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From: <pAlexander@doc.gov>
To: <wvogl@samhsa.gov>
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The Department of Commerce submits the following comments to the Federal Register notice, dated April 13, 2004, Document # 04-7984. Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA).

Subject: Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Program.

1. Section 2.4 - How is Each Type of Specimen To Be Collected?
HHS proposes to collect a split specimen for each type of specimen (hair, oral, sweat and urine).

We recommend that we continue to allow the agency to decide whether to collect a single or split specimen. A split specimen seems only to give a false sense of safety and security. Split specimen collection only provides twice as many opportunities for mistakes, errors and problems during the collection and laboratory analysis process, including: handling, packaging, transporting, analyzing, maintaining, and reporting requirements. If an error happens in the collection or laboratory process, all of the specimens collected/processed at the same time will be tainted no matter how many specimen bottles are used or labs the specimen are sent to. The Department of Commerce questions whether there is any valid research or study to show that it is safer and/or more efficient to collect two specimens at the same time.

2. Section 8.6 - What are the Responsibilities of a Federal Agency that Uses a Collection Site?
HHS proposes that agencies conduct annual inspections of all collection clinics.

Comments: It is always a good idea to try and continually improve the collection process, but it seems cost prohibitive and logistically impossible to require the inspection of 100% of all of the collection clinics, as there are thousands. Department of Commerce does not have the manpower or the funding resource to cover the additional workload. Would HHS provide the money to do the inspection? Would they develop training for those performing the inspection, to maintain a consistent inspection program? Could agencies share this responsibility when multiple agencies use the same labs?

The overall percentage of errors at collection clinics is 1%. Such a low percentage rate should not dictate a 100% inspection of the other 99% of the clinics that do collections properly. The Medical Review Officer can always throw the test out if there are significant problems. What is the basis for HHS determination that 100% of all clinics need to be inspected annually?

Suggested Options:

a. If inspections are required HHS should provide training for inspectors, and update the training annually.

b. Limit inspection to 1-5% of the clinics. Assign a portion of inspections to user agencies annually. Rotate inspection sites annually.

c. Require clinics to perform self inspections.

d. Collector certification, as required by Department of Transportation collection sites.

e. Inspection by outside entity.

f. On-line training course that would allow collectors to receive standard training. Assure that updated educational and procedures information is available.

g. Require collector (as overseen by the employing clinic) to undergo refresher training for any fatal flaw on the collections. This would be better at addressing the specific issue of following proper collection procedures.

3. Issues of Special Interest - Oral Fluid Collection

During the oral fluid collection process there is a possibility of the donor having
Dry Mouth (the inability to spit, especially when observed). Procedures should be written in the eventuality "dry mouth" occurs. Agencies should have uniform guidance in how to deal with this, as with "shy bladder."

Phyllis Alexander
Department of Commerce
Office of Human Resources Management
Office of Compensation, Innovation and Work Life Policy
Telephone: (202) 482-4840
Fax: (202) 482-3160
Internet Address: palexander@doc.gov