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From: "Stamerra, Robert" <Robert.Stamerra@DHS.GOV>
To: <wvogl@samhsa.gov>
Date: 7/12/04 5:59PM
Subject: FR Doc. 04-7984

Dr. Vogl,

Attached are Department of Homeland Security comments to the proposed rule on federal workplace drug testing programs. I'm also pasting the content from the attachment into the body of this message.

Thank you,

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Subpart B, § 2.4/5 Split Specimen Collection for Urine Testing

The single specimen collection procedure currently in place is working and should not be changed in favor of the proposed split specimen, requiring at least 30 mL for the primary specimen and at least 15 mL for the split specimen.

At times, it is difficult to get a donor to provide the required 30 mL sample. By requiring split specimen collection for all urine tests, there will be an increased risk that the donor will not be able to provide an adequate sample in the allotted time. Additionally, if the donor can not fulfill the 45 mL requirement, the Medical Review Officer (MRO) will have to get involved in potentially more cases. Finally, the use of split specimen collection will increase the Agency's overall costs for drug testing, i.e. more MRO case reviews, more discarded specimen containers for inadequate samples, etc.

Subpart H, § 8.5 Procedures for Collection of a Urine Specimen

Subparagraph 10 (ii) makes no mention of how long an employee can be given to provide a another specimen once the volume of the first specimen is below 45 mL (and therefore discarded). The DOT requirements in Part 40 allows up to 40 ounces of water within a 3 hour time frame. Is this allowable under HHS guidelines?

Subparagraph 10 (ii) (directing that urine be discarded if it is below 45 mL) seems in conflict with subparagraph 19, which allows for the minimum of 30 mL in Bottle A to be processed for testing even though there is no additional urine for the second specimen in Bottle B. In you can send less than 45 mL (Bottle A and Bottle B), why discard the specimen if the volume is less than 45 mL as stated in subparagraph 10 (ii)? Why not give the agency the option to let the donor waive his right to a split sample if more than 30 mL but less than 45 mL of urine is provided?

With regard to specimen volume, DHS recommends that agencies be given the option that is currently found in the Urine Specimen Collection Handbook for the New Federal Drug Testing Custody and Control Form, at Chapter 6, subheading "Specimen Volume", subparagraph B and C (Split Specimen Collection).

Subpart H, § 8.6 What Are The Responsibilities of a Federal Agency That Uses a Collection Site?

It is not logistically or fiscally practicable to conduct the proposed annual inspection of each collection site. For instance, the Customs and Border Protection (CBP) Bureau deals with approximately 3,000 clinic collection sites and 500 workplace collection sites. To meet the annual inspection requirement would result in CBP conducting 14 site inspections per Federal workday. In another example, the United States Secret Service (USSS) in FY03 used 468 different collection sites; out of the 2200 collections there were only 5 cancelled for fatal flaws, and those problems were investigated by the USSS and corrective action taken.

The current process uses "indirect" inspections and quality assurance assessments through the laboratory results reported to the agency. If a trend in fatal or nonfatal flaws from a particular collection site or collector is reported, and the agency cannot work it out with the contractor to reduce the potential for further discrepancies, that site or collector is no longer used. Additionally, since HHS is requiring formalized training for collectors, the incidence of collection site and collector deficiencies should be reduced.

DHS proposes to change 8.6 (b) to read: "A federal agency must respond to reports of collector and collection site deficiencies reported to them and must take appropriate action to preclude the recurrence of such deficiencies. If deficiencies recur, then that information will be submitted to SAMHSA to have the collection site banned from performing federal specimen collections".

Subpart O, § 15.1 Split Specimens - When May a Split Specimen be Tested?

Testing the Split Specimen It is not clear if the agency or the donor must pay for a donor's request to be tested at a different HHS-certified laboratory. It is also not clear if this provision applies to both job applicants and employees.

Testing at a Different HHS Laboratory Are agencies expected to have a second HHS laboratory on contract for testing of the split specimen?

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