



DoD INSTRUCTION 1010.16

TECHNICAL PROCEDURES FOR THE MILITARY PERSONNEL DRUG ABUSE TESTING PROGRAM

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Purpose: In accordance with the authority in DoD Directive 5124.02 and the policy in DoD Instruction (DoDI) 1010.01, this issuance:

- Establishes and updates policies, assigns responsibilities, and prescribes procedures for the Military Personnel Drug Abuse Testing Program (MPDATP).
- Promotes standardization and joint service operations among all Service forensic toxicology drug testing laboratories (FTDTL).

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

This issuance applies to OSD, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), 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.

1.2. POLICY.

a. Pursuant to DoDI 1010.01, drug testing will be conducted to deter Service members, including those members on initial entry and on active duty after enlistment or appointment, from abusing drugs, including illegal drugs, substances, and prescription medications.

b. Commanders will use drug testing to assess the security, military fitness, readiness, good order, and discipline of their commands and may use the results for punitive and non-punitive (e.g., administrative) actions, as appropriate.

c. Testing of foreign nationals employed by the DoD or attending U.S. military training schools may be conducted:

(1) Pursuant to this issuance

(2) Only as authorized by intergovernmental agreements negotiated on a country-by-country basis.

d. All personnel hired or assigned to the FTDTL, including contract personnel, will have a satisfactory background check, a negative pre-employment urinalysis drug test, and verification of education credentials and prior employment history. Indications of drug or 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.

1.3. SUMMARY OF CHANGE 1.

The changes to this issuance are administrative and update language to comply with Executive Order 14168.

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (USD(P&R)).

The USD(P&R):

- a. Establishes DoD policies for drug detection and deterrence.
- b. In coordination with the Under Secretary of Defense for Policy, directs the prioritization, allocation, and execution of counter-drug activity-appropriated resources to address existing and emerging drug demand reduction requirements.

2.2. DIRECTOR, DEFENSE HEALTH AGENCY (DHA).

Under the authority, direction, and control of the USD(P&R), through the Assistant Secretary of Defense for Health Affairs, the Director, DHA supports:

- a. The roles and responsibilities of the Armed Forces Medical Examiner System (AFMES), in accordance with DoDI 5154.30 and this issuance.
- b. Execution of this issuance with standardized administrative measures, to include:
 - (1) Supporting a standardized information technology network enclave and a standardized information assurance posture for the FTDTLs and the Special FTDTL (SFTDTL).
 - (2) Developing, identifying, and communicating standardized best administrative and operational practices to the Drug Demand Reduction Program (DDRP) and FTDTLs to bridge inter-Service differences and maximize efficiencies.

2.3. EXECUTIVE DIRECTOR, FORCE RESILIENCY (EDFR).

Under the authority, direction, and control of the USD(P&R), the EDFR administers the DDRP by:

- a. Developing procedures and standards for the technical aspects of the MPDATP.
- b. Monitoring compliance with the technical aspects of the MPDATP by providing oversight of the:
 - (1) Certification program and ensuring the quality and accuracy of the analyses performed at each FTDTL.
 - (2) External quality assurance (QA) program for the DoD-certified FTDTLs.

- (3) Biochemical Testing Advisory Board (BTAB).
- c. Approving the DoD authorized panel of drugs, to include:
 - (1) Drug panel additions and deletions.
 - (2) Changes to cutoff concentrations.
 - (3) Changes to testing rates.

2.4. SECRETARIES OF THE MILITARY DEPARTMENTS AND COMMANDANT, UNITED STATES COAST GUARD.

The Secretaries of the Military Departments and Commandant, United States Coast Guard will:

- a. Assign a 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 prescribed in this issuance are met.
- b. Ensure the receipt of appropriate and documented training of personnel involved in the:
 - (1) Collection, handling, and testing of specimens.
 - (2) Review and interpretation of drug test results.
- 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 issuance. The OP manual will include, at a minimum:
 - (1) Procedures for:
 - (a) Specimen receipt and laboratory chain of custody (CoC).
 - (b) Conducting initial screening, adjunct screening, and confirmatory tests.
 - (c) Retests.
 - (2) Data acceptability and data review criteria.
 - (3) 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 4.5.a.
- d. Ensure their respective Military Service use legally-supportable CoC procedures that, at a minimum, conform to the requirements of Section 4.
- e. Ensure that any forensic urine specimens, regardless of where they are collected, are submitted to the FTDTLs using the procedures described in Section 4.

(1) 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.

(2) Specimens collected solely for clinical diagnosis are not forensic specimens and will not be submitted to the FTDTLs.

f. Develop and manage a medical review process (MRP) to review all positive drug test results that could be the result of lawful or illicit prescription drug use.

(1) The MRP ensures that no adverse disciplinary action will be administered to those Service members who:

(a) Possess a valid medical prescription; or

(b) Were otherwise given a medication during a medical procedure, for the drug for which the member tested positive.

(2) For the purpose of this issuance, a prescription is valid for the period as written by the prescribing authority to the concerned Service member only.

(3) Absent a specified time period when prescribed, prescriptions for substances included on Schedules II through V of Section 812 of Title 21, United States Code, will be considered expired 6 months after the most recent date of filling, as indicated on the prescription label. For example, a prescription with a fill date of August 14th will be considered expired after February 14th of the following year.

(4) Use of any controlled medication without a valid prescription will be considered illegitimate.

(5) 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.

SECTION 3: ORGANIZATION WITHIN THE MPDATP – TECHNICAL QUALIFICATIONS AND RESPONSIBILITIES

3.1. DIRECTOR, OFFICE OF DRUG DEMAND REDUCTION (ODDR).

Under the authority, direction, and control of the USD(P&R) and through the Director, EDFR, the Director, ODDR:

- a. Is a member of the Military Services in the grade of O-5 or above and must have a:
 - (1) Doctor of Philosophy (PhD) degree, from an accredited university, in:
 - (a) Toxicology;
 - (b) Biochemistry; or
 - (c) A physical or biological science.
 - (2) Minimum of 4 years of leadership or managerial experience in the FTDTLs or the Division of Forensic Toxicology (FORTOX), AFMES.
- b. Develops, staffs, and provides execution oversight for policy and resources related to the technical aspects of the MPDATP, including updates to policy as recommended by the BTAB.
- c. Coordinates 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:
 - (1) Standardization.
 - (2) Common analytical methodologies.
 - (3) Purchasing contracts.
- d. Is responsible for the overall forensic integrity of the DoD DDRP.
- e. Ensures that:
 - (1) QA incidents that significantly impact the forensic integrity of the testing process are investigated; and
 - (2) The appropriate corrective or preventive actions are completed.
- f. Designates a drug testing information technology program manager to achieve a standardized and compliant information assurance posture across the DoD DDRP enterprise.

g. Designates an FTDTL information management system (IMS) program manager to provide management and oversight of the FTDTL-IMS.

3.2. DIRECTOR, FORTOX, AFMES.

Under the authority, direction, and control of the Director, AFMES, the Director, FORTOX, AFMES:

- a. Provides technical expertise to the EDFR through the Director, ODDR.
- b. Manages external QC and proficiency testing programs for the FTDTLs, in accordance with this issuance, that also include:
 - (1) Potential interfering compounds.
 - (2) Evaluation of the appropriate application of discrepancy codes.
- c. Coordinates the external QA program, consisting of three annual inspections at each FTDTL.
- d. Develops FTDTL inspection requirements to include:
 - (1) Detailed instructions specifying how the FTDTL is to prepare for each inspection. These instructions will include:
 - (a) A list of employees to be interviewed.
 - (b) Required documents to be assembled for review by inspectors, including:
 - 1. Data and laboratory records packages, as detailed in Paragraph 4.18.
 - 2. OP manuals.
 - 3. Summary of testing methods, to include instrument identifier, linearity values, method parameters.
 - 4. Training records.
 - 5. QA records.
 - 6. Previous inspection responses.
 - 7. Proficiency testing records.
 - 8. Testing summary for each specimen selected for review.
 - (2) Defined roles, responsibilities, and expectations of the inspection team. The composition of the team will be delineated with a minimal number of participants and

qualifications. Specific roles, responsibilities, and expectations for team members and all evaluated areas must be defined and covered via a comprehensive checklist. Several inspectors will be assigned as data auditors and all members will report to a lead inspector.

(3) Categorization of findings and corrective actions. Findings will be categorized to ensure that corrective actions are implemented in a timely manner and consistent with the requirements of this issuance.

e. Develops minimum FTDTL QA program requirements, in agreement with the:

(1) BTAB.

(2) Director, ODDR.

(3) Best-recognized forensic practices and standards.

f. Coordinates FTDTL certification and recertification actions for the drugs listed on the DoD drug testing panel and forwards recommendations to the Director, ODDR.

g. Evaluates, through on-site investigation and document review, all significant non-conforming events (NCEs) that impact the quality of forensic operations and forwards recommendations to the Director, ODDR.

h. Serves as the non-voting chair of the BTAB. The BTAB functions are outlined in Section 5 of this issuance.

i. Develops minimum requirements for initial, revised, and periodic instrument and method validation for initial screening and confirmatory tests, in agreement with the:

(1) BTAB.

(2) Director, ODDR.

(3) Best-recognized forensic practices and standards.

j. Conducts special drug testing, in accordance with Paragraph 7.3. of this issuance.

k. Oversees the operation of the SFTDTL to:

(1) Conduct testing for select drugs of abuse on the DoD-authorized panel of drugs (i.e., those with low prevalence rates, such as synthetic cannabinoids and fentanyl), subject to the procedures and standards for the technical aspects of this issuance.

(2) Conduct surveillance testing to:

(a) Determine the emergence or prevalence of drugs of abuse in the military population.

(b) Report on surveillance testing trends.

(3) Develop and validate testing methods, procedures, and techniques for emerging drug threats and disseminate these to the FTDTLs for adoption, when identified threats are added to the DoD-authorized panel of drugs.

3.3. COMMANDER, UNITED STATES MILITARY ENTRANCE PROCESSING COMMAND (USMEPCOM).

Under the authority, direction, and control of the Deputy Assistant Secretary of Defense for Military Personnel Policy, the Commander, USMEPCOM:

a. Ensures that all applicant testing is conducted at a DoD-certified testing laboratory and coordinates with that laboratory to maximize efficiency of testing, pursuant to Section 6 of this issuance.

b. Notifies applicants of positive test results, encourages the applicant to seek treatment, and provides them with a list of appropriate resources.

3.4. MILITARY SERVICE DRUG TESTING PROGRAM MANAGERS.

The Military Service Drug Testing program managers:

a. Are members of the Military Services in the grade of O-5 or above or civilian employees in the grade of GS-14 or above and must have a:

(1) PhD degree from an accredited university in:

(a) Toxicology;

(b) Biochemistry; or

(c) A physical or biological science.

(2) Minimum of 3 years of leadership or managerial experience in the FTDTLs or FORTOX, AFMES.

b. Serve as voting members of the BTAB.

c. Serve as representatives of their respective Service Secretary, coordinate and oversee their respective FTDTL's operations, and ensure compliance with all requirements of the MPDATP by maintaining a Service-specific standard operating procedure (SOP) manual, when the Service maintains more than one laboratory.

d. Provide input into the performance rating(s) of their respective Service FTDTL commanders/commanding officers.

e. Provide resource oversight and contract support for staffing, equipping, and maintaining FTDTLs that are capable of executing all technical aspects of the MPDATP.

3.5. FTDTL COMMANDERS/COMMANDING OFFICERS.

Under the authority, direction, and control of their respective chains of command, the FTDTL commanders/commanding officers:

a. Are members of the Military Services in the grade of O-4 or above and must have a:

(1) PhD degree from an accredited university in:

(a) Toxicology;

(b) Biochemistry; or

(c) A physical or biological science.

(2) Minimum of 3 years of experience in one of the DoD FTDTLs or FORTOX, AFMES.

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

c. Are responsible for ensuring their individual FTDTL's OP manual is current and reflects the standards described in this issuance and their individual Service standard operating procedure manual, if applicable. All:

(1) Changes to the FTDTL OP manual must be approved by the FTDTL commander/commanding officer.

(2) FTDTL OP manuals must be reviewed and approved annually, at a minimum, by the FTDTL commander/commanding officer.

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

e. Ensure that:

(1) All results from scheduled QA inspections, QA incident inspections, and investigated NCEs are documented; and

(2) Any required corrective or preventive actions are completed and documented in a timely manner.

- f. Attain certification as an FTDTL final, positive laboratory certifying official (LCO).

3.6. FTDTL DEPUTY COMMANDERS AND EXECUTIVE OFFICERS.

Under the authority, direction, and control of their respective chains of command, the FTDTL deputy commanders and executive officers:

- a. Are members of the Military Services in the grade of O-3 or above and must have a:
 - (1) PhD degree from and accredited university in:
 - (a) Toxicology;
 - (b) Biochemistry; or
 - (c) A physical or biological science.
 - (2) Minimum of 3 years of experience in one of the DoD FTDTLs or FORTOX, AFMES.
- b. Fulfill the duties of the FTDTL commander/commanding officer, in the commander/commanding officer's absence, and by delegation.
- c. Manage all aspects of daily FTDTL operations, including:
 - (1) Maintaining an adequate and trained staff.
 - (2) Monitoring and managing production throughput.
 - (3) Upholding best forensic and scientific practices.
- d. Attain and maintain certification as an FTDTL final, positive LCO.

3.7. FTDTL TECHNICAL DIRECTORS.

Under the authority, direction, and control of their respective chains of command, the FTDTL technical directors:

- a. Are appointed, in writing, by the FTDTL commander/commanding officer.
- b. Have a:
 - (1) PhD degree from an accredited university in toxicology, biochemistry, or a physical or biological science and possess a minimum of 3 years of experience in forensic toxicology; or

(2) Master's degree from an accredited university in toxicology, biochemistry, or a physical or biological science and possess a minimum of 4 years of experience in forensic toxicology.

c. Maintain technical expertise in the science of forensic toxicology by regularly reviewing publications in the peer-reviewed scientific literature.

d. Attain and maintain certification as an FTDTL final, positive LCO.

3.8. FTDTL EXPERT WITNESSES (EWS).

Under the authority, direction, and control of their respective chains of command, the FTDTL EWs:

a. Are appointed, in writing, by the FTDTL commander/commanding officer.

b. Have, at a minimum, a bachelor's degree from an accredited university in:

(1) Toxicology;

(2) Biochemistry; or

(3) A physical or biological science.

c. Complete a comprehensive training program, which includes but is not limited to:

(1) Attaining and maintaining certification as an FTDTL final, positive LCO.

(2) EW training.

(3) Knowledge of the requirements of this issuance, including certification requirements for the FTDTL.

d. Demonstrate the ability to clearly communicate information regarding:

(1) Laboratory procedures.

(2) Forensic toxicology theory and practice.

(3) Pharmacology.

(4) The physiologic effects of drugs.

e. Maintain technical expertise in the science of forensic toxicology by regularly reviewing publications in the peer-reviewed scientific literature.

3.9. FTDTL LCOS.

Under the authority, direction, and control of their respective chains of command, the FTDTL LCOs:

- a. Are appointed, in writing, by the FTDTL commander/commanding officer.
- b. Have, at a minimum, a bachelor's degree from an accredited university in:
 - (1) Toxicology;
 - (2) Biochemistry; or
 - (3) A physical or biological science.
- c. Complete, before appointment, a comprehensive and documented training program to achieve certification in all technical areas of the FTDTL. Training will include:
 - (1) Technical understanding of all testing methodologies.
 - (2) Forensic regulations used to process specimens.
 - (3) Criteria to review data and report results.
- d. Maintain:
 - (1) Documented understanding of all technical areas of the FTDTL via annual familiarization training.
 - (2) Certification(s) for all duties directly performed.

3.10. FTDTL QUALITY ASSURANCE OFFICERS (QAOS).

Under the authority, direction, and control of their respective commander/commanding officer, the FTDTL QAOS:

- a. Are appointed, in writing, by the FTDTL commander/commanding officer.
- b. Attain and maintain certification as an FTDTL final, positive LCO.
- c. Dedicate a minimum of 50 percent of work time to QA duties.
- d. Are responsible for the overall management of the FTDTL's QA program.
- e. Seek continuing education on NCEs and other quality processes (e.g., Lean Six Sigma).

SECTION 4: TECHNICAL PROCEDURES FOR THE MPDATP

4.1. GENERAL.

a. Procedures for collection of specimens will be established by the Military Departments and will incorporate the basic requirements in this section. To achieve joint collections at sites shared by multiple Military Services, the Military Departments will recognize as valid, and will accept, specimens collected using practices and protocols from all Services, provided they meet the requirements of this issuance. Military Services will implement on-site compliance checks, as well as monitor and minimize discrepancy codes, which are assigned to document potential faults in the collection process.

b. Specimen collection, custody transfer, and transport to the FTDTL must be pursuant to Service instructions and must be documented on the approved CoC form—either the DD Form 2624, “Specimen Custody Document – Drug Testing” or USMEPCOM Form 40-8-3, “Urine Sample Custody Document.” The Military Departments will ensure that documentation produced during the collection process is maintained in accordance with Service records retention requirements.

4.2. PREPARATION FOR SPECIMEN COLLECTION.

Service procedures will ensure that approved bottles are used for specimen collection.

a. Each bottle must be properly labeled with specific Service-required information to include the member’s full DoD identification number (DoD ID) and the member’s signed initials verifying the accuracy of the DoD ID and attribution of the specimen to the member. The acceptable DoD ID is the Electronic Data Interchange – Personal Identifier.

b. The social security number (SSN) is only acceptable as the specimen identification in limited cases where a DoD ID has not been issued to the specimen donor.

c. The member’s name must not be part of the information on the specimen bottle, CoC, or other documentation submitted to the FTDTL; however, other information regarding collection may be included (e.g., base area code, unit identifiers, date of collection).

4.3. COLLECTION OF SPECIMENS.

Military Services’ procedures will ensure that:

a. The volume of urine collected exceeds 30 milliliters, but is not greater than the maximum fill level indicated on the collection bottle (i.e., 75 milliliters).

(1) Volumes less than 30 milliliters will be screened but may limit the extent of testing conducted on poly-drug positive specimens. A specimen with a volume less than 30 milliliters will be reported with a testable discrepancy to the submitting command. If the specimen volume

upon arrival at the FTDTL is insufficient for testing, a non-testable discrepancy will be reported to the submitting command.

(2) A specimen with volume greater than the maximum fill level indicated on the collection bottle risks the potential for specimen loss. Any such leakage will be reported using the appropriate discrepancies described in Paragraphs 4.8.b.-c.

(3) Urine is the only type of specimen tested at the FTDTLs.

b. Specimens are to be collected under the direct observation of a designated and properly trained individual with the same sex marker in the Defense Enrollment Eligibility Reporting System as the Service member providing the specimen.

(1) 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 by watching the urine leave the body and enter the bottle, including all intermediate and final containers, if used.

(2) CoC procedures are designed to ensure the security of, and accountability for, specimens during all aspects of collection, storage, and transportation to the FTDTL.

(3) Service requirements for collection event policy (e.g., quotas, scheduling, observation, storage, transportation) are established by the Military Departments.

c. Each individual to be tested presents proof of identity.

(1) The Service member submitting the specimen will:

(a) Provide an unadulterated specimen.

(b) Verify that the DoD ID is accurately recorded on the CoC form and bottle label.

(c) Initial the bottle label.

(d) Sign the corresponding entry in the collection record.

(2) The collector will also verify this information by direct comparison of the identification provided and will affix the label to the specimen bottle only after the:

(a) Service member has urinated directly into the specimen bottle; or

(b) Service member's urine has been poured from a urine collection cup into the specimen bottle.

(3) Tamper-evident tape will be placed over the lid of the specimen bottle in the presence of the member and attached securely to the bottle label. This tape must contact the bottle label at both ends. Other types of tape will not be used for this purpose

d. In addition to the Service member submitting the specimen, a second individual (e.g., an additional collector, assistant collector, officer, non-commissioned officer, or designated civilian) at each urinalysis specimen collection site conducts a secondary review of each capped and labeled specimen bottle to ensure compliance with this issuance. The individual charged to execute this secondary review will verify that the lid of each bottle is tightly secured and properly sealed. The conduct of this secondary review will be marked on applicable CoC or collection documents, in accordance with Service requirements.

e. The appropriate CoC form is properly completed and the collection record is properly documented with Service-required information, including the:

(1) Name and signature of the Service member.

(2) Name of the observer.

f. Collection documentation is retained in accordance with Service records retention requirements.

4.4. TRANSPORTATION OF SPECIMENS.

In accordance with the requirements of Section 346.326 of U.S. Postal Service Publication 52, Service procedures must ensure that:

a. The lids of all specimen bottles forwarded to an FTDTL for testing are securely tightened and properly sealed. Each bottle must be enclosed in an individual, leak-proof, secondary container (i.e., a sealable plastic bag) to prevent and contain leakage. The secondary container(s) must contain sufficient absorbent material to absorb the entire specimen's contents in case of leakage.

b. When the bottle label and the accompanying CoC form with one-dimensional barcodes are used, the original CoC form is shipped with the specimen(s) and a copy of the original CoC is maintained at the collection site in accordance with Service requirements. When a bottle label and the accompanying CoC form with two-dimensional barcodes are used, no CoC form is submitted with the specimen(s) and the original and any copies are maintained at the collection site in accordance with Service requirements.

c. Each shipping package is sealed. Except for Military Entrance Processing Station (MEPS) collections, the signature or initials of the collection coordinator, or other appropriate individual, must be annotated across the package seal to ensure the integrity of the specimen packaging. This requirement applies to all methods of transportation, including specimens hand-delivered to the FTDTLs.

d. Packages are transported to the FTDTL via:

(1) The U.S. Postal Service;

(2) Commercial air freight;

- (3) Air express;
- (4) Surface transportation;
- (5) The Air Mobility Command;
- (6) The United States Transportation Command; or
- (7) Hand-delivery.

4.5. COOP DURING CATASTROPHIC INCIDENTS.

a. Each FTDTL will have a documented COOP in the event of a catastrophic incident (e.g., hurricane, tornado, flood, fire, earthquake, pandemic) during which FTDTL operations are temporarily suspended. The FTDTL network and FTDTL operations may also be adversely impacted by other events, such as:

- (1) Personnel shortages;
- (2) Extreme number of specimen submissions;
- (3) Laboratory relocations; or
- (4) Computer hardware and software failure.

b. The FTDTL must anticipate such events and establish an emergency notification, shelter, and recovery plan that is detailed in the FTDTL COOP. The COOP will include workforce measures to maximize the use of facilities and equipment by expanding work schedules and shifts, as allowed by human resource management rules and regulations. Each FTDTL's COOP will be tested periodically by conducting evacuation and shelter drills, personnel recall, and other exercises.

c. When FTDTL operations cannot be restored within 5 work days, the responsible Military Service drug testing program manager will coordinate with the Director, ODDR, and the other Military Service drug testing program managers, to redistribute specimen submissions to other FTDTLs. Each incident will be assessed to determine the proper utilization of manpower and resources in order to resume FTDTL operations, when feasible and as quickly as possible.

4.6. LABORATORY SECURITY.

a. The security of urine specimens, and aliquots thereof, subject to testing will be maintained at all times to secure them against possible contamination, adulteration, loss, or tampering. Access to, and the number of, individuals involved in the processing of specimens or aliquots will be kept to a minimum.

b. The FTDTL commander/commanding officer will delineate in writing, or by electronic means, the individuals with authorized entry to each limited access area of the FTDTL.

(1) For each of the limited access areas, the entry and exit of authorized personnel will be documented, preferably by an electronic security access system.

(2) Limited access areas will be designated by the FTDTL commander/commanding officer and will include, at a minimum:

(a) The areas of specimen processing or accessioning sections.

(b) All testing areas.

(c) All temporary and long-term specimen storage areas, to include rooms, freezers, or refrigerators used for such purposes.

(d) Drug testing document processing and archival areas.

(3) Visitors to any limited access area must be escorted at all times by an individual who is authorized access to that area. Access logs or memoranda for record (MFRs) will reflect the date, time, visitors, FTDTL escort, and purpose of the visit.

c. The FTDTL will 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. A copy of the annual security inspection report will be available for review by DoD certification inspection teams.

d. Security records (e.g., entry logs, security video, electronic key card assignment and card activity) must be retained for the same time period as required for positive results data.

4.7. INTERNAL LABORATORY COC.

a. All individuals involved in the processing of specimens or aliquots will be documented on a CoC. Specimens and aliquots must always be:

(1) In the possession of an authorized FTDTL employee;

(2) In a secured storage area; or

(3) Assigned to an instrument on which specimens are tested or processed.

b. Specimens or aliquots are considered to be in the custody of an authorized FTDTL employee, as long as the employee remains in the same secured, limited access area of the laboratory as the specimens or aliquots. If the employee leaves this area, custody must be transferred to:

- (1) Another employee;
 - (2) Secure temporary storage, or
 - (3) The appropriate laboratory instrumentation.
- c. Custody must **always** be transferred to the screening analyzer, mass spectrometer, or other instruments during processing and analysis.
- d. Internal laboratory CoC forms, whether paper or electronic, 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.
- e. Individual specimens are tracked using a unique laboratory accession number (LAN). The unique LAN is originally assigned to the specimen upon receipt at the FTDTL. A batch CoC form will accompany a batch of specimens or aliquots throughout each testing process to document and track handling and testing steps.
- f. Custody documentation for aliquots sent to another laboratory is described in Paragraph 4.16.e. of this issuance.

4.8. SPECIMEN RECEIPT AND PROCESSING.

Specimens arriving at the FTDTL will be transferred, with the original packaging intact, to the specimen processing area. Specimen processing personnel will:

- a. Examine the package, specimen, and CoC, if applicable, to identify and document submission discrepancies, and document the date of receipt of the specimens at the FTDTL. To achieve the policy set forth in Paragraphs 1.2.a.-b., each Service will maximize testing and reporting of results by complying with the list of discrepancy codes (Table 1) established by the Director, ODDR. The Military Services may impose more stringent testability standards (i.e., not test), provided a new specimen is submitted from the applicable Service member(s) within 72 hours of result notification, or as soon as practical.

Table 1. DoD Discrepancy List

Source	Code	Description	Disposition
Bottle	BA	Bottle / container unauthorized	TESTED
	BB	Bottle leaked in shipment	NOT TESTED
	BC	Bottle leaked in shipment, quantity not sufficient to test	NOT TESTED
	BD	Bottle - broken seal	TESTED
	BE	Bottle - no seal	TESTED
	BF	Bottle - two seals, no explanation	TESTED
	BK	Bottle leaked in shipment, within secondary container only	TESTED
	BU	Bottle empty - appears to have never contained urine	NOT TESTED
	BZ	Bottle discrepancy - record other reason	TESTED
	BY	Bottle discrepancy - record other reason	NOT TESTED

Table 1. DoD Discrepancy List, Continued

Source	Code	Description	Disposition
Specimen	SA	Specimen appears to be adulterated	NOT TESTED*
	SB	Specimen appears to be adulterated	TESTED**
	SC	Specimen quantity not sufficient to test	NOT TESTED
	SE	Specimen volume < 30 mL	TESTED
	SZ	Specimen discrepancy - record other reason	TESTED
	SY	Specimen discrepancy - record other reason	NOT TESTED
Custody Form	FA	Form - UIC or base/area code discrepant***/differs from bottle	TESTED
	FH	Form - date specimen collected discrepant***/differs from bottle	TESTED
	FL	Form not received	TESTED
	FM	Form received separately from bottle	TESTED
	FN	Form CoC entries discrepant***	TESTED
	GG	Form listed specimen, no bottle received	NOT TESTED
	FP	Form did not list specimen, bottle received	TESTED
	FR	Form on two pieces of paper - no linking identifiers	TESTED
	FT	Form - DoD ID discrepant***	TESTED
	GP	Form or other document shows Service member's name/signature	TESTED
	GR	Form marked void for received specimen	TESTED
	GZ	Form discrepancy - record other reason	TESTED
Package	PA	Package - no seal	TESTED
	PB	Package - broken seal	TESTED
	PD	Package missing signature / date	TESTED
	PH	Package - leakage noted	TESTED
	PI	Package - improperly packaged	TESTED
	PL	Package - leakage noted	NOT TESTED
	PZ	Package discrepancy - record other reason	TESTED
	PY	Package discrepancy - record other reason	NOT TESTED
Label	LA	Label missing / blank	TESTED
	LD	Label over label	TESTED
	LF	Label - collection date discrepant***	TESTED
	LJ	Label - Service member's initials discrepant***	TESTED
	LL	Label - collector or observer's initials discrepant***	TESTED
	LN	Label - DoD ID does not match form	TESTED
	LQ	Label has Service member's name/signature	TESTED
	LX	Label - DoD ID discrepant***	TESTED
	IT	SSN Received as DoD ID	TESTED
	IN	SSN Received as DoD ID	NOT TESTED
	LZ	Label discrepancy - record other reason	TESTED
2D Barcode	LY	Label discrepancy - record other reason	NOT TESTED
	2D	2D barcode does not read / scan	TESTED
	RF	Form 2624 received with a 2D specimen	TESTED
	HW	2D label contains handwritten information	TESTED
	MM	2D barcode has mis-matched information (label vs. scan)	TESTED
Other	MC	Memo received with 2D specimen - corrected information	TESTED
	OZ	Laboratory technical discrepancy - record other reason	TESTED
	OY	Laboratory technical discrepancy - record other reason	NOT TESTED
* Not tested for drugs of abuse, but specimen validity testing will be conducted			
** Tested for drugs of abuse and specimen validity testing will be conducted			
*** Discrepant = Incorrect, incomplete, illegible, missing, overwritten, not original, or not forensically corrected			

b. Inspect and document current or past leakage. As soon as practicable after receipt, on first opening any shipping package (i.e., a box or container designed to hold as few as one and as many as twelve individual urine specimen bottles), an FTDTL inspecting official (e.g., accessioning technician) will carefully inspect each enclosed specimen bottle and the shipping

package for signs of current or past leakage. Detecting signs of current or past leakage requires keen observation and assessment by the inspecting official. Signs of current or past leakage may include:

- (1) Wetness on:
 - (a) A specimen bottle;
 - (b) The packing materials; or
 - (c) Any document(s) enclosed in the shipping package.
 - (2) Wetness on or in:
 - (a) An individual leak-proof secondary container in which a single specimen bottle is enclosed; or
 - (b) The shipping package.
 - (3) The discoloration or distortion (e.g., wrinkling, smearing) of the:
 - (a) Label on a urine specimen bottle or shipping package;
 - (b) Shipping package itself;
 - (c) Packing materials; or
 - (d) Document(s) enclosed in the shipping package.
 - (4) Signs of crystallization from minerals/urea:
 - (a) On a urine specimen bottle, the packing materials, or on any document(s) enclosed in the shipping package; or
 - (b) On or in:
 1. An individual leak-proof secondary container in which a specimen bottle is enclosed; or
 2. The shipping package.
- c. Apply the appropriate discrepancy code, when the FTDTL inspecting official detects any sign of current or past leakage in conducting their inspection, in accordance with Paragraph 4.8.b.

(1) PH – Package Leakage Noted.

- (a) The PH discrepancy code will be assigned to each specimen bottle in the shipping package, when the inspecting official determines that there exists any possibility that leakage or

wetness associated with any bottle or its individual leak-proof secondary container (as applicable) affected:

1. Any other specimen bottle or secondary container;
2. The shipping package;
3. Packing materials; or
4. Any document enclosed in the shipping package.

(b) Aliquots derived from a specimen bottle coded as PH may be tested, provided that testing is not precluded by another non-testable discrepancy code assigned to the same specimen.

(c) “PL - Package Leakage noted” may be used as a more stringent application of this standard at Service discretion.

(2) BK – Bottle Leaked in Shipment, Within Secondary Container Only.

(a) The BK discrepancy code will be assigned to any individual specimen bottle that shows signs of current or past leakage or wetness. This code is only assigned when the inspecting official determines that two conditions are met:

1. All of the leakage or wetness associated with that bottle is contained within its individual leak-proof secondary container, as applicable.
2. None of the leakage or wetness has affected any other specimen bottle or secondary container, the shipping package, packing materials, or any document enclosed in the shipping package.

(b) Aliquots derived from a specimen bottle coded as BK may be tested, provided that testing is not precluded by another non-testable discrepancy code assigned to the same specimen.

(c) “BB – Bottle leaked in shipment” may be used as a more stringent application of this standard at Service discretion.

(3) PH and BK Discrepancy Codes.

If a specimen bottle meets criteria for the assignment of both the PH and BK discrepancy codes, both discrepancy codes will be assigned.

d. Link to one another, through documentation in appropriate laboratory records, all specimen bottles received in the same shipping package, and any urine aliquots derived therefrom. Any aliquots derived therefrom will be processed in the same screening batch. This documentation will be generated, tracked, and maintained in the laboratory IMS (LIMS) as part of the CoC or other similar documentation, to ensure that the FTDTL and any other person or

organization can identify and track all specimen bottles, and any aliquot derived therefrom, that were received in the same shipping package.

- e. Assign a unique LAN to each specimen.

4.9. DRUG TESTING.

a. The DoD-authorized panel of drugs to be routinely tested at the FTDTLs and their respective initial screening and confirmatory cutoff concentrations are shown in Tables 2 and 3, respectively.

Table 2. Initial Screening Test Cutoff Concentrations

Drug Class	Cutoff nanograms/milliliter (ng/mL)*
Amphetamines	500
Designer Amphetamines	500
Benzodiazepines	200
Cannabinoids (Marijuana)	50
Synthetic Cannabinoids	10
Cocaine Metabolites	150
Opioids (Morphine / Codeine)	2,000
Opioids (Heroin metabolite 6-monoacetylmorphine)	10
Opioids (Oxycodone / Oxymorphone)	100
Opioids (Hydrocodone / Hydromorphone)	300
Opioids (Fentanyl / Norfentanyl)	1.0
*Value given is immunoassay (IA) cutoff. For mass-spectrometry (MS) based screening, the confirmation cutoff in Table 3 will be used, when technically possible.	

Table 3. Confirmatory Test 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	3,4-Methylenedioxymethamphetamine	500	3,4-Methylenedioxymethamphetamine
	3,4-Methylenedioxyamphetamine	500	3,4-Methylenedioxyamphetamine
Benzodiazepines	Lorazepam	100	Lorazepam
	Nordiazepam	100	Nordiazepam
	Oxazepam	100	Oxazepam
	Temazepam	100	Temazepam
	α -hydroxy-Alprazolam	100	α - hydroxy-alprazolam
Cannabinoids	11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid	15	11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid
Synthetic Cannabinoids	Illicit synthetic cannabinoids derived from the following classes of compounds:		
	Naphthoylindole cannabinoids	1.0	Synthetic cannabinoid (SYCAN)
	Alkoylindole cannabinoids	1.0	SYCAN
	Indole carboxylate cannabinoids	1.0	SYCAN
	Indole carboxamide cannabinoids	1.0	SYCAN
	Indazole carboxamide cannabinoids	1.0	SYCAN
	Including indene, pyrrole, benzimidazole, azaindole, naphthalene, thiazolidene, carbazole, pyrrolo-benzoxazine, adamantoyl, and other cannabinoid derivatives	1.0	SYCAN
Cocaine Metabolites	Benzoylcegonine	100	Cocaine
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
Opioids, Cocaine Metabolites*	Fentanyl	1.0	Fentanyl
	Norfentanyl	1.0	Norfentanyl

*Either from initial screening (IA or MS-based) or from adjunct screening (IA or MS-based) triggered by cocaine metabolites or opioids presumptive-positive initial screening.

b. All FTDTLs will screen all testable Service member specimens for:

- (1) Cannabinoids, excluding synthetic cannabinoids.
- (2) Cocaine metabolites.
- (3) Heroin metabolite.
- (4) Amphetamines, including designer amphetamines.

c. The FTDTL will screen all testable Service member specimens for all other drugs listed in Table 2, unless a lower testing rate is determined by the EDFR.

d. The MPDATP will conduct prevalence/surveillance testing to monitor the use of drugs that are not on the DoD-authorized drug testing panel. Specimens will periodically be screened for additional drugs and confirmatory testing will be conducted on de-identified specimens, as determined by subject matter experts on the BTAB and at the AFMES to address emergent drug threats. Results of these prevalence studies, along with recommendations for changes to the testing panel, will be forwarded, through the BTAB, to the Director, ODDR, to support policy changes by the EDFR. Both objective (e.g., prevalence rates, technical capabilities, capacity, cost) and subjective (e.g., potency, lethality, notoriety) considerations will be taken into account in adjusting the testing panel.

e. All specimens received at the FTDTL will be tested, except for those specimens assigned non-testable discrepancies (see Table 1). All assigned discrepancies, coded in accordance with Table 1, will be documented and reported to the submitting unit. This documentation will be generated, tracked, and maintained in the LIMS as part of the CoC or other similar documentation, such that the FTDTL or any person or adjudicatory entity can identify and track all discrepancy codes assigned to a particular specimen.

4.10. INITIAL SCREENING TEST.

a. The purpose of the initial screening test is to eliminate negative specimens and to focus efforts and resources on those specimens that are “presumptively positive” (i.e., most likely to contain drugs on the DoD-authorized panel). All immunoassay (IA) test kits or alternate testing methods (e.g., MS-based screening) used for the initial screening test must be authorized by the Director, ODDR. Unless otherwise authorized, all IA test kits must be approved for commercial sale and distribution by the Food and Drug Administration. All initial screening tests must be validated prior to implementation. Method validation will be described in the FTDTL’s OP manual and conducted per requirements promulgated by the AFMES. IA method validation must include, at a minimum, evaluations of:

- (1) Linearity.
- (2) Precision and accuracy around the cutoff.
- (3) Carryover.
- (4) Specificity.
- (5) Positive and negative specimen differentiation.
- (6) Parallel studies and matrix effects, if applicable.

b. To process specimens for the initial screening test, the technician will complete the appropriate intra-laboratory specimen bottle and aliquot CoC documents. The technician will work with (i.e., open) only one specimen bottle at a time in preparing its aliquot. 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 validated by requirements promulgated by the AFMES and approved by the Director, ODDR.

c. All initial screening tests performed at an FTDTL will consist of specimens contained within discrete identifiable batches. Each batch will contain a minimum of 5 percent control samples, relative to the total number of Service member specimens in the batch. The instrument used in screening analysis will be calibrated at least daily and whenever maintenance or operational non-conformances dictate.

(1) Calibration and batch acceptance criteria include evaluation of an:

(a) Open negative control(s); analyte-free and must test lower than the open low control.

(b) Open low control(s); 50-75 percent of the cutoff concentration and must test negative.

(c) Open high control(s); 125-150 percent of the cutoff concentration and must test positive.

(2) Each batch of aliquots for the initial screening test will contain a minimum of one blind positive and one blind negative (i.e., analyte-free) control. The blind controls will be placed randomly in the batch pursuant to the FTDTL's OP manual. Blind positive controls must test positive. Blind negative controls must test negative with values below those for the lowest batch open low control.

(3) Multi-well plates and automated liquid handling systems may be used in conjunction with alternate initial and adjunct screening test techniques (e.g., MS-based). Manual-pipetting into multi-well plates is not permitted. Such systems must meet initial and ongoing validation requirements promulgated by the AFMES; additionally, the precision and accuracy of each pipetting channel must be evaluated at least weekly. Multi-well plates must be barcoded and the plate map containing the location of specimens and controls must be printed for review and uploaded to the MS instrumentation.

(4) MS-based initial screening techniques must meet validation, calibration, control, and other guidelines promulgated by the AFMES. The screening drug test is considered positive for a drug class, as shown in Table 2, when at least one analyte is equal to or greater than the screening cutoff concentration shown in Table 3. Qualitative criteria may be relaxed relative to those required for confirmatory tests, in accordance with Paragraph 4.12., and only a single transition needs to be monitored for the analyte and corresponding internal standard (IS), when used. Procedures that do not use an IS for each analyte must be recommended by the BTAB and approved by the Director, ODDR.

d. Upon completion of the initial screening test, the results and other documentation will be forwarded for appropriate forensic laboratory review. The FTDTL's OP manual will provide

guidance for partial batch acceptance and repeat testing whenever the open or blind control performance criteria are not met.

e. The FTDTL commander/commanding officer has the right to terminate or to direct repeat testing for any specimen, only when they have determined that the validity of the result is forensically or scientifically questionable. Rationale for these testing actions will be documented by MFR and maintained with the specimen's testing records.

4.11. ADJUNCT SCREENING TEST.

a. Pursuant to recommendations from the BTAB, the Director, ODDR, will authorize adjunct screen tests and may do so at cutoff concentrations distinct from those shown in Table 2.

b. Adjunct testing will be used when the initial screening test for a specific drug class identifies a large number of specimens as presumptively positive that would not test positive in the confirmatory test for the target analyte in the drug class of interest. Specimens may also be subject to adjunct testing due to known association with other drugs (e.g., heroin or cocaine being "cut" or laced with fentanyl). An adjunct screening test may be conducted on the same specimen aliquot used for the initial screening test or on a separate aliquot.

c. Negative adjunct screening test results may be used to eliminate specimens from further testing. Positive adjunct screening test results may be used to determine that a specimen requires further testing or may be used to complete the requirement for the initial test. Adjunct screening test batches must meet the same open control criteria as initial screening test batches; however, blind controls are not required.

4.12. CONFIRMATORY TEST.

a. The purpose of the confirmatory test is to specifically identify and quantify drug presence in specimens identified by the initial screening test and adjunct screening tests, if performed.

b. Specimens that screen presumptively positive will be confirmed by chromatography/mass spectrometry (C/MS). Alternate analytical methodologies may be approved by the Director, ODDR, pursuant to recommendations from the BTAB. To ensure the best use of limited specimen volume, the FTDTLs will prioritize confirmatory testing by first testing for Schedule I drugs and those infrequently prescribed by the DoD medical community (e.g., marijuana, heroin, designer amphetamines, synthetic cannabinoids, methamphetamine, cocaine) and then testing for the remaining drugs subsequently.

c. The general guidelines for all confirmatory extraction procedures performed at the FTDTLs include:

(1) Forensically-supportable practices must be used during all aliquot and extract transfer steps, as well as during transfer to C/MS instrumentation, to ensure correct identification and integrity is maintained at all times.

(2) Each batch of specimen aliquots will contain a minimum of 5 percent control samples relative to the total number of Service member specimen aliquots.

(a) The batch must contain:

1. An:

a. Extracted urine calibrator with an analyte concentration equal to the confirmatory cutoff concentration.

b. Analyte-free blind negative control.

c. Open low control with a concentration 40-50 percent of the cutoff concentration.

2. A blind positive control with a concentration at least 120-200 percent of the cutoff concentration.

(b) If a hydrolysis or oxidation step is included in the extraction procedure, a hydrolysis or oxidation control will be included in the batch, if available.

(c) All calibrators, controls, and specimens must be processed simultaneously and analyzed as part of the batch using the same procedures. For direct injection on liquid chromatography (LC)/tandem mass spectrometry (MS/MS) instruments, all calibrators, controls, and specimens in the batch must be prepared simultaneously using the same procedures.

(3) Internal standard will be added to all calibrator, controls, and specimens analyzed. If available, the IS will be a deuterated analog of the analyte being tested. Procedures that do not use deuterated analogs must be recommended by the BTAB and approved by the Director, ODDR. The intra-batch IS abundance will be tracked for each confirmatory method and IS acceptance criteria for all batch calibrators, controls, and specimens will be delineated in the FTDTL's OP manual.

(4) Multi-well plates and automated liquid handling systems may be used in conjunction with confirmatory testing techniques. Their use must meet the same requirements described in Paragraph 4.10.c.(3).

d. The general guidelines for all confirmatory C/MS analyses performed at the FTDTLs include:

(1) For C/MS instruments that have a practical daily autotune capability (e.g., gas chromatography/mass spectrometry (GC/MS)), an acceptable autotune must be performed within 24 hours prior to the injection of a batch calibration standard. For C/MS/MS, on a quarterly basis and after any maintenance that requires MS/MS venting, a full autotune will be performed using an appropriate tuning compound(s), as recommended by the instrument manufacturer. Autotune data will be retained for the same time period as required for positive results data. For C/MS/MS, an acceptable system verification sample (SVS) analysis must include the analyte(s)

of interest and be performed within 24 hours before the injection of the batch calibration standard. The criteria for an acceptable SVS include:

- (a) Transition retention times (RTs) within ± 3 percent of the expected RT for the compound.
 - (b) Area counts for the quantitative transition will be at or above a lower limit established by the FTDTL based upon historical values for the transition.
 - (c) Transition ratios will be consistent with historical values for the compound.
 - (d) Mass assignment for the transition should be within the manufacturer's recommended parameters.
 - (e) If area counts or transition ratios are unacceptable, the source may require cleaning. If source cleaning fails to return the SVS within acceptable ranges, a full autotune will be performed.
- (2) All batch calibrators, controls, and specimens 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 analysis. This drift control must be within ± 10 percent of its theoretical value, or re-processed value for a multipoint calibration. If the calibrator is exhausted, the low control may be used for this purpose and the initial and final injections of the low control must quantitatively be within ± 10 percent of each other. For in-line extraction instrumentation, the end-of-batch control will be the re-extraction of the calibrator. In this case, 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 paired IS must be analyzed and presented on the data printout for all GC/MS analyses. For MS/MS analyses, the data printout and analyses must include at least two transitions for the analyte and two transitions for the paired IS.
- (5) For GC/MS and MS/MS, respectively, the mass ion ratios or transition ratios for all controls and specimens must have values that are within ± 20 percent of the mass ion ratios or transition ratios for the extracted calibrator.
- (6) The RT for all analytes and paired ISs for all controls and specimens must be within ± 2 percent for GC/MS and ± 3 percent for LC/MS/MS of the RTs for the extracted calibrator. Relative RT (i.e., analyte relative to its internal standard) may be used for LC-based analyses.
- (7) The quantitative results for controls must be within ± 20 percent of their target values and the blind negative control must not quantitate above the established analyte-specific limit of detection (LOD).
- (8) For GC/MS and MS/MS, respectively, a minimum of 8 and 12 MS scans are required for each peak.

(9) Each FTDTL must validate and set minimum criteria for mass ion and transition abundances to ensure valid drug concentration determinations.

(10) Batch analyses interrupted by power failure must be restarted with a new autotune for GC/MS or a reinjection of the SVS for C/MS/MS followed by re-injection of the calibrator and open controls prior to continuing Service member specimen injections. Batch analyses may be continued the next business day, if the autotune or SVS is validated and the re-injection of the calibrator meets established acceptance criteria.

(11) For GC/MS, all mass ions for each drug must include part of the primary structure (i.e., parent compound) of the drug molecule. The use of isotopic ions is only permitted if a full complement of independent and unique qualifier ions useful for analyte identification are not available.

(12) Negative specimens in a failed batch may be reported as negative for the analyte being tested, if the nature of the failure does not prevent the identification of positive specimens.

(13) A diluted specimen may not be reported as positive, if the on-column amount of the analyte is less than the target concentration of the batch low control.

(14) Altering instrument conditions to separate interfering peaks is permitted, when limited to GC oven temperature and LC mobile phase gradients. All calibrators, controls, and affected Service member specimens must be analyzed under the new conditions and all batch acceptance criteria must be met.

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

(16) The FTDTL commander/commanding officer may cancel testing of Service member specimens that fail to meet acceptance criteria twice for the same reason by calling the result negative or invalid, but only the latter when interference is not resolved or the specimen is depleted prior to completing testing. Rationale for these cancellations will be documented by MFR and maintained with the specimen's testing records.

(17) The disposal of excess urine aliquots will be documented on the CoC.

(18) All ion or transition chromatograms must meet these minimum acceptance criteria:

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

(b) The peak asymmetry (A_s) factor for all quantifying and qualifying ions or transition must be within 0.5-2.0. The A_s factor is determined by drawing a perpendicular line from the baseline to the apex of the target drug peak. The A_s factor equals B/A , 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 in this section are met and the specimen quantifies at or above the confirmatory cutoff concentration.

(2) The FTDTL commander/commanding officer has the right to terminate or to direct repeat testing for any specimen, only when they have determined that the validity of the result is forensically or scientifically questionable. Rationale for these testing actions will be documented by MFR and maintained with the specimen's testing records.

(3) All lots of reagents (e.g., organic solvents, pH-specific reagents and buffers, derivatizing reagents, acids and bases, hydrolyzing reagents), solid-phase extraction cartridges, negative urine (i.e., analyte-free), calibrators, and controls will be certified, before positive results may be reported.

(a) Materials will be certified as free of interferences and, where applicable, will be verified to contain the analyte(s) of interest at the stated values prior to their use.

(b) It is permitted to certify reagents, solid-phase extraction cartridges, and other non-control/calibrator material(s) by use in routine batches with assessment of acceptability based on control performance.

(c) Documentation of these certifications will be retained for the same time period as required for positive results data.

(d) The methods for certification and acceptance criteria for these materials will be described in the FTDTL's OP manual.

(4) All confirmatory procedures, including those using automated liquid handling systems and multi-well plates, must be validated prior to implementation. Method validation will be described in the FTDTL's OP manual and in agreement with requirements promulgated by the AFMES. At a minimum, confirmatory method validation must include:

(a) Linearity studies to determine the LOD, limit of quantification, and limit of linearity, which must be assessed to the point of failure.

(b) Evaluation of precision and accuracy around the cutoff.

(c) Evaluation of carryover potential.

(d) Determination of interferences from similar and related compounds; this is required annually for non-synthetic cannabinoids, opioids, and amphetamines.

(e) Parallel studies for comparing existing to new method or technology.

(f) Annual evaluation of matrix effects for LC-based methods only.

(g) Evaluation of hydrolysis or oxidation effectiveness, as applicable, and at physiologically-relevant concentrations delineated by the AFMES.

f. New instruments models must be validated prior to being placed into use testing Service member specimens. Linearity determinations will be verified annually, or within each run, on each instrument certified for a particular method. Abbreviated or targeted validation studies may be performed, commensurate with the parameters that may be impacted by a given change to the assay or instrumentation component. All such abbreviated validations must be in agreement with requirements promulgated by the AFMES.

g. All documents related to method validation will be maintained in the FTDTL's historical data archive according to the Service's records disposition schedule or for a minimum of 3 years.

4.13. QC AND QA PROGRAMS.

a. Each FTDTL will maintain an internal QC program that includes at least 5 percent control samples relative to the total number of Service member specimens in the batch.

(1) QC samples intended to ensure the operation and accuracy of the assay will be identified as controls. Controls that are used to calibrate an instrument or establish an actual concentration will be classified as calibrators.

(2) The FTDTL will use separate sources (i.e., manufacturers) of stock material in the preparation of controls and calibrators. If separate sources of stock material are unavailable, material from separate lots from the same manufacturer or two separately-prepared solutions are acceptable. All stock material must have a certificate of analysis (COA) and drug purity provided by the commercial vendor. The COA must be maintained on file and in accordance with Service disposition schedules. Additionally, controls may be prepared from Service member specimens eligible for disposal, provided the provisions in Paragraph 4.15.b. have been met.

(3) All calibrators and controls must be certified prior to use. The FTDTL's OP manual will describe these certification requirements. Reagents and other testing materials must be certified and validated in accordance with Paragraph 4.12.e.(3). However, for screening calibrators, C/MS quantitative results from in-house testing or a vendor-provided COA may suffice as the initial certification for each lot. Screening controls may be verified by using the routine screening test acceptability criteria.

b. Each FTDTL will maintain a comprehensive QA program in agreement with requirements promulgated by the AFMES and these minimum criteria:

(1) The internal QA program must independently monitor all processes associated with accessioning, handling, testing, reviewing, reporting, and maintaining the forensic integrity of results; this includes:

(a) Ongoing and periodic review of internal methods development.

- (b) Instrument and method certification.
- (c) Personnel training and certification.
- (d) Overall data and legal documentation review.
- (e) Instrument and equipment calibrations.
- (f) Performance of testing controls.
- (g) Open and blind proficiency performance.
- (h) Internal/external audits of testing processes according to the FTDTL's OP manual.

(2) The FTDTL must have an OP manual element that describes the QA program and defines the documentation used by the FTDTL to manage the QA program. FTDTL documentation must include the use and tracking of MFRs and NCEs, which are used for any occurrence that does not follow the strict guidelines of the FTDTL's OP manual. Additionally, QA documentation will include a monthly report or meeting minutes that:

- (a) Summarizes all areas of QA oversight and monitoring.
- (b) Includes the tracking of active issues until they are closed.

(3) The QAO is responsible for the overall management of the QA program. The QAO is responsible for ensuring the classification, management, and investigation, when necessary, of all NCEs.

(a) The QAO:

- 1. Organizes supporting documentation related to the NCE.
- 2. Publishes an MFR or report that clearly defines the issue.
- 3. Makes recommendations for corrective and preventive actions to the FTDTL commander/commanding officer.

(b) For investigated NCEs, the commander/commanding officer must document, by signature and date, the completion of their review of:

- 1. The NCE and all NCE supporting material.
- 2. QAO recommendations.
- 3. Corrective and preventive actions taken or to be taken.

(4) The QAO will organize and lead a monthly meeting to present all areas of quality assurance oversight.

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 the 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.

4.14. REPORTING AND RECORDS.

a. Any specimen that fails to meet quantity or quality requirements for determination as positive, for the initial, adjunct, or confirmatory tests, will be reported as negative or invalid.

b. All results must be reviewed and certified by at least two LCOs. Certification of results consists of the:

(1) Review of all:

(a) Scientific testing data and relevant supporting documentation (e.g., CoC documents, NCEs, MFRs, submitting unit request letters, certificates of correction) to ensure compliance with the technical procedures and CoC requirements in the FTDTL's OP manual.

(b) Test results for each Service member specimen for consistency, whether accepted for reporting or not, such that any disparities are addressed properly and before reporting. The FTDTL's OP manual will describe the requirements for consistency of results and any actions to be taken to address inconsistencies (e.g., re-pouring initial screening test batches, re-extracting confirmatory test batches, suspending reporting for affected specimens).

(2) Documentation of all reviews and results in the LIMS and on forensic data reports.

c. Results may be reported either by groups of specimens (i.e., by form) or by individual specimen.

d. All discrepancies will be:

(1) Coded using the approved list in Table 1.

(2) Recorded in the LIMS so that they will be reported to the submitting unit.

e. The report to the submitting unit will only specify which specimens were positive, negative, invalid, or not tested. No analytical information on negative specimens will be reported to the submitting unit, unless meeting the exceptions stated in DoDI 1010.01, or when:

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

(2) A Service member who is facing disciplinary or administrative proceedings based on suspected drug use offers, or is expected to offer, as proof of innocence, prior negative urinalysis

results. The submitting unit's legal representative may then request further information on the reported negative results for rebuttal or impeachment purposes.

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

(4) The negative result:

(a) Supports or refutes the determination of prescription drug diversion.

(b) Is necessary to interpret positive drug testing results for multi-analyte assays (e.g., amphetamines, opioids, benzodiazepines).

(c) Was obtained due to a valid prescription being verified by an *in situ* MRP (e.g., electronic Prescription Review System) and the presumptive determination of the presence of drug(s) or drug metabolite(s) may facilitate the adjudication of:

1. Other specimens shipped in the same shipping container; or

2. Processed in the same analytical batch of specimens.

f. Negative results will be handled in accordance with the guidelines listed in this paragraph.

(1) Negative test results should be reported within 4 working days, based on monthly average, of specimen receipt at the FTDTL. Workforce elements of the FTDTL's COOP will be initiated when this reporting goal is not met for 3 consecutive months.

(2) Any specimen with a valid initial screening test, adjunct screening test, or confirmatory test that is negative for a drug will be reported as negative for that drug.

(3) Before reporting a negative test result, an FTDTL LCO will ensure that the results have been reviewed and certified as required in Paragraphs 4.14.a.-b. of this issuance.

(4) All testing and CoC documentation for negative specimens will be maintained, according to the respective Service's records retention requirements or for a minimum of 1 year.

(5) The electronic LIMS database/records will be retained for a minimum of 75 years.

g. Positive results will be handled in accordance with the guidelines listed in this paragraph.

(1) Positive test results:

(a) Should be reported within 6 working days, based on monthly average, of specimen receipt at the FTDTL. Workforce elements of the FTDTL's COOP will be initiated when this reporting goal is not met for 3 consecutive months.

(b) Will only be reported for specimens that are determined to be positive on the initial screening test, the adjunct screening test, if applicable, and the confirmatory test. Prior to

reporting a specimen positive, all tests to which the specimen was subject must meet the scientific and forensic requirements described in the FTDTL's OP manual.

(2) Before reporting a positive test result, an FTDTL LCO will ensure that:

(a) The results have been reviewed and certified as required in Paragraph 4.14.b.of this issuance.

(b) An LCO has verified that the information on the specimen bottle and submitted CoC form, if any, is consistent, and that this information is accurately reflected in the LIMS.

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

(4) The submitted CoC documents, if any, for positive specimens, along with their associated testing documents (e.g., analytical results, equipment maintenance, QC control and calibrator certification, employee training and certification records, OP manual, QA reports, method and instrument validation, and all other documents that may be recalled for legal proceedings), will be archived in a secure storage area according to the respective Service's records retention requirements or for a minimum of 3 years.

(5) The electronic LIMS database/records will be retained for a minimum of 75 years.

h. Invalid results obtained during routine testing (i.e., not part of specimen validity testing (SVT), as detailed in Paragraph 7.4.) will be handled in accordance with the guidelines listed in this paragraph. The invalid determination will:

(1) Only be used when chromatographic interference is not resolved for a given analyte or when the volume of urine is insufficient to complete testing (i.e., depleted during the testing process).

(2) Be reported for the affected analyte(s) or for the entire specimen, if no results were obtained for any analyte.

(3) **Not** indicate an attempt to defeat the drug test; rather, it represents an indeterminate outcome that is neither positive nor negative for a given analyte.

i. The FTDTL's OP manual must:

(1) Adhere to all requirements of this issuance.

(2) Be maintained to allow the reconstruction of procedures that were in effect when a given specimen was received and tested. Appropriate FTDTL OP manual maintenance includes:

(a) A "summary of changes" sheet documenting the implementation date and version number for all changes.

(b) A documented employee notification process to record that employees have been notified (i.e., read, understood, and will execute) of changes to policies and procedures prior to implementation.

(c) Procedures for the retirement of obsolete sections.

(d) Retention for 75 years.

j. If a specimen's results are reported and a submitting unit or Military Service identifies that an incorrect DoD ID was employed at the point of collection, the FTDTL may update the drug testing result with the accurate DoD ID when the:

(1) Submitting unit's investigation identifies the error and corrects the procedures that resulted in the fault.

(2) Military Service for the submitting unit:

(a) Concurs with the investigative findings and actions.

(b) Forwards a request to the respective Military Service drug testing program manager to notify the FTDTL, LIMS team, and DMDC, if outside the current fiscal year, to correct the record.

4.15. DISPOSITION OF SPECIMENS.

a. Negative specimens will be handled in accordance with the guidelines listed in this paragraph.

(1) Negative specimens may be discarded after transmission of the negative report. The negative specimen's discard date must be documented in the LIMS.

(2) Negative specimens may be retained, without consent from the Service member, for use in developmental work, prevalence studies, and special projects, in accordance with Section 219.102(e) of Title 32, Code of Federal Regulations. If retained for these purposes, the transfer of these specimens to special projects must be documented. However, after this is completed, no further CoC documentation is required for these specimens. Specimens or screening aliquots designated for destruction may be used for research, if all specimen identifiers that could be used to trace a specimen back to an individual are removed or redacted.

b. Positive specimens will be handled in accordance with the guidelines listed in this paragraph.

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

(2) During this initial 1-year frozen storage period, the submitting unit, or their legal representative, may send a written request to the FTDTL asking the FTDTL to retain the

specimen for an additional year, unless a longer time period is required. The request must explain the reason for a longer retention period. The FTDTL will document the extended retention period in the LIMS and notify the requestor of the new disposal date.

(3) Upon expiration of the retention period, positive specimens may be:

(a) Discarded. This discard event must be documented in the LIMS.

(b) Retained for use in developmental work, prevalence studies, control preparation, and special projects, as long as all specimen identifiers that could be used to trace a specimen back to an individual are removed or redacted. The transfer of these specimens to special projects must be documented. However, after this is completed, no further CoC documentation is required for these specimens.

(4) Specimens suspected of adulteration will be retained in accordance with Paragraph 4.15.b. These specimens will be submitted for SVT, in accordance with Paragraph 7.4. The FTDTL will notify the submitting unit of all results that indicate a loss of integrity during the collection process (i.e., adulterated or substituted).

4.16. RETESTING OF SPECIMENS.

a. After receiving a positive test result, the Service 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 positive result. A specimen retest requires a C/MS procedure to confirm the presence of the reported drug or drug metabolite. On retest, the drug does not need to quantify above the DoD confirmation cutoff concentration. The retest only requires the drug to quantify at or above the FTDTL's established LOD for the specific C/MS method.

b. The FTDTL commander/commanding officer has the right to direct the retesting of any Service member specimen, only when they determine that the validity of the result is forensically or scientifically questionable. The rationale for this retest must be documented by an MFR and maintained with the specimen's testing records.

c. A specimen may be:

(1) Retested at the FTDTL that confirmed and reported the positive result; or

(2) Sent to another DoD-certified FTDTL, the SFTDTL, or the AFMES for retesting.

d. If executing a retest would result in a volume less than 10 milliliters remaining for any additional purposes, the FTDTL must obtain authorization from the respective Military Service drug testing program manager.

e. If forwarding an aliquot of the specimen to another laboratory for retesting, the FTDTL will document specimen handling on the submitted CoC, if any, or a supplemental CoC form. A

new CoC form will be prepared to document the handling of the aliquot and will be forwarded, with the aliquot, to the designated FTDTL. The original specimen bottle with the remaining urine, the submitted CoC, if any, 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 will forward a copy of the requestor's letter that contains this information.

f. A specimen may be sent to a Department of Health and Humans Services-certified commercial laboratory for retest, if the requirements in Paragraphs 4.16.a., 4.16.d., and 4.16.e. are met. The specimen must be retested under conditions used for federally-regulated specimens. The request must include:

(1) The complete address of the laboratory where the specimen is to be sent along with their point of contact.

(2) Documentation that arrangements have been made to pay for any tests.

(3) A statement relieving the FTDTL of any monetary charges associated with the testing.

(4) The commercial courier account number to pay for shipping the aliquot to the designated laboratory.

g. Retest results below the LOD do not automatically indicate an original false positive result, since analyte degradation may be concluded from an investigation. When a retest result is below the LOD, the FTDTL will, as part of their investigation:

(1) Re-verify the result by re-confirming.

(2) Send an aliquot:

(a) For retesting at a laboratory using a different method, if possible.

(b) To a Department of Health and Human Services-certified laboratory for SVT.

4.17. SPECIMEN BOTTLE REQUESTS.

Submitting unit commanders, judges, administrative board presidents, and trial counsel may request that the FTDTL provide the original specimen bottle for a court-martial or administrative board.

a. Such requests will be honored if the written request contains sufficient information to identify the specific specimen, as well as the name, mailing address, and phone number of the point of contact.

b. The submitted CoC, if used, or supplemental CoC form will be annotated to document the transfer of the remaining specimen urine to a new bottle and the transfer will be documented in the LIMS, including the subsequent storage location of the new bottle.

c. The new bottle will be labeled with duplicate identifying information from the original bottle label and an image of the original label in its entirety will be captured and stored with the specimen's testing records.

d. A new custody document or an affidavit will be generated to document the shipment of the original specimen bottle to the court.

4.18. DOCUMENT AND INFORMATION REQUESTS.

a. Requests for documentation and additional information must be submitted in writing through the submitting unit or an attorney representing the submitting unit. Requests must include:

- (1) Sufficient information to identify the specific specimen.
- (2) Trial or board date, if known.
- (3) The name, mailing address, and phone number of the point of contact.

b. When a complete laboratory records packet is requested,

- (1) The FTDTL will provide, at a minimum:
 - (a) Copies of all CoC forms for tests attempted and performed.
 - (b) All accepted instrument printouts that directly involved the specimen.
 - (c) All instrument printouts for acceptable and failed tests of all calibrators and controls associated with the specimen.
 - (d) Any associated MFRs and NCEs.
- (2) These packets will include a statement of business records certification. An 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 by the FTDTL for a minimum of 1 year.

c. The FTDTL may also provide a summary packet upon request. The summary packet will include, at a minimum:

- (1) A summary sheet that documents the tests performed.
- (2) The dates of these tests.
- (3) The 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 to 6 months before and after

a specimen was reported is considered reasonable. However, this time period may be extended at the discretion of the FTDTL commander/commanding officer. A records request exceeding this time period may be considered unreasonable and will not be granted unless specifically directed by judicial order.

4.19. EW REQUESTS.

a. The FTDTL will:

- (1) Comply with judicial orders to produce an EW.
- (2) Attempt to accommodate reasonable requests for EWs in accordance with the FTDTL OP manual.
- (3) Require accounting information or travel orders, from the requesting unit, at least 10 working days in advance of the EW's travel date or as soon as practical in order to comply with a judicial order.

b. Requesting commands will coordinate scheduling of expert testimony with the FTDTL. The requesting command:

- (1) Is responsible for all travel expenses (e.g., per diem, lodging, transportation) to include a rental car or other personal, local transportation, as appropriate.
- (2) Will ensure that adequate dining accommodations are available.

4.20. CUTOFF CONCENTRATIONS AND REPORTING REQUIREMENTS.

a. The cutoff concentrations for screening and confirmatory testing are documented in Tables 2 and 3, respectively.

(1) The DoD authorized panel of drugs may be updated by memorandum from EDFR to include:

- (a) Drug panel additions and deletions.
- (b) Changes to cutoff concentrations.
- (c) Changes to testing rates.

(2) 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. When an IA kit or alternate methodology is used for an initial screening test that is calibrated using a single analyte within a drug class, as shown in Table 2, it is acceptable to conduct confirmatory testing on and to report positive results for all analytes of that class.

c. All FTDTL drug testing results for routine testing (i.e., substances listed in Table 3) and associated discrepancies listed in Table 1, if any, will be downloaded to a secure, common access card-enabled, encrypted web results portal for retrieval by authorized users.

4.21. INFORMATION TECHNOLOGY REQUIREMENTS.

a. System security of the FTDTL-IMS must comply with DoDI 8500.01. The FTDTL COOP will 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 network or LIMS operations.

b. Each specimen received by the FTDTL will be tracked within the LIMS using specific identifiers to include the:

- (1) DoD ID.
- (2) LAN.
- (3) Submitting unit code.
- (4) Dates of specimen receipt and results reporting.

c. The LIMS will:

(1) Maintain a forensic record (e.g., user, function, and date) of each action taken on each individual specimen.

(2) Be capable of verifying that the DoD ID on the CoC matches the DoD ID on the bottle.

(3) Maintain an audit trail of changes to the records, which will include the:

- (a) Original information.
- (b) New information.
- (c) Date and time of the change.
- (d) Individual who made the change.

d. LCOs who review and approve any screening or confirmatory result will be identified and this information will be retrievable from the LIMS. Also, the LIMS will be able to verify that these steps have been completed before results are reported, manually or electronically.

e. On a 5-year cycle, negative and cancelled specimen testing data will be purged from the LIMS at each FTDTL. This requirement does not apply to data on the web portal, which will be maintained for 75 years.

4.22. LABORATORY INSTRUMENTATION AND EQUIPMENT.

a. Major equipment utilized for screening and confirmatory testing at the FTDTLs, including aliquot or extract preparation, must be:

(1) Recommended by the BTAB.

(2) Authorized by the Director, ODDR.

(3) Maintained and inspected at least semi-annually by the original equipment manufacturer (OEM) or a vendor certified by the OEM.

b. Maintenance service on major equipment must be done by OEM-trained technicians. The OEM-trained technician must certify the conduct of services performed by signing and dating the laboratory instrument maintenance documents.

c. Centrifuges must be certified annually and after major repair.

d. Minor equipment (e.g., analytical balances, automated aliquotting devices, pipetting devices, and any other equipment used to make quantitative measurements for forensic purposes) will be certified for accuracy, at least annually. Pipettes must be certified for accuracy at the volume(s) for which they are used and in accordance with additional guidelines promulgated by AFMES and the manufacturer.

e. Both weights used to certify analytical balances and temperature monitoring devices must be National Institutes of Standards and Technology certification-traceable.

f. Maintenance records, documenting all certification and repair, must be retained according to the respective Service's records retention requirements or for 3 years, at a minimum.

4.23. LABORATORY CERTIFICATION.

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

(1) Maintain:

(a) An OP manual as well as a COOP.

(b) And document specimen and aliquot CoC from receipt to disposal.

(c) Training and certification records for laboratory personnel.

(d) Records for equipment certification, evaluation, maintenance and repair.

- (e) Records for validation of all analytical methods and instruments for each analyte.
 - (f) An internal:
 - 1. QC program consisting of at least 5 percent control samples, relative to the total number of Service member specimens, in each specimen testing batch.
 - 2. QA program to verify and document the quality and accuracy of testing results.
 - (g) A compliant information assurance posture to appropriately safeguard forensic systems and data.
- (2) Satisfactorily participate in:
- (a) A certification round of AFMES proficiency sample analyses for each drug group being tested.
 - (b) Ongoing AFMES proficiency (open and blind) programs.
 - (c) The ongoing AFMES QA inspection process.
- b. After the FTDTL has completed the validation requirements in Paragraphs 4.10.a. and/or 4.12.e.(4), a request for a certification set of samples and subsequent participation in the proficiency testing program will be made, in writing, to AFMES via the appropriate Military Service drug testing program manager.
- c. After the FTDTL has satisfied the applicable requirements and performed successfully during certification analysis, the AFMES will submit a written request for DoD laboratory certification to the Director, ODDR. An FTDTL may not report test results to submitting units until certified, in writing, by the Director, ODDR. The QA inspections will assess the performance of the FTDTL and ensure its adherence to the requirements in Paragraph 4.23.a. A copy of each inspection report will be forwarded to the Director, ODDR.

4.24. DRUG ANALYSIS CERTIFICATION.

- a. The FTDTLs will:
 - (1) Participate in the AFMES proficiency (open and blind) program for drug groups that are approved by the EDFR and listed on the DoD-authorized drug panel (see Tables 2 and 3), and for which they are certified.
 - (2) Ensure that at least two instruments are certified for each validated method, if available.
- b. All reference laboratories that test proficiency samples will be certified:
 - (1) In accordance with this issuance; or

(2) By a reputable forensic authority (e.g., the American Board of Forensic Toxicologists or the National Laboratory Certification Program), as approved by the Director, ODDR.

c. The AFMES will prepare and send a certification set to the FTDTL.

(1) The certification set will consists of:

(a) Negative, analyte-free, urine samples.

(b) Urine containing the analyte(s) at:

1. Various concentrations surrounding the DoD cutoff.

2. Concentrations that allow for the assessment of carryover.

(2) The specific contents of the certification set are determined by the drug(s) requested and will include five replicates for each drug concentration. In cases where the reference laboratory group size consists of only three laboratories, the AFMES may:

(a) Direct repeat analyses on multiple days or multiple instruments; or

(b) Otherwise increase the sample size.

(3) When an FTDTL is being certified for more than one drug, the certification set samples may be formulated with multiple drugs, as necessary. The FTDTL will be instructed as to which specimens are to be tested for which drugs.

d. The FTDTL will:

(1) Summarize the results by listing quantitative values for each sample, as determined by confirmatory testing using all validated confirmatory methods for the analyte(s) for which certification is sought.

(2) Indicate whether samples are positive or negative by the initial screening test.

(3) Send to the AFMES, the certification set summary sheet, along with initial screening and confirmatory testing data. All confirmatory tracings will include RTs, peak areas, peak heights, ions or transitions monitored, and sample identification. Repeat extractions or analyses to bring outlier quantitative results into agreement with other samples are not permitted.

e. Quantitative criteria include:

(1) For analyte-free samples, the quantitative values determined by C/MS may not exceed the FTDTL's LOD, for which all ions or transitions must be present. The LOD for each drug tested must be listed on the summary sheet provided to the AFMES.

(2) No more than one quantitative value:

(a) In the drug class, may be more than ± 20 percent from the FTDTL's mean for each concentration with analyte evaluated.

(b) For a given analyte, may be more than ± 20 percent from the group mean for each concentration with analyte evaluated. The group mean values are derived from analyses conducted by the AFMES DoD QA laboratory and at least one reference laboratory certified in accordance with Paragraph 4.24.b.

f. MS analyses must meet the criteria given in Paragraph 4.12.d.

g. Continuous satisfactory participation in the AFMES proficiency (open and blind) program is required to maintain certification. In cases where the reference laboratory group size consists of only three laboratories, the AFMES may direct repeat analyses in accordance with Paragraph 4.24.c.(2).

(1) If an FTDTL, without prior excusal from the AFMES, does not report data for the monthly open proficiency samples for analyte(s) from all validated confirmatory methods for which it is certified, then all five data points will be considered incorrect.

(2) For the AFMES open proficiency samples, the FTDTL must take action whenever two replicates for the same analyte quantify outside ± 20 percent of the monthly group mean (i.e., all relevant, reported results in a single month). An FTDTL reporting such results must:

(a) Document an investigation, via an NCE, assessing factors affecting precision and any biases in accuracy.

(b) Determine whether action is warranted.

(c) Implement and document any necessary remedies, including additional QA monitoring to assure that decisions were sound.

(3) For a given analyte in the AFMES open proficiency samples, an analysis is considered unacceptable whenever two replicates in each of 2 consecutive months, or three or more replicates in a single month, quantify outside ± 20 percent of the group mean of all relevant, reported results. When an FTDTL is not in compliance with this requirement:

(a) The AFMES will immediately contact the:

1. FTDTL.

2. Respective Military Service drug testing program manager.

3. Director, ODDR.

(b) The FTDTL must:

1. Immediately suspend the reporting of results for the relevant drug class.

2. Conduct a documented investigation via an NCE. This investigation must determine whether any Service member specimens were affected, depending on the root cause(s) identified or bias noted. The investigation and corrective action plan to address the root cause(s) of the issue must be sent to the:

- a. Respective Military Service drug testing program manager.
- b. AFMES.
- c. Director, ODDR.

(c) The AFMES, in consultation with the BTAB, will review the investigation and corrective action plan and will recommend to the Director, ODDR, whether additional actions are necessary (e.g., retesting of open or blind proficiency samples, or retesting of Service member specimens). Once approved by the Director, ODDR, the FTDTL may implement the corrective action plan.

(d) Based upon the corrective action plan, retesting results, and recommendations from the AFMES, including any resulting from a special/directed inspection, the Director, ODDR may direct:

1. Decertification of the FTDTL for the drug class in question when retesting of open proficiency samples fails to yield acceptable results (i.e., at least 4 of 5 samples within ± 20 percent of the group mean for that month) or when it is determined that a Service member specimen was incorrectly reported positive. Based upon successful completion of any corrective actions and an AFMES-provided certification set, the Director, ODDR, will recertify the FTDTL for the drug analysis based upon recommendations from the AFMES.

2. Resumption of results reporting, based on:

a. Successful implementation of corrective actions that yield acceptable proficiency testing results (i.e., at least 4 of 5 samples within ± 20 percent of the group mean for that month); or

b. Other remedies to address the root cause(s) of the imprecision or accuracy bias.

3. An on-site inspection be conducted that is:

- a. Led by the AFMES, including via contract.
- b. Accompanied by ongoing QA monitoring.

4. Additional requirements for personnel retraining or adoption of alternate procedures, techniques, methods, and processes.

(4) For the AFMES's blind proficiency samples, analyses are considered correct if negative samples are reported negative and positive samples are reported positive. To ensure

that the number of false negative results is minimized, at least 95 percent of positive samples received during the quarter must be correctly reported. When an FTDTL is not in compliance with this 95 percent reporting requirement, it must follow the procedures outlined in Paragraph 4.24.g.(3), where decertification will be based on retest results that show any inability to correctly report positive specimens as such. Single false negative results for AFMES blind proficiency samples will be handled in accordance with Paragraph 4.25.b.(1).

(5) An FTDTL that reports a false positive on an AFMES blind proficiency sample will be decertified by the Director, ODDR, pursuant to Paragraphs 4.25.a.-b.

4.25. FTDTL DECERTIFICATION AND RECERTIFICATION PROCESSES.

a. An FTDTL may be decertified when it:

(1) Has reported a false positive result. Errors in non-critical information associated with a testing result (e.g., date of collection, base area code, testing premise):

1. Will not necessarily challenge the forensic integrity of drug presence reported for a drug positive specimen.

2. Do not constitute a false positive result.

(2) Has failed to correctly report proficiency sample results in accordance with Paragraph 4.24.g. Administrative review of an FTDTL's reporting procedures may be required when the FTDTL fails to correctly report an AFMES blind positive proficiency sample result.

(3) Has been recommended by the AFMES, as a result of inspection findings.

(4) Fails to maintain a compliant information assurance posture.

b. When an FTDTL reports a false negative or false positive result for an AFMES blind proficiency sample, the AFMES will contact the FTDTL, the BTAB, and the Director, ODDR.

(1) When the AFMES notifies an FTDTL that it has reported a false negative result for a blind proficiency sample, the FTDTL will immediately sequester the sample and review the reported testing data.

(a) If available, the FTDTL will immediately retest the sample and, if the sample fails to test positive, send an aliquot to the AFMES for retesting.

(b) The FTDTL, via the respective Military Service drug testing program manager, will:

1. Maintain communication with the BTAB and the Director, ODDR, on the status of its review and investigation.

2. Report the basis of the error, corrective or preventive actions taken, and any additional reviews conducted.

(c) The written report will be submitted to the respective Military Service drug testing program manager and the AFMES who will determine whether any additional action is warranted.

(d) The FTDTL will document the event, via an NCE, to ensure that findings and corrective or preventive actions are tracked in a closed-loop manner.

(2) When the AFMES notifies an FTDTL that it has reported a false positive result for a blind proficiency sample, the FTDTL will:

(a) Immediately suspend reporting results for all drugs and initiate a documented investigation via an NCE.

(b) If available, immediately retest the sample; and, if the sample fails to test negative, send an aliquot to the AFMES for retesting.

(c) Maintain, via the respective Military Service drug testing program manager, communication with the BTAB and the Director, ODDR, on the status of its review and investigation. The Director, ODDR, will immediately:

1. Notify the EDFR of the situation.

2. Decertify the FTDTL entirely or for specific drug analyte(s), as appropriate.

(d) Report, in writing, the basis of the error and the corrective or preventive actions taken, any additional reviews, and submit the report to the BTAB, via the respective Military Service drug testing program manager.

1. Based upon status updates and the written report, the BTAB, in conjunction with the Director, ODDR, will determine whether any additional action is warranted (e.g., retesting Service member specimens; possible on-site inspection; implementation of alternate training, procedures, materials, methods, etc.; recertification for the affected analyte(s)).

2. When the BTAB, in consultation with the Director, ODDR believes that the actions taken by the FTDTL are adequate, the Director, ODDR, will recertify the FTDTL for resumption of results reporting.

c. When an FTDTL discovers that it has erroneously reported a Service member's specimen as positive, the FTDTL will:

(1) Immediately:

(a) Suspend reporting results for all drugs and initiate a documented investigation via an NCE.

(b) Contact the BTAB and the Director, ODDR, via the respective Military Service drug testing program manager. The Director, ODDR, will immediately:

1. Notify the EDFR of the situation.
2. Decertify the FTDTL entirely or for specific drug analyte(s), as appropriate.

(c) Contact the submitting unit to apprise the unit commander of the incident and to ensure that no adverse action is or was taken against the Service member. The original, incorrect result must be withdrawn and the correct result reported.

(2) Conduct a documented investigation of the issue via an NCE. This investigation must include whether any other Service member specimens were affected. The corrective action plan to address the root cause(s) of the issue must be sent to the BTAB and the Director, ODDR, via the respective Military Service drug testing program manager. The plan will state the cause(s) of the error and the corrective and preventive actions to be implemented.

(a) The BTAB will:

1. Review the corrective action plan and proposed remedies.
2. Recommend to the Director, ODDR, additional actions that may include the retesting of:
 - a. Open proficiency samples;
 - b. Blind proficiency samples; or
 - c. Service member specimens, as applicable.

(b) Once approved, the FTDTL may implement the corrective action plan.

(c) Based upon the corrective action plan, retesting results, and recommendations from the BTAB, including those from any directed inspection, the Director, ODDR, may direct:

1. Recertification and resumption of results reporting, based on successful implementation of corrective actions.
2. An on-site inspection, led by the AFMES, be conducted and accompanied by ongoing QA monitoring.
3. Additional requirements for personnel retraining and adoption of alternate procedures, techniques, methods and processes.
4. Approval to proceed with the recertification process for the affected analyte(s).

(d) When AFMES notifies the Director, ODDR, of their approval of the recertification analysis, if conducted, the Director, ODDR, will recertify the FTDTL to resume drug analysis and reporting.

(3) In consultation with the respective Military Service drug testing program manager, place an MFR into the files of affected specimen records. This MFR will include:

- (a) A written summary of the incident.
- (b) Corrective actions taken.
- (c) Results of the retesting of member specimens.
- (d) Copies of notifications to the affected command(s).

(e) If known, a summary of actions taken against any member whose results may have been incorrectly reported.

d. FTDTLs must maintain an information assurance posture that safeguards forensic drug testing systems, platforms, and databases, in accordance with the standards established by DHA and any other applicable oversight authority. When an FTDTL is notified by DHA or the drug testing information technology program manager that their information management systems are non-compliant with the standards required to maintain an ongoing authority to operate, the FTDTL must:

(1) Immediately implement risk mitigation measures, including:

- (a) Patches.
- (b) Scans.
- (c) Any other required actions to remedy the situation.

(2) Achieve and maintain a network and hardware posture that is standardized with those required to maintain the DDRP enterprise authority to operate.

(3) Upon recommendation from the drug testing information technology program manager and with concurrence from the BTAB, be subject to:

- (a) Decertification from testing specimens; or
- (b) Reporting of results, when remedies are not implemented as required.

SECTION 5: DoD BTAB

5.1. ORGANIZATION AND MANAGEMENT.

The DoD BTAB will advise the Director, ODDR, on technical and policy issues related to the MPDATP. Members will be active duty military members or full-time civilian employees of the U.S. Government.

a. For technical issues, the BTAB membership will be composed of Service members and/or full-time or permanent part-time DoD civilian employees, as follows:

- (1) The Director, FORTOX, AFMES, who serves as the non-voting Board chair.
- (2) The Military Service drug testing program managers.
- (3) Any other non-voting subject matter experts as designated by the Board chair.

b. For policy issues, the BTAB membership will be composed of:

- (1) The Director, ODDR, who serves as the non-voting Board chair.
- (2) One voting representative from each the cognizant Army, Navy, Air Force, Marine Corps, and National Guard Military components.
- (3) Any other non-voting subject matter experts as designated by the Board chair.

5.2. FUNCTIONS.

The BTAB will make recommendations to the Director, ODDR, 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 to the DoD-certified FTDTLs.
- 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. The addition or deletion of testable drugs on the DoD-authorized drug panel.
- f. Applied research projects to improve the effectiveness of the MPDATP.

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

5.3. MEETINGS.

a. The BTAB will meet:

(1) Semiannually, at a minimum.

(2) As required by the Director, ODDR, or the Director, FORTOX, AFMES.

b. The Board chair is responsible for:

(1) Issuing minutes for each meeting.

(2) Forwarding the minutes with accompanying recommendations to the Director, ODDR.

SECTION 6: PROCEDURES FOR SUBSTANCE ABUSE TESTING AND THE ADMINISTRATIVE PROCESSING OF APPLICANTS AND NEW ENTRANTS TO THE MILITARY SERVICES AND THEIR RESERVE COMPONENTS

6.1. TESTING PROCEDURES.

In compliance with Section 521 of Public Law 100-456, testing for drug and alcohol use and evaluation for dependency will occur within 72 hours after the Service member's initial entry on active duty (IEAD) following enlistment or appointment. For Reserve Component members not entering extended active duty, these tests will be administered no later than 72 hours after the beginning of their first scheduled annual training or initial active duty training.

6.2. REQUIRED TESTING.

Individuals required to be tested and evaluated are:

- a. Applicants and new enlisted entrants in the Military Services, including officer candidates undergoing initial training in an enlisted status.
- b. Appointees to Service Academies, who will be tested within 72 hours of reporting to an Academy.
- c. Reserve Officer Training Corps (ROTC) cadets and midshipmen, who will be tested pursuant to individual Service policy and as a component of their commissioning physical examination.
- d. Other individuals to whom a commission may be offered following the completion of a Service commissioning program (e.g., advanced training under the ROTC program).
- e. Regular and Reserve officers appointed from the civilian community.
- f. Prior Service applicants for enlistment in the:
 - (1) Active Component with a break in service of more than 6 months.
 - (2) Selected Reserve with a break in service in the Selected Reserve or Active Component of more than 6 months, who are to be tested as facilities and resources permit. The Services will fund appropriate resources and facilities to ensure that all such applicants are tested.

6.3. TIMING OF TESTING AND EVALUATIONS.

- a. Individuals covered by Paragraphs 6.2.a. or 6.2.e. will undergo testing and be evaluated within 72 hours after IEAD.

b. Officers not covered by Paragraphs 6.2.b., 6.2.c., or 6.2.d. will undergo testing and be evaluated during the officer basic courses. If an officer's IEAD does not occur at a basic course, alternative testing and evaluation arrangements must be made by the appointing authority.

c. Individuals covered by Paragraphs 6.2.b. or 6.2.c. will undergo testing and be evaluated during the physical examination given to the applicants:

- (1) Before appointment as cadets or midshipmen at a Service Academy; or
- (2) For an ROTC scholarship.

d. Individuals covered by Paragraph 6.2.d. will undergo testing and be evaluated during the pre-commissioning physical.

e. Individuals covered by Paragraph 6.2.f. will be tested and evaluated:

- (1) In conjunction with a reentry physical, if conducted; or
- (2) Within 72 hours following reentry at accession locations specified by the Military Service concerned (e.g., first duty station).

6.4. TESTING PANEL AND PROCEDURES.

a. All urine specimens will be tested for the same panel of drugs as the military population. These analyses will be conducted in a DoD-certified FTDTL following the testing requirements of Section 4 of this issuance. Testing results will be obtained as soon as practicable. Testing outside a DoD-certified FTDTL is strictly prohibited. All specimens will be:

- (1) Collected under direct observation.
- (2) Submitted to a DoD-certified FTDTL, in accordance with Paragraphs 4.1-4.4, using the CoC form:

- (a) DD Form 2624 (or successor).
- (b) USMEPCOM Custody Form 40-8-3, "Urine Sample Custody Document," if collected through a MEPS,

b. All individuals covered by Paragraph 6.2, with the exception of Paragraph 6.2.f.(1), will 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 through analytical results determination. Alcohol testing is not conducted at the DoD FTDTLs.

c. Individuals covered by Paragraph 6.2 will be medically evaluated for dependency using the appropriate medical and psychiatric criteria.

6.5. SEPARATION FOR DRUG OR ALCOHOL DEPENDENCY DURING ACCESSION.

a. Voided Enlistment or Appointment.

The enlistment or appointment of any person determined to have a drug (non-tobacco) or alcohol substance use disorder at the time of such enlistment or appointment will be voided as a release from custody or control of the Military Service, in accordance with DoDIs 1332.14 and 1332.30. A person whose enlistment or appointment is voided will be referred to a civilian treatment facility.

b. Enlisted Members.

The basis for discharge of enlisted members, pursuant to the policies established by this issuance, will normally be erroneous enlistment (uncharacterized), in accordance with DoDI 1332.14. The Military Services are not precluded, in appropriate cases, from taking appropriate disciplinary action against a member or processing a member for discharge, with or without a characterization, under an alternative basis. The counseling requirement in DoDI 1332.14 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 issuance.

(1) Enlisted personnel:

(a) Who refuse to consent to drug or alcohol testing or evaluation during IEAD will be discharged.

(b) Confirmed positive:

1. For any drug on the testing panel, who do not possess a valid prescription to account for the positive drug test result, will be:

a. Discharged in accordance with regulations of the Military Service concerned.

b. Permanently disqualified from military service unless the Secretary of the Military Department concerned grants a waiver following an individual assessment of the particular case.

2. At or above a 0.05 percent blood alcohol level, who are not alcohol dependent, will be discharged unless the Secretary of the Military Department concerned grants a waiver following an individual assessment of the particular case.

(2) During national emergencies when conscription is authorized, the 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) 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 dis-enrolled, in accordance with DoD Instruction 1215.08, 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, the 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 who test positive after appointment, who do not possess a valid prescription to account for the positive drug test result, or who refuse to consent to testing or evaluation, will be given an honorable discharge 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. 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, pursuant to applicable Service regulations.

(4) Individuals covered under Paragraphs 6.5.b.(1)(b) and 6.5.b.(2) who are confirmed positive at or above a 0.05 percent blood alcohol level and who do not have an alcohol use disorder, will be denied appointment or discharged, as appropriate, unless the Secretary of the Military Department concerned 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, within 2 duty days following separation, the separation authority will furnish the DMDC with:

(1) The individual's:

(a) Name;

(b) DoD ID; or

(c) Other personal identifier (e.g., SSN), if not yet granted a DoD ID, reentry code.

(2) Other appropriate data.

6.6. 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 alcohol, the disqualification periods detailed in this paragraph apply.

(1) Disqualification Period, First Positive Alcohol 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 test administration (i.e., collection date). 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 administration. In such cases, applicants must have documentation from a MEPS-directed medical provider (preferably a behavioral health provider) indicating that the individual does not meet criteria for an alcohol use disorder.

(2) Disqualification Period, Second Positive Alcohol Test.

Applicants testing positive on a second test are not eligible for military service for a period of 24 months (730 days) from the test administration date (i.e., collection 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 administration date of the second positive test.

(3) Disqualification Period, Third Positive Alcohol Test.

Applicants testing positive on a third alcohol test will be permanently disqualified for military service.

(4) Combined Use of Alcohol and Drugs.

The Military Services may implement more restrictive standards of applicant qualification and disqualification for use of alcohol or drugs. If an applicant tests positive for:

(a) Both alcohol and drugs on the same processing day (i.e., date of test), this will be counted as one positive test.

(b) Alcohol on 1 day and positive for drugs on a subsequent day, or vice versa, this will be counted as two positive tests.

c. When applicants test positive for any drug on the testing panel, the disqualification periods detailed in this paragraph apply.

(1) Disqualification Period, First Positive Drug 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 test administration (i.e., collection date). 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 administration. In such cases, a MEPS-directed medical provider, at their discretion and based upon their level of suspicion of substance misuse, may refer the applicant for psychiatric or behavioral health consultation to document that the individual does not meet criteria for a substance use disorder.

(2) Disqualification Period, Second Positive Drug Test.

Applicants testing positive for any drug on the testing panel on a second test are permanently disqualified for military service.

d. Applicants testing positive for a combination of testable drugs or alcohol are processed in accordance with this paragraph.

(1) An applicant testing positive for:

(a) A combination of drugs on one specimen will be counted as one positive test and processed pursuant to the drug positive standard in Paragraph 6.6.c.(1).

(b) Alcohol or drugs on one specimen, at any time, and who subsequently tests positive for drugs will be permanently disqualified from military service.

(c) Alcohol and drugs on one specimen, at any time, and who subsequently tests positive for alcohol will be processed pursuant to Paragraph 6.6.b.(2).

(2) If the applicant provides a third positive specimen for alcohol, the applicant will be permanently disqualified for military service pursuant to Paragraph 6.6.b.(3).

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

SECTION 7: SPECIAL DRUG TESTING

7.1. SPECIAL DRUG TESTING.

a. Offenses under the Uniform Code of Military Justice include the wrongful use of:

(1) Anabolic steroids, as specified in the Designer Anabolic Steroid Control Act of 2014 and subsequent amendments.

(2) Controlled substances regulated in Sections 802 and 812 of Title 21, United States Code.

(3) Other products (e.g., inhalants, cleaning agents, or other substances) taken into or applied to the human body for reasons:

(a) Outside of their intended purpose; or

(b) That degrade security, military fitness, readiness, and good order and discipline.

(4) Prescription drugs and over-the-counter medications by Military Service members.

b. In addition to anabolic steroids, performance-enhancing drugs explicitly listed in Classes S1, S2, and S4 of the World Anti-Doping Code Prohibited List, including all updates and amendments by the World Anti-Doping Agency, will be reported to submitting units because these substances are often used:

(1) In conjunction with anabolic steroids as part of on-off use cycles; or

(2) To suppress unwanted side effects.

c. Commanders must be:

(1) Aware of the potential harm that abuse and misuse of drugs and other substances have on the health, well-being, safety, and morale of the:

(a) Individual Service member.

(b) Entire unit.

(2) Attuned to incidents of drug and substance misuse not covered by testing conducted within the MPDATP. Special testing is available for many of these substances; and requests for such testing requires coordination with:

(a) Legal authority to establish an appropriate collection premise, in accordance with DoDI 1010.01.

(b) The Military Service drug testing program managers.

- (c) The AFMES, in accordance with Paragraph 7.3 of this issuance.

7.2. STEROID, ANABOLIC STEROIDS, AND PERFORMANCE-ENHANCING DRUG TESTING.

a. Steroid and performance-enhancing drug testing will only be conducted at a DoD-approved laboratory (e.g., a reputable laboratory recommended by the Director, ODDR).

b. 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.

c. Prior to the submission of specimen(s) for steroid testing, a written, signed request must be submitted to the Military Service personnel DDRP manager or Military Service designee describing the basis for submission. Failure to coordinate prior to submission may result in:

- (1) The specimen(s) not being tested; or
- (2) A delay in the submission of the specimen(s) to the contract steroid testing laboratory.

d. Specimens submitted only for steroid testing must contain a minimum of 60 milliliters of urine and must be collected using the same CoC, observation, and security procedures described in this issuance for routine drug testing specimens. However, these specimens must not be placed in the same shipping container with other specimens being submitted for routine drug testing to the Military Service FTDTL.

e. If routine drug testing is requested in addition to steroid testing on a single individual, two separate specimen bottle submissions are required. A minimum of 60 milliliters must be collected for steroid testing; and a separate specimen, containing a minimum of 30 milliliters, must be collected for routine drug testing. Separate CoC documentation must be completed for each specimen collected from the individual. The two specimen bottles and CoC documentation for the single individual:

- (1) May be submitted in the same shipping container.
- (2) Must not be comingled with other specimen bottles submitted for testing.

7.3. OTHER SPECIAL TESTING REQUESTS.

a. Special testing will only be conducted at:

(1) A DoD-approved laboratory (i.e., a reputable laboratory recommended by the Director, ODDR and with the approval of the Military Service drug testing program manager); or

(2) FORTOX, AFMES.

b. Testing for drugs, chemicals, compounds, or their metabolites other than those routinely tested pursuant to this issuance (i.e., those listed in Tables 2 and 3) may be requested with prior consultation with the:

- (1) Respective legal authority.
- (2) FTDTL Commander/commanding officer.
- (3) Military Service drug testing program manager.
- (4) Military Service personnel DDRP manager.
- (5) Director, FORTOX.

c. Service member specimens:

(1) Will be collected and transported under the same policy requirements of Paragraphs 4.3 and 4.4.

(2) May be directly submitted, or aliquots may be forwarded by the FTDTL, to the DoD-approved laboratory or the AFMES. The recipient laboratory must:

(a) Have demonstrated expertise in conducting urine drug testing and use certified and validated reference standards in their analyses.

(b) Employ two independent methodologies, based on different scientific principles, to report results for specimens. If two independent methodologies are not available, positive results reporting using only DoD-approved separation techniques with MS detection is permitted; however, duplicate analyses must be completed with distinct aliquots for each analysis.

d. Since administrative cutoff concentrations are not established for drugs other than those in Tables 2 and 3, the DoD-approved laboratory or the AFMES may report a specimen as positive when the concentration of the drug or metabolite exceeds the laboratory-determined limit of quantification.

e. When submitting specimens to FORTOX, AFMES:

(1) Consultation with legal authority to establish an appropriate collection premise, in accordance with DoDI 1010.01, is recommended. Specific guidance regarding approval and specimen collection requirements for special drug testing is published on the AFMES Forensic Toxicology Website at <https://health.mil/afmes>.

(2) Failure to coordinate with the FTDTL or the Director, 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 18, “Forensic Toxicology Analysis Request”—located at on their website. Specimen(s), with prior

coordination for special drug testing and their accompanying CoC form, can be mailed directly to the FORTOX at the address provided on their website.

7.4. SVT.

SVT:

- a. May be requested by a:
 - (1) Trial judge;
 - (2) Staff judge advocate;
 - (3) Medical review officer;
 - (4) Unit commander;
 - (5) Military Service personnel DDRP manager; or
 - (6) FTDTL commander/commanding officer.
- b. Includes pH, specific gravity, general oxidant, and creatinine testing, the results of which may be used:
 - (1) To identify substitution, validity, adulteration; or
 - (2) If a drug positive is residual from the previous positive result or represents new drug use.
- c. Requests should be coordinated through the respective FTDTL. FTDTL Fort Meade:
 - (1) Is certified to perform SVT under Mandatory Guidelines for Federal Workplace Drug Testing Programs.
 - (2) Will perform SVT on Military Service member specimens, upon request.

7.5. OVER-THE-COUNTER SUPPLEMENT TESTING.

When legal or command authority deems it necessary to test a supplement for the suspected presence of a controlled substance, reputable laboratories recommended by the Director, ODDR, must be used. All such testing will be at the Service member's expense. A pristine, unopened portion of the supplement must be obtained:

- a. At the Service member's expense.
- b. From the same lot as that suspected of contamination.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
AFMES	Armed Forces Medical Examiner System
A _s	asymmetry factor
BTAB	Biochemical Testing Advisory Board
C/MS	chromatography/mass spectrometry
COA	certificate of analysis
CoC	chain of custody
COOP	continuity of operations plan
DDRP	Drug Demand Reduction Program
DHA	Defense Health Agency
DMDC	Defense Manpower Data Center
DoDI	DoD instruction
DoD ID	DoD identification number
EDFR	Executive Director, Force Resiliency
EW	expert witness
FORTOX	Division of Forensic Toxicology
FTDTL	forensic toxicology drug testing laboratory
GC	gas chromatography
IA	immunoassay
IEAD	initial entry on active duty
IMS	information management system
IS	internal standard
LAN	laboratory accession number
LC	liquid chromatography
LCO	laboratory certifying official
LIMS	laboratory information management system
LOD	limit of detection
MEPS	Military Entrance Processing Station
MFR	memorandum for record
MPDATP	Military Personnel Drug Abuse Testing Program
MRP	medical review process

ACRONYM	MEANING
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NCE	non-conforming event
NG/ML	nanogram/milliliter
ODDR	Office of Drug Demand Reduction
OEM	original equipment manufacturer
OP	operating procedures
PhD	Doctor of Philosophy
QA	quality assurance
QAO	quality assurance officer
QC	quality control
ROTC	Reserve Officer Training Corps
RT	retention time
SFTDTL	special forensic toxicology drug testing laboratory
SSN	social security number
SVS	system verification sample
SVT	specimen validity testing
SYCAN	synthetic cannabinoid
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USMEPCOM	United States Military Entrance Processing Command

G.2. DEFINITIONS.

Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

TERM	DEFINITION
adulterated	When reported as part of specimen validity testing, a urine specimen to which a substance has been added to alter the normal physiological composition of urine. This determination is based on measurement of a non-physiological pH and/or the presence of substances that are not normal constituents of urine or substances that are normal constituents of urine but are at non-physiologically-relevant concentrations.
aliquot	A portion of a specimen used in drug analysis.

TERM	DEFINITION
analyte	A drug or drug metabolite for which a specimen or sample is being analyzed or tested.
approved bottles	National Stock Number 6640-01-681-3575.
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 calibrator(s), open and blind controls, and actual Service member specimens. A certification batch consists of calibrator(s) and controls only.
certification set	A series of samples prepared by the AFMES for purposes of certifying an FTDTL to conduct testing and reporting of selected drugs.
controls	<p>Samples prepared to exact specifications and analyzed to ensure the reliable performance of an analytical procedure. Controls include:</p> <p>blind control. A positive or negative control, included in a batch, where the location and composition is unknown to the technician involved in the analytical procedure.</p> <p>calibrator. A control used to establish a standard or reference concentration, such as the cutoff, in an analytical procedure.</p> <p>negative control. A control that is absent the analyte(s) of interest in an analytical procedure.</p> <p>open control. A positive or negative control, included in a batch, where the location and composition is known to the technician involved in the analytical procedure.</p> <p>positive control. A control that contains the analyte(s) at a concentration above the cutoff.</p>
cutoff	The decision point that determines whether a specimen is negative or positive and is specified as a concentration value. A specimen is deemed positive if the concentration of analyte is equal to or greater than the cutoff.
discrepancy	A deviation in the proper collection and/or submission of a specimen or accompanying documentation to an FTDTL.
error in reporting	A report issued by an FTDTL in which there is an inconsistency in non-critical member identity information between the FTDTL report and DD Form 2624 (e.g., error in date of collection, base area code, testing premise).

TERM	DEFINITION
false negative	An erroneous negative reporting of a specimen when analyte is actually present in the specimen.
false positive	A specimen reported positive for an analyte that was subsequently found to be negative for that analyte (i.e., not present or below the LOD).
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.
IEAD	The member's first period of full-time duty in an active Military Service following enlistment or appointment.
invalid	When reported from routine testing, the laboratory was unable to finalize confirmatory testing, due to either chromatographic interference or depletion of the specimen during the course of testing. When reported as part of specimen validity testing, this refers to a situation that prevents the laboratory from completing testing or obtaining a valid drug test result, due to an unidentified adulterant, an unidentified interfering substance, an abnormal physical characteristic, or the presence of a routine physiological substance at an abnormal concentration.
limit of quantification	The lowest analyte concentration that can be accurately and precisely measured.
LOD	The lowest analyte concentration that can identify the presence of a drug or its metabolite.
metabolite	A compound that is excreted in the urine whenever the parent drug is modified by processes within the human body.
Military Services	Refers to the Army, Navy, Air Force, Marine Corps, Space Force, Coast Guard, and the Active, Guard, and Reserve Components.
non-conforming event	An occurrence that is outside the normal FTDTL business processes, as delineated in the OP manual.
non-testable discrepancy	A discrepancy that prohibits testing of the specimen by an FTDTL.

TERM	DEFINITION
on-off cycles	Steroids are often used in patterns that involve taking varied doses of steroids over a period of time. The variation in steroid use can include increasing, substituting, overlapping, and decreasing doses.
opioids	A class of natural or synthetic narcotic analgesics.
presumptive positive	A specimen that tests positive above a pre-determined concentration in the initial screening test but has not been confirmed by C/MS analysis.
proficiency test samples	Samples submitted to an FTDTL by the AFMES for purposes of assessing the accuracy, sensitivity, and specificity of testing conducted at the FTDTL.
RT	The amount of time that an analyte is retained on a chromatographic column during a C/MS analytical procedure.
specimen	A urine sample collected from a Military Service member and submitted to an FTDTL for analysis.
steroid	Defined in the Designer Anabolic Steroid Control Act of 2014, and subsequent amendments.
substituted	When reported as part of specimen validity testing, a result indicating that another substance has been submitted for testing in place of the Service member's urine. This result is based on measurements of endogenous substances that are outside of the physiologically-relevant ranges for human urine.
summary packet	An abbreviated laboratory record.
testable discrepancy	A discrepancy that does not preclude testing of the specimen by an FTDTL.
unadulterated specimen	A urine specimen that has not been tampered with or intentionally altered from its normal physiological composition.
validation	A process of performing multiple tests designed to verify that an analytical system (i.e., instrument or procedure) is suitable for its intended purpose and is capable of providing scientifically accurate and precise analytical data. Method validation includes, but is not limited to, evaluation of linearity, precision (i.e., reproducibility), accuracy, interference, specificity, and carryover.

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