OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

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MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Packaging, Documenting, Tracking, Testing, and Reporting of Specimens Received at Department of Defense Drug Testing Laboratories

With a view to ensuring the integrity of the Military Personnel Drug Abuse Testing Program, DoD components will adhere strictly to the provisions of Department of Defense Instruction (DoDI) 1010.16, *Technical Procedures for the Military Personnel Drug Abuse Testing Program (MPDATP)*, as clarified by the guidance set forth below.

DoDI 1010.16 requires that "[t]he lids of all specimen bottles forwarded for [drug] testing are securely tightened, properly sealed and the bottles are enclosed in a leak-proof secondary container. The secondary container(s) must contain sufficient absorbent material to absorb the entire specimen contents in case of leakage."

Beginning as soon as practicable, but no later than September 1, 2018, the label bearing the collection and identifying information of the individual Service member submitting a urine sample will be affixed to the specimen bottle containing that Service member's urine only ***after*** the Service member has urinated into the specimen bottle (or the Service member's urine has been poured from a urine collection cup into the specimen bottle), and the lid has been emplaced and tightened on the specimen bottle. The Service member will wipe the bottle dry, if needed. The collector and Service member will verify the accuracy of the label information by direct comparison to the Service member's presented identification (e.g., CAC), before applying the label. The Service member will observe the label being affixed to the dry specimen bottle containing his or her urine sample. All collection steps for each Service member will be conducted under the direct observation of a designated observer.

Beginning as soon as practicable, but no later than September 1, 2018, in addition to the designated collector, a second individual (e.g., additional collector, assistant collector, officer, non-commissioned officer, or designated civilian) at each urinalysis sample collection site will conduct a secondary review of each capped and labeled specimen bottle to ensure compliance with DoDI 1010.16. 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 chain of custody documents.

Beginning as soon as practicable, but no later than September 1, 2018, each specimen bottle will be enclosed in an **individual**, leak-proof secondary container (e.g., a sealable plastic bag), to prevent and contain leakage. Each individual, leak-proof secondary container will contain sufficient absorbent material to absorb the entire contents of the specimen bottle, should leakage occur.

On or after September 1, 2018, any specimen bottle that is received by a Military Forensic Toxicology Drug Testing Laboratory, but is not enclosed in an individual leak-proof secondary container with absorbent material will be assigned the discrepancy code of "PI – Improperly Packaged." ***Samples derived from a specimen bottle coded as PI may be tested,*** provided that testing is not otherwise precluded by a separate, non-testable discrepancy code assigned to the same bottle.[1] For purposes of this clarifying guidance, a "discrepancy code" includes all such codes established by this memorandum and by other applicable policies and procedures.

For purposes of this clarifying guidance, the term "shipping package" refers to a box or container designed to hold as few as one and as many as twelve individual urine specimen bottles. A shipping package will be opened as soon as practicable after receipt by a Military Forensic Toxicology Drug Testing Laboratory. On first opening any shipping package, a Laboratory inspecting official will carefully inspect each enclosed specimen bottle and the shipping package for signs of current or past leakage or wetness. Detecting signs of current or past leakage or wetness may require keen observation and assessment by the inspecting official.

Signs of current or past leakage or wetness may include:

- Wetness on a specimen bottle or on or in an individual leak-proof secondary container in which a single specimen bottle is enclosed;
- Wetness on or in the shipping package, or on the packing materials or any document enclosed in the shipping package;
- The discoloration or distortion (e.g., wrinkling or smearing) of the label on a urine specimen bottle or shipping package, of the shipping package itself, or of the packing materials or any document enclosed in the shipping package; or
- Signs of crystallization from minerals/urea on a urine specimen bottle or on or in an individual leak-proof secondary container in which a specimen bottle is enclosed, on or in the shipping package, or on the packing materials or any document enclosed in the shipping package.

Effective immediately, when a Military Forensic Toxicology Drug Testing Laboratory inspecting official detects any sign of current or past leakage or wetness in or on a shipping package containing one or more specimen bottles, discrepancy codes will be applied as follows:

"PH – Package Leakage Noted" will be assigned to ***every*** 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 any other specimen bottle or secondary container, the shipping package, packing materials, or any document enclosed in the shipping package. ***Samples derived from a specimen bottle coded as PH may be tested,*** provided that testing is not precluded by a separate, non-testable discrepancy code assigned to the same bottle.[2]

[1] A specimen bottle and/or specimen may be assigned as many separate discrepancy codes as deemed applicable.

[2] A specimen bottle and/or specimen may be assigned as many separate discrepancy codes as deemed applicable.

"BK – Bottle Leaked in Shipment" will be assigned to any individual specimen bottle that shows signs of current or past leakage or wetness, but only when the inspecting official determines that all of the leakage or wetness associated with that bottle is contained within its individual leak-proof secondary container (as applicable), and that 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.[3] ***Samples derived from a specimen bottle coded as BK may be tested***, provided that testing is not precluded by a separate, non-testable discrepancy code assigned to the same bottle.[4]

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

In addition, effective immediately, each Military Forensic Toxicology Drug Testing Laboratory will:

- Link to one another, through documentation in appropriate laboratory records, ***all*** specimen bottles received in the same shipping package and any urine sample derived therefrom, and process any sample derived therefrom in the same screening batch. This documentation will be generated, tracked, and maintained in the Laboratory Information Management System (LIMS) as part of the chain of custody or other like documentation, such that the laboratory, and any other person or organization, can identify and track all specimen bottles, and any sample derived therefrom, that were received in the same shipping package.

- Assign all applicable discrepancy codes to a specimen bottle and any sample derived therefrom, and document all codes assigned to a specimen bottle and any sample derived therefrom in appropriate laboratory records. This documentation will be generated, tracked, and maintained in the LIMS as part of the chain of custody or other like documentation, such that the laboratory, and any other person or organization, can identify and track all discrepancy codes assigned to a particular specimen bottle or sample.

Each Service member's urine sample will be processed and the outcome reported to the appropriate unit official as negative, positive, or untestable, in accordance with DoDI 1010.16. In addition, the information reported to the unit will include all discrepancy codes assigned to each Service member's urine specimen bottle and sample, and a "plain language" explanation of each such code.

Compliance with the documentation, tracking, testing, and reporting of leaked or wet specimens, as set forth in DoDI 1010.16 and this clarifying guidance, will be verified by quality assurance oversight. This includes evaluations as part of the Armed Forces Medical Examiner System quality assurance inspection and proficiency programs. Compliance will also be

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[3] A determination that an individual specimen bottle shows signs of leakage or wetness that is ***not*** contained within the individual leak-proof container, or that leakage or wetness from the bottle ***has*** affected any other specimen bottle or secondary container, the shipping package, packing materials, or any document enclosed in the shipping package, requires assignment of the PH discrepancy code to every specimen bottle in the shipping package.

[4] A specimen bottle and/or specimen may be assigned as many separate discrepancy codes as deemed applicable.

monitored on an ongoing basis as part of routine laboratory quality assurance audits conducted by laboratory Quality Assurance Officers. The Office of Drug Demand Reduction will document non-compliance (e.g., the failure to enclose each specimen bottle in an **individual**, leak-proof secondary container with sufficient absorbent material), in its annual report, *Status of Drug Abuse in the Department of Defense.*

The standards set forth in DoDI 1010.16, as clarified by the guidance set forth in this memorandum, are the minimum to be applied. The Secretaries of the Military Departments may direct organizations under their respective authority, direction, and control to apply more stringent standards.

The next update of DoDI 1010.16 will include this clarifying guidance. This memorandum supersedes and rescinds Office of the Under Secretary of Defense Memorandum, *Standards for Specimen Shipment Preparation and Leakage*, dated June 20, 2018.

Please direct questions to CAPT Eric R. Welsh, Director, Office of Drug Demand Reduction, at (703) 697-8690, or by email at eric.r.welsh2.mil@mail.mil.

Stephanie Barna
Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

cc:
Director, Army Substance Abuse Program
Director, Navy Drug Detection and Deterrence Branch
Army Drug Testing Program Manager
Navy Drug Testing Program Manager
Air Force Drug Testing Program Manager
Marine Corps Drug Demand Reduction Program
Army National Guard Substance Abuse Program Manager
Chief, Drug Demand Reduction Program, Air National Guard Bureau
Chief, Army Reserve Substance Abuse Program
Chief, Division of Forensic Toxicology, Armed Forces Medical Examiner System
Commander, U.S. Military Entrance Processing Command