug(s) due to an error in specimen processing during accessioning or analysis.

false positive. An erroneous positive reporting of a specimen for drug presence when the drug of interest is absent or not reportable in the specimen.

administrative false positive. A specimen result in which drug(s) is presented by C/MS analysis and is reported by the FTDTL as positive for the presence of drug(s); however, either the administrative or analytical requirements to permit reporting the specimen as positive for drug(s) is not met.

technical false positive. A specimen result that is reported by the FTDTL as positive for the presence of drug(s) when review of the original analytical measurement indicated that no drug is present at the level of detection by C/MS.

forensic. A term used to denote a set of accepted procedural and reporting standards that adhere to scientific and legal requirements for evidentiary purposes in court proceedings.

limit of quantification. The LOQ is considered the lowest analyte concentration that can be accurately and precisely measured.

metabolite. A compound that is excreted in the urine whenever the parent drug is modified in the human body.

method validation. A process of performing multiple tests designed to verify that an analytical system (instrument or procedure) is suitable for its intended purpose and is capable of providing useful and valid analytical data. Method validation includes, but is not limited to, evaluation of sensitivity and specificity, LOD, LOQ, LOL, reproducibility, and accuracy.

non-conforming event. An occurrence that is outside the normal FTDTL business processes.

opiates. A class of natural or synthetic narcotic analgesics that may also be referred to as opioids.

presumptive positive. A specimen that tests positive above a pre-determined concentration in the initial immunoassay testing but has not been confirmed by C-MS analysis.

proficiency test samples. Specimens submitted to an FTDTL by AFMES for purposes of assessing the accuracy, sensitivity and specificity of testing conducted at the FTDTL.

retention time. The amount of time that a compound is retained on a chromatographic column during the C-MS analytical procedure.

specimen. A urine sample submitted for analysis.

standard. A reference point. A specimen containing a drug(s) at an established concentration for purposes of calibrating an analytical instrument used for measuring drug concentration.

unadulterated specimen. A urine specimen that has not been tampered with or intentionally altered from its normal physiological composition.