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**From:** "Pat Carpenter" <PCarpenter@DrugRisk.com>
**To:** <wvogl@samhsa.gov>, "David Brill" <DBrill@DrugRisk.com>
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Walt;

Attached are our comments regarding the proposed alternate matrix guidelines.

Thanks

Pat

Draft Response to NLCP Alternative Matrix Guidelines from Drug Risk Solutions

Subpart B Section 2.5 What is the minimum quantity of specimen to be collected for each type of specimen?

The collection requirement of 100 mg, split into two equal portions, does not recognize the "A" lab's need for more of the sample. For labs using 20mg each for screening and confirm it would limit the number of confirms available to be done without the option of any screen of confirm repeats. A larger collection is an option, as is 2/3 A - 1/3 B, which is more consistent with the technical requirements. Of course this is all based on the collector's ability to "eyeball" the amount collected. Therefore, picture examples of numerous types of hair (100 mg samplings of numerous hair types) needs to be part of collector training materials.

There are no acceptance/rejection criteria for short samples. What does the lab do when less than 100mg (or the A lab minimum) is received? QNS/reject? Should a priority scheme be used to screen and confirm for drugs, when there is less than the minimum received?

Body hair (i.e. axillary, arm, chest, back or leg) should be allowed when people show up for sample collection that do not have enough head hair for an adequate sample. Alternatively a number of urine tests could be used to substitute for a hair sample. The deterrent effect of multiple urine samples or a hair sample needs to be preserved.

Subpart C Section 3.1 Which tests must be performed on a specimen?

Up front validity testing on hair samples is not necessary, as hair testing requires an observed collection. Validity testing could always be conducted if there is a problem with analysis, or specimens could yield an "invalid" result as with current urine testing rules. An invalid result could then require a second specimen to be collected. Since this requires an observed collection, collector training, feedback and accountability is a must.

Subpart C Section 3.4 What are the cutoff concentrations for hair samples?

The confirmation cutoff for THCA should be 0.1 pg/mg. The 0.1 pg/mg is going to be needed by the labs to allow the 40% of cutoff control. A 40% control using the current proposed 0.05pg/mg would be 0.02pg/mg. This is near the end for sensitivity of a GC/MS/MS. Another factor is whether ion ratios needed and what limit (i.e. 20% as the urine program or 30% that most hair labs use).

Subpart C Section 3.8 What validity tests must be performed on a hair sample?

Up front validity testing on hair samples is not necessary, as it requires an observed

collection. Validity testing could always be conducted if there is a problem with analysis, or specimens could yield an "invalid" result as with current urine testing rules. An invalid result could then require a second specimen to be collected. Since this requires an observed collection, collector training and accountability is a must.

The validity testing suggested would not clearly rule out a specimen as being adulterated. The testing suggests is very manually intensive as well as being not very specific or sensitive.
(1) What is a digestion test?
(2) The microscopic examination will only show gross abnormalities. It cannot distinguish between human and animal hair.
(3) What is the dye test?
(4) Determine solubility of head hair in methanol will only give an indication if the hair is plastic.
(5) If a lab as a part of the accessioning or processing notices problems, validity testing should be allowed to characterize the problems.

There should be no requirement for the lab to make any other special accommodation for dyed or bleached hair.

Subpart K Section 11.14 What are the batch quality control requirements when conducting an initial drug test?

It is not currently possible, with the limits of today's screening technology (immunoassay), and the extremely low levels of drugs in hair (pg vs. ng) to require the open QC criteria to be +/- 25% of the cutoff. These limits should be determined by empirical data in each laboratory. More realistic for open OC to hair testing is 50% and 200% of cutoff for screening.

Subpart K Section 11.15 What are the requirements for a confirmatory drug test?

Need acceptance criteria to be determined for the newer MS/MS or CI-MS methods where only one ion or one transition is monitored. Obviously these methods need to have some consensus on what is forensically defensible.

There is no evaluation of the economic impact of the proposed rules on the laboratory costs, or the final cost to the end user of the hair test results.