Walter F. Vogl, Ph.D
SAMHSA Division of Workplace Programs
5600 Fishers Lane
Rockwall II – Suite 815
Rockville, MD 20857

#04-7984
P.C. 840015

June 17, 2004

Re: HTWG Response to SAMHSA Request for Comments (FR Doc 04-7984 Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs)

Dear Dr. Vogl:

It was a great pleasure for the Hair Testing Working Group (HTWG) to meet on four (4) separate occasions from 1998 to 2001 to establish consensus guideline recommendations for the Drug Testing Advisory Board (DTAB) and Division of Workplace Programs (DWP) in general. As the Department of Health and Human Services (DHHS) Substance Abuse and Mental Health Services Administration (SAMHSA) developed laboratory requirements for those involved in drug testing using matrices other than urine, you probably recall that our working meetings were federally sponsored, involved a wide range of experts in the production of hair drug testing results, research and development and the programmatic side of hair testing. We were pleased that our input was generally well received by DTAB.

For clarity of the record, these 4 SAMHSA/DTAB – sponsored meetings of the HTWG were held:

1. At USAMEDCOM HQ, Fort Sam Houston, San Antonio, Texas; 0800-1600h, 13 November 1998. (9 Attendees representing 3 commercial hair testing laboratories, plus Military and Independent research stakeholders)

2. At USAMEDCOM HQ, Fort Sam Houston, San Antonio, Texas; 0800-1700h, 7 January 1999 and 0800-1500h, 8 January 1999. (16 Attendees representing the first 3 commercial hair testing laboratories plus 2 additional labs, plus Military and Independent research stakeholders and ONDCP)

3 At USAMEDCOM HQ, Fort Sam Houston, San Antonio, Texas; 0800-1700h, 29 March 1999 and 0800-1330h, 30 March 1999. (15 Attendees representing the first 3 commercial hair testing laboratories plus 3 additional labs, plus Military and Independent research stakeholders)

4. At Bally's Hotel and Convention Center, Las Vegas, Nevada; 0800-1800h, 29 January 2001. (23 Attendees representing the first 3 commercial hair testing laboratories plus 7 additional labs, plus Military and Independent research stakeholders and RTI)

Given the recent release by SAMHSA of the Notice of Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (NPRMG, FR Doc 04-7984), we were very excited to see the first formal acceptance and proposed rulemaking by the federal government using much of our input from these four sponsored HTWG meetings. A

great deal of energy and effort had been spent by the dozens of hair drug testing experts, researchers and interested individuals over our four years of collaborative work, so this marked a culmination in part for the HTWG's early mission and development goals.

Once the Request for Comments to FR Doc 04-7984 was published, we set forth to gather as much input at we could from former members of the HTWG, in order to forward a consensus document that would follow our normal strategy of providing the most consistent feedback to SAMHSA on the proper applications and interpretations of hair drug testing practices. We reviewed the NPRMG in light of newly received written and verbal input, documentation in the field, and also re-read and applied the outcome documents from the four HTWG meetings (previously provided to DTAB at the time of their generation). Through this approach, our goal was to provide current input and historically relevant context consistent with previous HTWG discussions and input to DTAB.

With that in mind, the remainder of this document is designed to help DTAB and SAMHSA generally as you convert the first draft of these Proposed Revisions to the Mandatory Guidelines into the final rules which will govern drug testing for federal employees and likely become the *de facto* standards for all workplace drug testing in the world, for the foreseeable future. We share the common concern that the final guidelines reflect the best technical and administrative policies and procedures, uphold fairness to tested individuals, while providing the best environment for detection and deterrence of drug use among our working populations.

This HTWG input is broken into two parts. The first contains general comments on the NPRMG, including discussion on the preamble component and general discussion on the Revised Guidelines themselves (this follows the format used in the composition of the NPRMG itself). The second section of our HTWG input has itemized comments, referencing specific components of the NPRMG. It is our hope that the DTAB/SAMHSA process will be best assisted by the HTWG through this format, but can reformat and resubmit this document as directed.

We also recognize that SAMHSA will likely receive detailed feedback from many groups and individuals in the field of workplace drug testing. Therefore, we do not expect a written response directly from SAMHSA or DTAB. However, we strongly recommend that all future DTAB meetings related to the NPRMG be open to HTWG members and others in subdisciplines related to the NPRMG (those involved with hair, urine, oral fluid and sweat drug testing). We would understand that such presence should be controlled. For example, no comments might be allowed from attendees outside of the public comment periods of these meetings, and pre-registration requirements may be imposed to minimize attendance by non-stakeholder public members who inadvertently happen upon the meetings or attend all government proceedings, regardless of their direct importance to the fields involved.

However, we also recognize that some of the previous lack of clarity and consensus on issues, and lack of favorable acceptance of some NPRMG decisions by those in the field, was caused by the previous DTAB meeting format. This DTAB format usually had many hours of closed sessions, and one or two hours of public comment without any DTAB feedback, in a two-day working meeting. We hope that you will strongly consider our recommendation for a more open process in the future, given the importance of the final Guidelines on the public, industry,

government, employment companies and (frankly) the world.

General Comments by the HTWG on the NPRMG Preamble

We find it encouraging that the NPRMG recognizes some of the less than favorable elements of urine drug testing approaches and applications, and recognizes the complementary nature of urine, hair, oral fluid and sweat drug testing. We believe that this complementary nature is embedded in a great deal of the NPRMG format and discussions, and are quite in favor of this recognition. No single matrix provides the information necessary for every investigation, detection and deterrence strategy, and the NPRMG is building a much better environment for complementary uses of drug testing technologies for the future. The comments made at page 13 of the NPRMG regarding the significant role that hair testing will play in the overall improvement of detection and deterrence – and therefore safety – within federal workplaces are incredibly accurate, timely and constructive.

Discussion of Potential Bias Should Be Removed

One point of over-discussion in the preamble appears to be discussion of possible biases that exist among populations of tested individuals. For example, any discussion of the possibility of testing bias related to hair color (which has been demonstrated to be FALSE in real samples and real applications of the testing technology) is inappropriate unless equal discussion is made related to the possibility of testing bias in urine, sweat and oral fluids. For example, testing bias has been proposed as a possibility (and even demonstrated in real subjects, in some instances) in the cases of:

- Urine testing gender bias
- Urine testing age bias
- Urine testing hydration bias (we do not correct urine test results for creatinine levels, even though we routinely test for creatinine and could make this correction)
- Urine testing idiosyncratic creatinine excretion leading to "dilution" reported results
- Urine testing diet bias
- Urine testing weight/body size bias
- Sweat testing activity bias
- Sweat testing climate bias
- Sweat testing thermoregulation ability bias based on medical status
- Mouth hydration bias
- Mouth stimulation bias involved with collection techniques

The urine matrix itself has a tremendous effect on what drugs are capable of being detected and for how long. Yet, urine effects are not mentioned in the current or Proposed Guidelines at all. Hair, sweat and oral fluid testing are not being added to the Guidelines in a vacuum. Therefore, if there is a concern for normalization of testing for individuals, then the possible sources of concerns noted above should be addressed for urine and other matrices in the Preamble and NPRMG.

As one example of difficulty that comes along with this discussion, HHS/SAMHSA has

set an "uncorrected cutoff level" in its urine program and has not taken into account any of the many areas that can create an effect on the outcome of that result. If the Department is going to broach this area now with hair testing, this also needs to be done with urine and other matrices. If the Department is not going to do this with its urine program, then it is inappropriate to single out any potential (even unsupported) effects in one or the other "alternate" matrices.

There are many other possible biases which could be mentioned and will be forwarded by those opposed to drug testing technologies in general. We believe the best course of action by SAMHSA is to remove any mention of possible bias for ANY matrix from the NPRMG. In this way the NPRMG is more appropriately designed to develop consensus Guidelines in collection and testing operations, not to try to answer fears and questions by some individuals and groups who will never be satisfied that the industry has a complete set of knowledge.

If Discussion of Potential Bias is Maintained in the Preamble

If SAMHSA wishes to MAINTAIN discussion of possible biases, we note that the Preamble indicates that the role of hair color is of "major concern" to the Department and cites animal studies and *in vitro* soaking exercises that show effects of hair color, as well as several human clinical studies indicating that some drugs may be affected by hair color. All of the studies cited that suggest color bias suffer from one or more serious flaws, including: 1) extracting hair with NaOH, a method that could never be used for workplace samples because it hydrolyzes 6-monoacetylmorphine; 2) failing to adequately wash the hair before extraction to remove sweat and contamination as the source of the measured drug; 3) use *in vitro* models that mimic soaking/contamination but are not valid models of *in vivo* incorporation into the growing hair fiber within the hair follicle; and 4) use animal models which are not appropriate to the incorporation mechanisms understood for humans, and do not recognize behavioral, environmental and hygienic differences between humans and these species.

The Preamble also refers to population studies in peer-reviewed literature that did not indicate any significant association between hair color or race and drug analyte. The Preamble cites three (3) such studies with over 5,000 data points that show no significant hair color effects. These studies can be supplemented by additional studies with 1,200 participants, 56,000 participants and 40,000 participants (citations: A. Mieczkowski, T and Newel, R. "An evaluation of patterns of racial bias in hair assays for cocaine: black and white arrestees compared". *Forensic Science International* V63, pp. 85-98 (1993); B. Mieczkowski, T and Newel, R. "An Analysis of the Racial Bias Controversy in the Use of Hair Assays", in: Drug Testing Technology: Assessment of Field Applications (ed: Mieczkowski T.), CRC Press, Boca Raton, pp. 313-348 (1999); C. Mieczkowski, T and Kruger, M. "Assessing the Effect of Hair Color on Cocaine Positive Outcomes in a Large Sample: A Logistic Regression on 56,445 Cases Using Hair. Analysis", *Bulletin of the International Association of Forensic Toxicologists*. V31(1), pp. 9-11 (2001); and D.Mieczkowski, T., Lersch, K., Kruger, M. "Police Drug Testing, Hair Analysis and the Issue of Race Bias", *Criminal Justice Review*, V27(1), pp. 124-139 (2002)). These studies pair hair and urine results on the same individuals. Paired hair and urine tests in side-by-side studies on the same individuals have shown – through tens of thousands of samples – that the methodology utilized in those studies demonstrate no statistically significant hair color effects. We are also aware of other studies that have been performed which clearly demonstrate the lack of a statistically significant bias among individuals due to hair color. We're sure that if DTAB or SAMHSA wished to receive these and other data on the subject, they would be made available by the researchers

involved.

The published studies with tens of thousands of data points utilized Psychemedics testing. There are also other laboratories which have incorporated techniques close to the Psychemedics aggressive washing, and taken together these have borne out their reliability with millions of real hair samples. The proficiency samples that the Department has sent out have made it quite clear that hair-testing results are methodology dependant. Without question, results are influenced by both the ability to remove externally-deposited drugs (such as through sweat), as well as the ability to remove drugs from the hair shaft itself through various extraction methodologies. Since the results are not consistent between the two groups of studies, shown in the Preamble, the methodologies employed in each need to be taken into account. For example, there could be extraction methodologies that may be more effective with thicker, porous hair and less effective with thinner, nonporous hair. The washing mechanisms may be non-existent or fail to remove externally-deposited or sweat-deposited drugs or metabolites. It is extremely important that the Department weigh the information in the studies based upon the particular laboratory methodology used by the researchers and the laboratory's results in the Department's proficiency surveys.

Along with efficient extraction methods (discussed below in some length), washing of the hair to remove sweat or environmentally deposited drug is the other major component of valid quantitative testing of drug deposited by ingestion. Any study performed without aggressive washing of the hair samples cannot be interpreted to represent ingestion, much less to assess the presence of a color effect. Considering the issue of sweat alone (and as mentioned above), it is known that individuals vary greatly in the amount of sweat produced, and that sweat varies depending on gender, exertion, stress, climate and season, hormonal status, clothing, nutritional and hydration states, and many other factors.

To compound the uncertainties due to variations in sweat production, the varieties and frequencies of shampoo and conditioner treatments used with different hairstyles may remove these varying amounts of sweat to greater or lesser degrees. Additionally, the effects of an individual's sweat exposure on his/her own hair can vary greatly for different hair types. For example, porous hair may easily soak up hundreds of times more drug than a nonporous hair, but such drug can also be removed with similar ease by effective washing procedures (reference: Cairns, T et al. "Removing and identifying drug contamination in the analysis of human hair". *Forensic Science International* in press (2004)). Information from studies cited in the Preamble that purport to show hair color effects that have improper or undemonstrated decontamination and/ or extraction methodologies must be weighted accordingly.

The overwhelming preponderance of evidence, with extremely large numbers of samples, performed with methodology that includes aggressive washing and effective extraction, indicates no hair color effect bias. What the studies show is that some methodologies may enhance or even create a hair color effect while other methodologies avoid it. With tens of thousands of paired hair and urine results showing the same urine and hair positive rates based on hair color, it has clearly been demonstrated that either no significant effects are present or any effect of hair color across large populations is identical for urine and hair. There is absolutely no justification for the Preamble to indicate a hair concern when all of the large population paired urine and hair data show identical results. Therefore, we believe

that no mention of this concern should appear in the Preamble. In the alternative, we believe the section should be clarified to indicate that, "large population studies have consistently shown hair color effects to be non-existent or insignificant when using appropriate hair testing methodologies."

IITF

Discussion and treatment of the Instrumented Initial Testing Facility (IITF) in the NPRMG (Section M) lowers the overall testing standards of the industry. We believe there should be reliance on the application of equivalent standards for collection (eg. assurances of volume and mass collected, freedom from cross-contamination during handling), testing (eg. cutoffs, specificity of testing, forensic defensibility of results) and interpretation (eg. medical review process, legal and technical defensibility of results) for all drug programs, whether point-of-care (POC)/on-site/field or laboratory based. Otherwise, lower standards for POC tests will lead to public concerns, hurt the overall acceptance of drug testing and minimize the quality of drug deterrence programs in general. This would hurt the public perception of SAMHSA and the federal government in general, which should be avoided whenever possible.

IITFs are essentially "screen-only" labs, and present a potential risk of a loss of integrity to the Federal testing program. Because of the lessened requirements in both personnel and equipment to conduct screening without confirmation, many labs would be able to qualify as SAMHSA certified facilities with little investment and little liability. On the contrary, confirmatory labs would assume nearly all (if not all) of the risk associated with testing a sample from start to finish. Then, any related litigation would fall on confirmatory labs, with the IITFs having no stake at all in the outcome.

Even more significantly, an IITF may perform virtually no Federal testing and have the bulk of its business be non-Federal testing, for which samples the IITF could perform both screening and confirmation. While able to describe themselves as SAMHSA certified facilities, these labs could be providing non-SAMHSA screening and confirmation quality assurance levels, using inappropriate methodologies and inadequate instrumentation. Based on current National Laboratory Certification Program (NLCP) bifurcation requirements, such deficient testing would not be evaluated in any SAMHSA inspection. Therefore, the credibility of being a SAMHSA-certified laboratory would be undermined and the integrity of the program would be diminished.

Our recommendation is that if IITFs are permitted, that they be permitted only in conjunction with a full laboratory certification i.e.: a company with a full SAMHSA certification would be permitted to utilize IITFs in remote locations. In this manner, there would be no financial incentive for fully certified labs to undermine or destroy the SAMHSA program, and the risk of an IITF doing substandard testing in the private sector would be substantially diminished.

Incorporation Mechanisms and Appropriate Pre-Analytical Techniques

Discussion in the Preamble states that drugs and drug metabolites may be incorporated into hair by several different pathways, including from the bloodstream and via secretions of the apocrine sweat glands and sebaceous glands. It also states that, "sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion." In our opinion, incorporation of drug into the hair during growth, before and during keratinization, must be distinguished from external deposition of drug on the keratinized mature

hair fiber.

Drug found on hair segments not corresponding to the time of ingestion is externally deposited drug that can and must be largely removed by aggressive washing techniques. Without such washing to remove drug that is deposited rather than incorporated, neither cutoffs nor metabolite criteria will allow consistent interpretation of hair analysis results. It has been shown, for example, that 100% of hair samples from 72 proven cocaine users in a clinical study contained external contamination in amounts ranging from 4 – 2000% of the drug content of the hair after washing (reference: Cairns, T et al. "Removing and identifying drug contamination in the analysis of human hair". *Forensic Science International* in press (2004)). We would recommend that the word "incorporation" in the sentence, "sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion" be changed to "deposition" to clarify this point. Additionally, the following sentence needs to be added. "Such deposition needs to be removed or accounted for."

The Preamble also states, "While washing the hair sample may remove some of the contamination, ultimately we can differentiate environmental contamination from actual use because of the presence of the metabolite which is not present when environmental contamination is the source of drug." This statement is only partially true. When a sample is above the cutoff for incorporated (not externally-deposited) parent drug, there are certain metabolites that can differentiate with certainty between external contamination and ingestion. Other metabolites present via metabolic processes can also be present via environmental sources and the latter must be removed by aggressive washing in order for their presence to add to the certainty of ingestion interpretation. It is, therefore, the combination of metabolite identification along with washing of the sample, analysis of the wash, and the application of cutoff levels that completely differentiate environmental contamination from actual use. We, therefore, recommend that this section be changed to indicate that, "...ultimately we can differentiate between environmental contamination and actual use because of the presence of metabolites, in combination with effective washing techniques and cutoff levels".

Initial proficiency testing with hair samples has shown the critical need for improved methodologies for some laboratories, especially in washing techniques and extraction methods. Even when washing issues are avoided in the surveys, a number of laboratories were unable to extract even 50% of the drug content of the samples. To accept conclusions in studies regarding quantitative levels of drug in hair from any laboratory that has not demonstrated near 100% extraction efficiency for all types of samples – whether porous or nonporous, fine or thick – and to extrapolate data obtained by such inadequate methods to demonstrate a hair color bias, is completely without merit (as noted above).

Use of Two Amphetamine Screens to Include MDMA and Other Amphetamines

The Preamble requests recommendations on the use of a single amphetamine test kit or the need to use separate test kits for the detection of MDMA. While the use of separate test kits may be appropriate for urine, the one FDA-approved hair drug test kit has been shown to detect MDMA with equal sensitivity to methamphetamine in a single kit. We would therefore recommend that the use of separate test kits not be required where it would have no benefit.

Preamble and Guidelines – Comments on Direct Citations

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 4/ "...it has been very helpful to keep in sight important areas of consideration that have remained visible as the program matured over the next 15 years. These include, but are not limited to, custody and control that ensures donor specimen identity and integrity, specimen collection procedures, analytical testing methods, quality control and quality assurance, reporting results, the role of the medical review officer (MRO), and HHS certification issues that include testing site inspections and performance testing (PT) samples." Make sure that the document actually covers these, and remember that the Federal rules didn't cover many of these areas well for urinalysis ever or for many years.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 5/ "...alternative specimens and drug testing technologies, including head hair, oral fluid (saliva), and sweat for possible application in Federal workplace drug testing programs." Why is hair limited to head hair? This severally limits the collected specimen available, and the population tested, based on experience within the industry and agencies already using hair as the primary collected sample. We recommend reconsideration to include body hair other than public hair, if a head hair collection would lead to quantity not sufficient (QNS) samples.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 9/ A section describing hair testing is not limited to head hair. It states: "The Department is proposing that hair testing be included in the Federal Workplace Drug Testing Program." Clearly, the Department had been advised to include all types of hair when it received previous input from the HTWG that we co-chaired. However, toward the end of our repeated input to DTAB our advice recognized the public statements that some parties had made and eliminated pubic hair from the list of body sites from which a workplace subject's hair would be collected under the proposed Federal standards. The acceptability of pubic hair samples was not diminished, just the likelihood that the Federal government would authorize collection from Federally-mandated workers.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 10/ Discussion of hair growth states that: "Hair grows in three stages: about 85 percent of hair follicles are in active growth (anagen), while the others are in a transition phase (catagen) before the resting phase (telogen)." Clearly, this does not recognize the growth rate differences between head hair and hair from other body sources. This will have to be addressed when an (appropriate) change is made from "head hair only" regulations to include other body sites (other than pubic sources).

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 10/ The text states: "At the vertex region of the scalp, the average growth rate of hair is about 0.4 millimeters per day or about 1 centimeter per month." and cites Nakahara's 1999 article as the source. This growth rate (for head hair) would actually equate to about 1.2 centimeters per month, not 1 centimeter per month.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 10/ The text says that cannabinoids are detected using THCA by the laboratory. By remembering that THC predominates in hair of marijuana users by a factor of up to 100X, laboratories should be allowed to use THC detection instead of THCA detection to capture marijuana use in a subject, especially in screening

techniques. If confirmation continues using THCA, the cutoff should be increased from its current value so that incorporation of a "60% of cutoff" control is achievable.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 11/ The text states: "While washing the hair sample may remove some of the contamination . . .". In actual cases (and as discussed above) appropriately washing hair often removes all of the environmental contamination from the sample prior to extraction or dissolution. In addition, parent drugs often predominate over metabolites; therefore, requiring the detection of metabolites in every positive case may create false negatives as a result of testing. This factor should be carefully considered by DTAB/SAMSHA for some amphetamines and other drugs currently targeted or which may be included in the future.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 11/ The text states: "...ultimately we can differentiate environmental contamination from actual use because of the presence of the metabolite, which is not present when environmental contamination is the source of the drug." This statement presumes that environmental contamination never arises due to unknowing ingestion of a drug by an individual. In reality, many complaints arise from positive individuals, based on their purported innocent exposure to drugs in their environment, in which case they claim to have unknowingly ingested these drugs. These interpretive questions must be addressed on a case-by-case basis, as they are for testing results from any biological matrix.

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 11/ The text states: "The role of hair color is also a major concern." This text has been followed by a relatively balanced review of the role of melanin on drug incorporation of hair from subjects in certain subpopulations. This opening sentence is an overstatement of the scientific reality involved in hair color bias. Therefore, this opening statement should be changed to reflect the last ten years of research which have demonstrated hair color bias is not an issue in hair drug testing (see discussion above).

FR Doc 04-7984/Page of NPRMG on Web in Acrobat = 37/ The text states: "...the Department believes it is more appropriate to conduct a drug test using a different specimen rather than attempting to collect hair from another body site." Experience with casework has demonstrated that privacy concerns with hair samples other than pubic hair are not an issue. Given the fact that hair drug testing provides a time period of drug use knowledge far superior to other biological samples, the Department should accept testing of hair samples collected from sites other than pubic areas, as discussed above.

FR Doc 04-7984/Section 2.2 / The text clearly sites the use of hair testing in "pre-employment, random, return-to-duty [and] followup" scenarios. We completely agree and reflect again our appreciation to SAMHSA for the recognition it is now providing to hair drug testing, for the first time in writing, through this NPRMG. This recognition has been present from thousands of employers using millions of hair drug tests over the last 15 years, and it is good to see the federal government applying this technology in the future to meet our drug use reduction goals.

FR Doc 04-7984/Section 2.5 / The text clearly sites the minimum quantity of specimen to be collected in the NPRMG. We support the agency's recommendation that 100 mg of head hair, divided as approximately 50 mg per sample, is the appropriate quantity of specimen to be

collected. (This amount is more than twice that currently utilized in the majority of workplace testing). However, collector handling of the sample needs to be as minimal as possible to avoid getting the root ends misaligned or turned around, and avoiding cross-contamination. We therefore recommend that the collector take an (A) sample in accordance with the procedures, place the sample in the "(A)" collection container, then immediately take the "(B)" sample from approximately the same area. This will reduce the chance of collector error and would be a more workable procedure if a 75/25 procedure were desired. Split samples have been collected in this manner for years.

FR Doc 04-7984/Section 3.2 / The text appears to state criteria used to report a hair sample as adulterated. Laboratories and researchers in the field of hair drug testing regularly review and test products that claim to remove drugs from hair. HTWG members have found no effective adulterants and there are no published references indicating effective adulterants or tests for adulterants, at this time in hair analysis. We recommend that section 3.2 be eliminated. While it may appear reasonable to prepare for the eventual existence of adulterants, at this time it appears that the Department is attempting to correct a non-existent problem.

FR Doc 04-7984/Section 3.4 / The text clearly sites the cutoff concentrations to be used under the NPRMG. For the most part, the HTWG supports the initial test cutoff concentrations, but believe the confirmatory test cutoff concentration for marijuana should be raised from .05pg/mg to 0.1pg/mg. There appears to be consensus among laboratories that the .05 pg/mg cutoff is too low to maintain in a commercial setting with appropriate controls. Raising the cutoff to .1pg/mg is more in line with the current cutoff used in the bulk of hair testing performed today would, when coupled with effective extrication methodology, permit adequate detection rates commensurate or better than urinalysis.

Also, on the confirmation for opiates, note 3 indicates that a specimen meeting the cutoff level for 6-acetylmorphine must also contain morphine at a concentration greater than or equal to 200 pg/mg. We believe that this should be changed to reflect that a specimen that is positive for 6-acetylmorphine, an absolute marker of heroin use, would need only contain morphine at a concentration above the limit of detection (LOD).

Finally, the requirements related to reporting methamphetamine confirmation should be altered to reflect the current, industry-adopted standards. In short, the most common approach by many laboratories is to determine both the d-methamphetamine and d-amphetamine isomer contents immediately upon quantifying methamphetamine above the cutoff, not waiting for an MRO request. If the predominant quantitative finding is for the l-meth and l-amp isomers, the initial reported result for the hair drug test would change from an inappropriate Positive finding to an appropriate Negative finding. This would avoid confusion and waiting by the submitting agency and MRO involved with the case, and build greater acceptance by submitting agencies for the implemented reporting standards for the industry. Also, adoption of the industry-standard cutoff of 500 pg/mg methamphetamine with 200 pg/mg amphetamine required would make the d/l-isomer determinations more analytically straightforward for (especially low) positive hair samples in most laboratories.

FR Doc 04-7984/Section 3.8 / The text clearly describes required validity tests for hair samples. While the HTWG supports such testing for other matrices in which unobserved collections are

common (urine, especially), we believe that validity sample testing is unwarranted for observed collections. One of the benefits of hair analysis compared to urine analysis is that not only is the sample obtained in full view, it is obtained by a trained collector. The observed collection does not give the donor the opportunity to substitute samples. We believe that section 3.8 should be deleted. In the alternative, the laboratory should be able to determine if a sample is valid by conducting one of the tests on the list that has been validated by the laboratory. Performing all of the tests on every sample would be overly burdensome and would not add to the program in any meaningful way.

FR Doc 04-7984/Section 3.9D / The text clearly cites the NPRMG criteria to report a hair sample as invalid. The Guidelines state that the primary sample should be called invalid if the physical appearance of sample (A) and (B) are clearly different. Differences between the A sample and B sample would not be apparent, however, as the B sample would be sealed and not opened unless the A sample was positive. If the A sample was positive, a different lab would be opening the B samples. We believe that information on the color and length of the A sample should be sent to the second lab whenever a B sample is forwarded. There is no way for the laboratory testing sample A, however, to know the physical appearance of sample B.

FR Doc 04-7984/Section 4.2 / The text clearly cites the need for collections by a trained collector. The HTWG believes that item (a) requiring collectors to read and understand the guidelines in their entirety is overly burdensome. The collectors should need to read and understand the guidelines <u>as pertains to their functions as collectors.</u> If they work for an agency that collects multiple types of samples (urine and hair, for example) they should be familiar with those two types of collections, as found in the Guidelines.

FR Doc 04-7984/Sections 4.1, 5.1 & 5.5 / These criteria clearly cite the limitation to Head Hair Collections, under the NPRMG. The HTWG believes (as discussed at length, above) that in the Preamble, SAMHSA indicates that head hair would the only sample allowed, based on its rationale that the head is the least invasive area to collect a hair sample and affords the donor the most privacy. The Preamble notes: "The Department believes it is more appropriate to conduct a drug test using a different specimen rather than attempting to collect hair from another body site."

On the surface this seems reasonable. However, when the rest of the guidelines are reviewed, it becomes apparent that sweat patches can be applied to an arm, back or chest, and that observed collections are allowed for urine testing. Certainly, an observed urine collection is far more intrusive than collecting hair from an arm. In order to be consistent in eliminating any invasive collections and perhaps all hair collections via the arm or the chest, the Department would have to disallow the application of sweat patches on arms and chests as well. Additionally, observed urine collections would no longer be permissible. It should be remembered that <u>all</u> urine testing, observed and not observed, involves the genitals. The HTWG agrees that hair testing could be limited to head hair, arm, leg, underarm, or chest hair, without ever involving the genital region for any collection.

Body hair collections have been performed in private industry without issue for years (most corporations simply eliminate pubic hair, even though there are a large number of important pubic hair collections used to address military casework needs every year). When body hair is

limited to sites other than pubic hair, the collection of these samples is less intrusive than urine testing. If SAMHSA felt that it was absolutely necessary for privacy reasons, the collection of arm or chest hair could be performed by the donor themselves under observation and would certainly be less intrusive than observed urine collections.

The proposed elimination of body hair would allow donors to "game" the system by shaving their heads to purposely obtain the shorter detection window of urine or saliva which would be more likely to be negative. This would have a detrimental effect on the integrity of the program. For the above reasons, the HTWG believes that the limitation of hair collections to head hair should be changed and that body hair, with the exception of pubic hair, should be allowed to be collected.

FR Doc 04-7984/Section 8.2 / This Section clearly limits collection of a head hair sample when lice are observed. The guidelines indicate that evidence of lice will require stopping the collection procedure and obtaining a different type specimen. The HTWG believes that the concern should be more general and applicable to all matrices. For example, phrasing could be used that stated: "If collection of a sample is problematic and/or the collector believes an adequate or appropriate sample cannot be obtained, the collector may obtain a different type of sample." This is a more generally applicable to all matrices, and could apply to cases involving lice, shy bladder, dry mouth and skin that the patch will not stick to.

FR Doc 04-7984/Section 8.2 (a) 9 / The HTWG believes that this Section is too specific. The collection procedure indicates that the collector folds both foils length-wise and each sample is placed in an envelope with root ends to the left. The indication of root ends going to the left is unnecessary; the collector simply needs to place the sample in the envelope and then apply the appropriate forensic sealing practice governed by the laboratory's collection device.

FR Doc 04-7984/Section 9.3 / This Section defines the process to become certified. The HTWG recommends that the word "applicable" be inserted in front of "guidelines" so that the requirement of a laboratory, or IITF, to become certified is that they "Read and understand these applicable guidelines." As pointed out above, it is not necessary for a laboratory that is certified in urine to necessarily understand the procedures regarding sweat, and vice versa.

FR Doc 04-7984/Sections 9.5 (a) (2) & (3) / These Sections specify the technical requirements for the Proficiency Testing (PT) samples. The HTWG believes that because of the low levels of drugs found in hair, we recommend that the concentration of a drug or metabolite to be at least 50% above the cutoff concentration for the screen and 25% for confirmation.

FR Doc 04-7984/Sections 9.10 (a) (8), (9) & (10) / These Sections refer again to validity testing requirements. The HTWG would ask SAMHSA to consider our comments related to Section 3.2, 3.8 and 3.9D (above).

FR Doc 04-7984/Section 11.12 / This Section of the NPRMG specifies requirements for Initial Drug Tests. The HTWG supports the requirement that drug test kits meet FDA requirements for commercial distribution. As more and more laboratories enter the field of "alternative matrices" and/or develop tests for urine, there needs to be a mechanism to insure accuracy and reliability. FDA has served in this capacity since 1987 with the urine program, and we support

its continued inclusion in the requirements.

FR Doc 04-7984/Sections 11.14 (a) (2) & (3) / These Sections of the NPRMG specify batch quality control requirements when conducting Initial Drug Tests. The HTWG believes that because of the low drug and metabolite levels found in hair analysis as compared with the urine matrix, we would recommend that 11.14 (2) & (3) be amended to allow the use of controls with drug or metabolite targeted at 50% of the cutoff.

FR Doc 04-7984/Section 11.15 / This Section of the NPRMG specifies requirements for Confirmatory Drug Tests. The HTWG agrees with SAMHSA in 11.15(a) that validated triple quad mass spectrometry analysis is not only appropriate, but for some analytes, the most effective instrument available. Therefore, others who may wish to relax from this standard may be providing forensic results which would call the overall SAMHSA certification program, as defined by the NPRMG, into question.

FR Doc 04-7984/Sections 11.18 & 11.22 / These Sections refer again to validity testing requirements in the NPRMG, in these sections specifically the analytical and Quality Control requirements for conducting validity tests on hair samples. The HTWG would ask SAMHSA to consider our comments related to Section 3.2, 3.8 and 3.9D (above).

FR Doc 04-7984/Section 15.1 / This Section of the NPRMG provides requirements for Split Specimen Testing. Specifically, the NPRMG at Section 15.1(c) states that if split specimens cannot be tested due to insufficient specimen or a lost sample, the MRO can direct the Federal agency to collect another specimen. The HTWG supports this inclusion in the regulations. We agree with the agency and support the ability of the MRO to order the collection of another specimen. While in some instances the donor may have taken evasive maneuvers to avoid a positive result, in other instances this may not be possible and it provides at least an opportunity to corroborate a first specimen, should an issue arise about the split sample.

FR Doc 04-7984/Section 15.3 / This Section of the NPRMG provides requirements for the testing of the Split Specimen for adulterants, when the Primary Specimen has been reported as adulterated. The HTWG feels that this section needs clarification, as there are no known adulterant tests in the literature for hair testing or any demonstrated effective adulterants.

As a final, closing, statement, the HTWG wishes to express our appreciation to SAMHSA for the generally high level of the NPRMG. Although a great deal of work remains (anytime changes are made of this magnitude by ANY agency to ANY regulation, it involves significant effort by all involved!) The Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs that contain provisions for hair, oral fluid, and sweat testing can only serve to enhance the effectiveness of the drug testing programs that have been in existence for years for urine. The HTWG believes that it is in the public's best interest to provide employers and agencies with all the tools available to deter workplace drug use.

Sincerely Yours,

Carl M. Selavka ***Donald J. Kippenberger***

Carl M. Selavka, Ph.D.
Co-Chair – Hair Testing Working Group

Donald J. Kippenberger, Ph.D.
Co-Chair – Hair Testing Working Group