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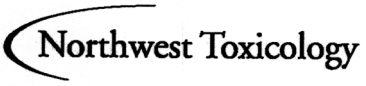

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July 1, 2004

Attention: Walter Vogl Ph.D.,
Drug Testing Section,
Division of Workplace Programs, CSAP,
5600 Fishers Lane,
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Rockville, MD 20857

Comments to Federal Register FR Doc. 04-7984
Tuesday April 13th 2004 Notices
Department of Health and Human Services,
Substance Abuse and Mental Health Services Administration,
Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

From:
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On behalf of:
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Dear Dr Vogl,

I have read the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and I appreciate all the work that went into preparing these proposals. At Northwest Toxicology and Lab*One,* Inc., we are pleased with the Department's acknowledgement that alternative technologies deserve consideration to be part of the federal drug testing program. I would like to thank the HHS for the opportunity to comment on these proposed changes.

Hair

Subpart B. Section 2.5, H.8.2: amount of specimen required for analysis.

There are no acceptance or rejection criteria for samples with an insufficient amount of hair. Presumably, the laboratory should reject specimens with less than 100 mg of head hair. If that is the case, how is the collector to know when they have met the appropriate criteria? Is this just an eyeball judgement? HHS has historically published a collector's guide. Collection protocols and guidance, for each specimen type, should be included. Examples would include guidance to assist the collector at approximating the proper amount to collect for all the various hair types and length scenarios, and what the collector should do if the hair is shorter than a typical 90 days length (3.9 cm)? The 100 mg, split into two equal portions, does not recognize the initial (A) lab's need for more of the sample (initial and confirmation responsibilities). A 2 to 1 split would be more consistent with laboratory practical needs. Since specimen adequacy is much more of an issue with hair than with urine, any specimen screening positively for more than one drug class may not contain enough sample to confirm more than one. In such a case, a priority scheme should be recommended and used to confirm for drugs, when there is less than the minimum received, or more than one drug class is positively screened.

While it is understood that federal privacy requirements will rule when determining alternative sites for hair collection, certain body hair (arms, legs) should be allowed when bald men (since this may be a common occurrence) show up for collection of a hair sample.

Subpart B. Section 3.16 – 3.17 – There are no provisions for reporting a hair as substituted. Substitution of hair is a very conceivable response of persons trying to beat the test, and this potential problem should not be ignored. How are collectors to determine if someone is wearing a convincing wig? Northwest Toxicology has, in fact, received artificial and non-human hair.

Subpart C. Section 3.4: drugs and proposed cut-off concentrations.

A consensus of hair testing industry members, at the recent Society of Hair Testing Meeting in Chicago (May 2004) agreed that 0.1 pg/mg THCA would be an appropriate confirmation cutoff. Yet, recent data presented by Marilyn Huestis Ph.D. (NIDA, NIH) at the conference, showed that even lower cutoffs might be needed to correlate to actual use. However, this creates significant technical and quality control issues. What's even more important is that there is no data currently available to correlate results between proposed hair testing and the current urine program.

Although we have offered MDEA confirmations in urine, hair and oral fluid matrices, for more than 4 years, we have not yet reported one confirmed positive. We believe that it is not necessary, it is a waste of resources, and it should not be included in the amphetamines confirmation procedure.

Subpart C Section 3.4 – 3.7: The alternative specimen cutoffs were proposed as the result of industry working group recommendations rather than true scientific studies. How the specimen cutoffs interrelate still needs to be determined. This is important regardless of whether commercial methods can achieve such cutoffs. It is also essential that the relationship between cutoffs for different specimens be understood, so that the results from one specimen type would

not be used to refute another.

Subpart C. Section 3.8: validity tests on hair.

Up front validity testing on hair testing is not necessary, as the collection for this specimen type is observed. Artificial hair, if not caught by the collector, may be determined through the extraction process, through its behavior during treatment with organic solvents. Other alternative 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. Additionally, an invalid result could require a second specimen to be collected. Since hair testing requires an observed collection, collector training and accountability is a must, particularly in being able to provide a sample of the donor's actual hair.

If validity testing is required for a particular specimen, there are problems with the list of "validity" tests as described:

1. To determine the integrity of the hair by performing a digestion, essentially destroys the hair, and may render the remainder impossible to analyze according to a lab's standard operating procedure.
2. There are no criteria for a microscopic examination of the hair in the proposed rule – how extensive should this be, who should perform the test, what are their qualification/training? What is the point of the microscopic exam? To differentiate between human and non-human hair? Damaged and non-damaged hair can still be tested. Since no commercial laboratories currently conduct such a test, the suggestion of its inclusion with no other guidance is problematic.
3. What is meant by "dye test", and what are the scientific justifications for such a test? A dyed hair can still be tested for drugs. There should be no requirement for the lab to make any other special accommodation for dyed or bleached hair.
4. The requirement for an A/B comparison does not make sense. It is not possible to compare specimens A and B without actually opening both specimens. Presumably Specimen B, if A is positive, will be sent to another laboratory.

Subpart I. Section 9.5: quality control specification required during proficiency testing (and presumably specimen testing).

Since alternative matrices, especially hair, contain much lower concentrations of drug than urine, and since the ELISA screening technologies are by nature less precise than current highly automated EIA, to require the same precision around the cut-off (+/- 25%) is not scientifically viable. Since ELISA has less precision involving timing steps and temperature controls, the variations are typically higher than with high throughput EIA analyzers. The QC ranges need to be broadened to 0.5x through 2x, with x being the cutoff.

Subpart K. Section 11.15: requirements for a confirmatory drug test.

With tandem mass spectrometers, and/or single ion chemical ionization spectra being necessary for the detection levels of some drugs in hair, some degree of guidance from HHS on the criteria for the acceptability of single ion spectra, and transitions, are necessary. How many ions or transition must be monitored; how many ratios need to be calculated, and what are the acceptance criteria for their allowable ratio(s)? It must be recognized in the new guidance

document that chemical ionization may only generate a molecular ion fragment, and, therefore, what would be considered forensically acceptable data in this situation. Also, it must be determined whether one or two transitions for tandem MS meets the forensic standard.

IITFs

Why are these being proposed? Has anyone done any kind of economic impact study on how they will affect laboratories participating in the current federal program? IITFs have precedence in military and NRC programs. But businesses in the private sector that would likely be interested in providing initial testing services (regional hospitals, occupational medicine clinics, third party administrators, etc), may not be set up to separate the logistical and financial interests of the collector, laboratory and medical review services, which the program has required. Also, the use of an IITF necessarily involves a further transmittal of a urine specimen and associated paperwork for non-negative specimens (i.e., collection site to IITF to laboratory for confirmation testing to MRO). HHS has not addressed the potential problem of additional administrative error, chain of custody problems, or loss of specimens or paperwork created by introducing this additional step. In addition, DOT and HHS have been careful, under the current rules, not to permit or encourage reporting of negative results to an employer before non-negative results, since employers and other employees could make inferences about screening test results solely from the timing of the reports. Adding a separate step for the IITF-laboratory transfer makes preventing such inferences more difficult. But HHS does not propose any steps to mitigate the problem its proposal could create.

Since the IITF must forward all non-negative specimens to an HHS-certified laboratory, which only performs the confirmatory testing, data sets for reported non-negatives will be generated by two separate facilities, and the reporting process will not include a the current certification step to correlate the screening and confirmation data. Has HHS considered how this will effect the legal challenge process and preparation of litigation packets?

POCTs

Laboratories have to meet one performance standard; HHS proposes to have POCTs meet a lower one. Yet, POCTs can not be equivalent to the sample processing and initial testing of a laboratory. The proposed rule will require the POCT device to correctly identify only 80% of challenge samples (**L.12.6**) to be on the approved list, yet requires Agencies to report any PT failure (**L12.12**), which would result in the device being removed from that list. Is this not inconsistent? There is no information on how will the PT program be implemented/managed?

On a more practical level, the POCT subpart of the proposal provides no requirements for how POCT devices or device lots are to be validated or how they are to be verified as to the accuracy of their day-to-day performance out in the field. In the proposed HHS regulations, no true controls are required to be run with the devices each day to support the likely accuracy of a particular employee's test, on that day, by that test administrator. HHS only plans to assess a POCT device brand when it originally certifies it. HHS then relies on the device manufacturer to inform HHS if there has been a change to the device or a problem is uncovered by an Agency that causes HHS to reassess whether the device is to remain certified. HHS relies on the laboratory as its backup, to flush out false positive POCT readings, and it requires 10% of specimens being reported as negative to be forwarded to the laboratory for quality control testing. How will the discrepancies be documented for the Agency and or HHS? In its certification process, HHS should additionally consider some type of evaluation of a device

brand/lot as it starts to head towards the end of its shelf life.

HHS will require the Agencies wishing to use POCTs to ensure that the testers and the sites comply with the guidelines. How are the Agencies to accomplish this?

It is generally acknowledged that, in the present urine-testing program, collectors are the "weakest link." To propose a new form of testing that would put the entire program into the hands of the weakest link is to knowingly introduce the probability of additional extensive errors in the drug-testing program. Use of HHS-approved POCT devices – whatever the quality controls proposed for the devices themselves – necessarily relies on the existence of well-trained and qualified POCT testers. The proposal does not contain specific training requirements for POCT testers sufficient for them to be trained to do the job. For example, HHS would need to develop material comparable to those DOT established for urine collectors or a model course such as DOT prescribes for breath alcohol technicians (BATs) in the alcohol testing program, who play a role analogous to that of the POCT collector.

Subpart G – Collection Device

HHS instructs that if the FDA has not cleared a collection device as to not affect the specimen collected, it becomes the job of the Federal agency. How is this to be done? What criteria is to be used? This does not seem to be a practical requirement.

Subpart Q – Electronic Technology

HHS does not offer recommended changes to address requirements for electronic transmission, storage, and security of laboratory and MRO results. It is time for HHS to develop procedures for electronic signatures and electronic custody and control forms that can be used with specimens sent to laboratories. Specimens can still be documented and controlled in a manner suitable to maintain forensic defensibility of the specimen and results. It is long over due for HHS to begin work on this. Without guidance or minimum specifications, technologies will develop in separate, perhaps incompatible, directions.

In conclusion, as discussed in the preamble, there are holes and inconsistencies that must be addressed before the rules can be adopted. Additional scientific study is still required, and both practical and procedural considerations still need to be incorporated, to be a useful and defensible guidance document. The federal program needs to rise above political and economic issues to meet these objectives. Again, I would like to thank HHS for the opportunity to comment on these proposals.

Respectfully submitted,

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