

Comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004)
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Executive Summary:

The proposed guidelines do not meet the "gold standard" that has been established by the Department for federal workplace drug testing. This proposal contains serious problems and omissions that render major sections of the document unacceptable as presented. The document itself acknowledges numerous serious concerns and limitations associated with its own proposals; particularly regarding alternative specimens. Current state-of-the-science knowledge does not provide an adequate foundation on which to build procedural guidance for the use of alternative specimens. Substantive gaps in knowledge and research exist regarding the use of sweat, hair and oral fluids for drug testing. An attempt to formulate federally mandated policies and practices at this time, without further study, is unwise. The proposal to utilize alternative specimens for federal workplace drug testing should be withdrawn. Point of collection testing (POCT) represents a technology that has not achieved the level of scientific or legal acceptability necessary for use in federal drug testing programs. Many questions remain unanswered as to whether POCT can produce forensically defensible results. As such, the proposal to utilize POCT for federal workplace drug testing should be withdrawn. Additional concerns regarding this proposal are addressed within.

General Comments on Alternative Specimens:

In the late 1980's when employment-related, forensic urine drug testing evolved from a disparate set of laboratory procedures into a formalized federal workplace program, the development process that shaped the drug testing guidelines focused on "how" to do it. While the laboratory procedures being utilized for drug detection were not well standardized, the testing of urine samples for drugs had been successfully performed for nearly two decades. As a result of this solid scientific and technical foundation, the establishment of guidelines for the testing of federally-regulated samples dealt mainly with procedural issues - how can the testing of urine for abused drugs be performed in a manner that will withstand both scientific and legal scrutiny. In other words, the discussions were primarily procedural - how to accomplish the task at hand.

With the release of the **Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs** (Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004) addressing the testing of alternative specimens, it appears that the tenor of the ruling making deliberations has changed significantly. Rather than discussing "how" to establish testing guidelines, many issues have been raised about "whether" the use of alternative matrices is forensically viable in a federal workplace context. Framed as a question: Is the scientific foundation associated with the testing for abused drugs in

sweat, oral fluids and hair sufficiently solid to support an attempt to develop specimen handling and analytical procedures designed to ensure that results are forensically defensible for federal employees? One might also ask: Do the proposed guidelines, as presented, satisfy the fundamental requirement of a solid scientific underpinning that has wide acceptance within the toxicology/drug testing community? Can the DHHS document as it currently exists be used to develop appropriate testing protocols given the number of unresolved scientific issues? Does this document provide the sufficient technical basis necessary for establishment and implementation of federal workplace drug testing procedures?

The internal and external pressure from both governmental and commercial entities to develop these proposed guidelines is well known. Yet despite these demands it took the "best minds in the business" over six years to compose this proposal. The length of this effort may, in part, reflect the bureaucratic constraints associated with any endeavor of this magnitude. However, even a casual reading of the proposed guidelines reveals the enormous complexity of the scientific and technical issues being addressed. No doubt, the framers of this document spent untold hours wrestling with these issues, many of which remain unsettled.

What is the true risk of environmental contamination associated with hair testing? Does the testing of hair have an ethnic or racial bias? Does dark-colored hair absorb more drugs (from whatever source) than light-colored hair? What is the true risk of environmental contamination associated with sweat patch testing? Which skin cleansing techniques actually remove all surface drug residues prior to sweat patch application? Does the variation of sweat production between individuals have an effect on testing results? Are there reasonable conditions under which drugs can migrate from the environment, through the patch's membrane, into the patch's collection layer? What is the actual detection window for drugs in oral fluids? Is the detection of THC in oral fluids possible in a forensic context (with or without additional/alternative specimens)? Do we fully understand the role of pH and its effects on the detection of drugs in saliva? Without the answers to these and other essential questions, it is even possible to articulate laboratory procedures that are legally defensible? Would DHHS actually consider the institution of governmentally mandated rules that have the potential of ethnic and racial bias?

The existing federal workplace program has been portrayed as the model, if not the gold standard, for fair, effective and appropriate employment-related drug testing - and rightfully so. The urine testing program was based on a proven scientific and technical footing. However, the basic questions raised (and left unanswered) by these proposed guidelines for alternative specimens create an environment that is not similarly conducive to the establishment of "gold standard" procedures. In fact, procedures developed to implement alternative specimen testing could actually undermine the hard-earned reputation of the established urine-based program. Without a proven scientific and technical foundation, decisions regarding "how" to perform drug testing in sweat, oral fluids and hair could formalize practice standards that would ultimately be detrimental to the goals of federal workplace testing. If the Department of Health and

Human Services is indeed responsible for establishing the scientific basis from which federal workplace testing procedures are to be developed (based upon the current state-of-the-science), it appears that the proposed guidelines fail to meet that fundamental mandate. As a result, procedural discussions designed to guide laboratories' analytical efforts become problematic, if not illusionary.

Even if all of the unresolved scientific issues associated with alternative specimens were adequately addressed, there remains another fatal flaw associated with this proposal - drug detection equity. With the use of a single drug detection specimen (urine), all federal employees are essentially treated equally when it comes to the drug detection time window. The introduction of alternative samples turns the drug detection time window on its head. Where is the equity for a federal employee or applicant who takes a hair test (with a drug detection window of up to 90 days) versus another worker who is subjected to a federally mandated urine test (with a drug detection window of up to five days)? Is there any equivalence between a federal worker who undergoes an oral fluid test (with a drug detection window of 24 hours) and one who wears a patch for seven days? Because so little is known about how the testing cutoffs associated with alternative specimens relate to the drug detection window (both within a specimen type and between different specimens), the principle of drug detection equity as it relates to workplace testing is totally compromised. The difficulties associated with the interpretation of two different specimens, both with accurate yet differing results (i.e. a positive hair test and a negative urine test) are obvious. This level of potential confusion will certainly not enhance the prospects of a drug-free federal workforce. Combined with the loss of drug detection equity, the use of alternative samples (as currently proposed) will likely be seen (and litigated) as arbitrary.

It is for these reasons that I respectfully submit that the proposed guidelines for the testing of alternative specimens be withdrawn until such time as a scientific consensus can be reached on the most significant outstanding issues. Clearly, additional research is necessary. The drug testing program currently in place (that utilizes urine) provides the Department with very adequate procedures for maintaining a drug-free federal workforce. The political and commercial pressures notwithstanding, there is no need to "rush to judgment". The proposed guidelines in its current version represents a major step toward standardizing the use of alternative specimens and outlines the scientific challenges that lay ahead. But these guidelines also pose at least as many questions as they answer, and as such require additional evaluation, research and review prior to the implementation of procedural guidance. To attempt to establish forensically defensible programmatic guidelines based upon the current proposal would set in motion procedures that could undermine the veracity of the entire federal workplace drug testing program.

General Comments on Point of Collection Testing:

A strong quality assurance system is the heart and soul of a successful forensic program. The current federal workplace drug testing program can trace much of its

success to the accountability that is maintained between the various components of the program (i.e. collection site, laboratory, MRO, employer) and the checks and balances that ensures forensically valid results. Each element of the system verifies the procedures and, to some extent, the documentation of other parts of the federally-regulated drug testing process. This serves to guarantee that the quality of the service will be maintained as mandated by federal law.

The Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004) proposes to permit the testing of federal employees at the point of sample collection - so called Point of Collection Testing or POCT. The rationale for POCT (as stated in the proposed guidelines) is to allow the testing of employees "located in remote areas of the country" "or overseas". The promulgation of these proposed POCT rules raises serious questions. Why would the Department develop and propose this significant body of guidelines and establish a detailed POCT validation and inspection program and evolving list of certified devices for such a limited number of end users? Does the Department believe that with the multitude of shipping options available worldwide (including many next day services), that it is *not* possible to send a sample to a certified laboratory from a distant point of origin and receive results in a reasonable time frame? The very premise of the proposed POCT rules seems erroneous (assuming the premise has been accurately stated). Is it logical to create an entire new bureaucracy of drug testing guidelines for a relatively few number of employees?

The proposed POCT guidelines also represent a major policy shift. If a federal agency chooses to use POCT, "then it accepts some of the same responsibilities for ensuring compliance within their agency as the Department currently maintains for the laboratory-based Federal drug testing program". The key word in this phrase is *some*. Simply put, it is not possible for a federal agency choosing to use POCT, to accept the same responsibilities for ensuring compliance as the Department currently maintains for laboratory-based Federal drug testing programs. In fact, it is not possible for a federal agency choosing to use POCT, to accept most of the responsibilities for ensuring compliance as the Department currently maintains for laboratory-based Federal drug testing programs. Rather, a selected group of responsibilities is proposed for POCT. The end result is that POCT would have to meet a substantially *lower* standard than laboratory-based testing **AND** accept few of the checks and balances imposed on the current system that delegates distinct duties to specific parties (i.e. collectors, laboratories, MROs).

The success of the proposed POCT-based program relies on two components; the testers and the devices. From a historical perspective, the testers (i.e. collectors) present an enormous problem. It is widely acknowledged within the urine drug testing program that sample collection services and their personnel represent the most error-prone segment of the entire process. Even after years and years of definitive and detailed program guidance, statistics demonstrate that some laboratories have a greater number of *anceled* samples (due to collection errors) than confirmed positive samples. These guidelines propose that the functions of sample collection, drug testing and

quality control utilizing POCT devices, security, custody and control and result reporting all be provided by sample collectors (that part of the program with the highest error rate). From the point of view of a laboratory, that has had to endure over a decade of collector-related problems, simply put - this prospect is very unsettling.

The Department has provided references that suggest "laymen" can utilize POCT devices with equivalent success when compared to "laboratory technicians". However, a closer review of these publications reveals that the error rates for non-technicians was significantly higher in some categories. In addition, these studies did not investigate the non-technician's capabilities to successfully complete the entire drug testing process including sample collection, custody and control, drug testing, quality control, result reporting, etc. Of further concern is that this proposal offers no detailed training guidelines for the POCT testers! Even if one were to accept the concept that laymen could be trained sufficiently to perform a forensically acceptable POCT, the proposal lacks any specifics on how this would be accomplished. At an absolute minimum, a program similar to DOT's breath alcohol technician (BAT) training course and certification must be implemented. Regardless, even if the POCT devices themselves were error-free (which of course they are not); the utilization of collection personnel as federal workplace drug testers raises insurmountable forensic hurdles. Recent criminal justice hearings (to which this commenter was a party) questioned the drug testing results from a certified laboratory merely on the grounds that the specimen *collector* was not adequately trained and/or certified. Imagine the legal challenges when the collector becomes the entire process. Can the Department truly envision a system where the group responsible for the majority of errors in the existing federal workplace drug testing program are allowed to take on the added responsibilities outlined in this proposal associated with POCT?

The POCT devices themselves pose additional concerns. By their very nature, POCT devices represent a more "subjective" type of drug detection. Laboratory-based instrumentation produces a numerical value (drug concentration) which can be directly compared to a cutoff calibrator. This allows for a precise, objective discrimination between samples being identified as "positive" versus those samples determined to be "negative". There is no guesswork; a sample is either at or above the cutoff or below the cutoff. Non-instrumented readings requiring "visual eye" determinations rely upon a more subjective observation (i.e. a color either appearing or disappearing). In order to render a determination, the POCT tester must ascertain whether a color change on a test strip has changed sufficiently to indicate a drug's presence or absence. POCT devices are in wide use nationally in many criminal justice programs. As a result, there is an experiential database (albeit anecdotal) that suggests that different POCT testers "see" results differently. One person may call a result negative based upon a color change while another person witnessing the exact same reaction may interpret the change as positive. In the event of a false positive determination, the discrepancy would be identified by laboratory-based confirmation. However, false negative determinations under the proposed guidelines would remain unidentified (unless that sample was selected as a 1 in 10-quality assurance sample). And since all negative POCT samples "must" be discarded, there is no mechanism to determine the true POCT false negative

occurrence frequency.

In addition to these major problems, there are also numerous other concerns. There is no guidance that POCT testers abide by the expiration dates of the POCT devices (even though this is an obvious requirement). The reliability standards proposed for POCT appear to represent a lower *actual* standard of accuracy than that mandated for laboratory-based testing. The requirement that POCT testers identify their own failures to a federal agency has serious compliance shortcomings and further illustrates the lack of checks and balances. In fact, the entire issue of POCT failures is without requisite specificity. The validation criteria for POCT devices at the testing site are poorly defined. The POCT daily QC requirements are virtually unenforceable. An unscrupulous POCT tester could simply annotate a document indicating QCs had been assayed without actually performing the QC analysis. In laboratory-based testing, an instrument paper trail makes this type of fraudulent scheme nearly impossible.

The Department acknowledges that there are no POCT devices for either hair or sweat. POCT devices for saliva suffer from the same marijuana detection problems that affect laboratory-based oral fluid testing (necessitating the collection of a urine sample) - rendering on-site saliva testing not worthwhile (see later comments). The proposed guidelines identify only four references evaluating the accuracy of urine drug testing by POCT (only three of which address forensic testing). Crouch et al., (2002), reported "few false negative and false positive results"; Kadehjian, (2001), found "impressive performance capabilities" and the SAMHSA study (1999), indicated: "The favorable performance of the devices was encouraging considering the simplicity of their design and operational requirements. Some devices were able to identify more positive specimens, but this was accompanied by a higher percentage of false positive results. Other devices were more conservative, giving few false positive results but missing many true positives." Score: two votes yeah; one vote undecided. This research (or the lack thereof) reflects the dearth of peer-reviewed, controlled studies in evaluating the reliability of POCT in a forensic urine context and illustrates the inadequacy of the data that might otherwise be used to make an informed judgement as to the applicability of POCT for employee testing. Is the Department willing to stake the future reputation of the federal drug testing program on what essentially is unproven technology (at least in the workplace testing environment)? Does the Department truly believe that "real-time" evaluations/validations of POCT devices (*post* rule making) is the appropriate approach to dealing with the lack of scientific data on POCT reliability? While additional studies may be currently underway, data comparing testing results from a POCT site with POCT testers versus results obtained in a certified laboratory are simply not available for review. During the six-year development phase of this proposal, why was that comparison not done?

Point of Collection Testing is currently not compatible with federal workplace employee testing and as proposed is unworkable in a forensic context. POCT is not appropriate for three main reasons: (1) an all-in-one testing concept that eliminates effective checks and balances, (2) the competency and reliability concerns regarding POCT testers who will be drawn primarily from existing specimen collection personnel and (3) visual result

determination of POCT devices which is subject to considerable variability. Additionally, based upon the number of employees located in remote areas or overseas, the premise for establishing federally-certified POCT is not supportable and therefore represents an unnecessary body of rulemaking. Lastly, POCT and procedures that direct their use have the potential of becoming a source of great confusion. The responsibility for developing a POCT program with its incumbent standard operating procedures rests on the employer (in the case of this proposal, the federal agency using POCT). The development of drug testing SOPs that encompass sample collection, chain of custody, security, drug testing, quality control, sample handling, result reporting, etc. is a complex and technical challenge. It is unlikely that agencies (or perhaps individual employers - if the proposed program is adopted by the DOT) have the expertise to create such documentation. As employers (agencies) attempt to develop their own practice guidelines (for which few, if any, have the training or expertise to accomplish) the results could be hundreds of POCT sites with differing SOPs. A federally regulated POCT program for federal employment testing would be impossible to control and regulate in any meaningful way.

Specific Issues:

- 1) First and foremost, the DHHS rules (in whatever form) need to be developed in consultation and in cooperation with the Department of Transportation. Federally-certified laboratories test primarily DOT samples. In reality, federally-regulated drug testing *is* DOT testing. A two-tiered federal drug testing program with divergent rules will only serve to add significant complexity to all parts of the system - collectors, laboratories, MROs and employers. There is little doubt that if/when these rules are finalized that DOT will come under considerable pressure to adopt some equivalent standard. However, many of these proposed guidelines (in their current version) are unworkable in a DOT scheme that covers tens of millions of regulated employees.

One of the most important aspects associated with federal workplace drug testing is consistency - all federally-regulated workers being treated equally. To be sure, the topics presented in this response reflect this commenter's concerns about the technical and scientific issues presented in this proposal. But these comments are motivated to a greater extent by the potential (perhaps unintended) consequences that these proposals pose to DOT testing - than by their effects on *federal* employees. Our laboratory, like many other certified laboratories, perform little drug testing for the federal agencies covered by DHHS. Almost all of our federally-regulated testing is performed for DOT clients. Nonetheless, we are keenly aware of the impact that DHHS rules have on the total drug testing universe (both regulated and non-regulated).

It is essential that agencies directing federally mandated drug testing attempt to speak with one voice. This has not always been the case. The outcomes of conflicting efforts have not always been pleasant or resulted in effective employee

management. The Department is strongly urged to seek consensus with DOT on these important and far-reaching issues.

- 1) The guidelines propose that a urine sample be collected at the same time as oral fluid collection in order to eliminate the possibility of incorrect test results for marijuana. This proposal is unprecedented. The burdensome aspects of this requirement alone make this proposal (and therefore the use of saliva as a drug testing specimen) unfeasible in addition to impractical. The fact that this dual-specimen proposal made it through the rule-making process at all suggests the tortured logic being applied to "force" alternative specimens to be made workable in the federal workplace testing arena. Why would any federal agency (or employer) select oral fluids as a drug testing specimen knowing urine would have to be collected anyway? Given that marijuana is the drug most frequently identified by the current federal testing program, why would the Department propose rules that legitimize a specimen (saliva) known to produce problematic (and perhaps erroneous) results? This commenter has already outlined concerns sufficient to support the withdrawal of oral fluids as a proposed alternative specimen for federal workplace testing. This comment reinforces the unacceptability of saliva for the purpose of workplace testing at this time.

- 1) The proposed guidelines define and limit alternative specimen collection and testing to specific employment-related situations (i.e. hair - for pre employment, random, return to duty, follow-up, but not for reasonable cause; sweat patch - for return to duty, follow-up, but not for pre employment, random, reasonable cause or post-accident, etc.). As mentioned earlier, sample collection services and their personnel represent the most error-prone segment of the entire federal drug testing program. With multiple CCFs (one for each specimen), collections restricted to only specific employment-related situations, different collection schemes for different employers, etc., the complexity of the collection process increases exponentially. Simply put, the collection system (as it is currently regulated or not regulated) is not capable of handling the provisions of this proposal. Organizations such as DAITA have made significant progress in the education and certification of collectors. However, estimates place the number of "certified" collectors at no more than 10% of the total specimen collector population. Without a proper, forensically acceptable specimen collection, the quality of the other components of the drug testing program (laboratories, MROs) is almost irrelevant. Before engaging in an ambitious modification of the mandatory guidelines, the Department should actively consider fixing the part of the current system that is broken - *collections*. The Department must consider developing requirements that mandate the education and certification of specimen collectors and/or collection sites.

- 1) POCT testers are required to submit "one specimen out of every ten specimens that test negative" to a HHS-certified laboratory for verification. No guidance is provided on how that "one specimen" is selected. Is it randomly selected? How is the randomness of the selection ensured? It seems logical that POCT testers

might select only "clearly" negative samples (as opposed to samples that produce "borderline" results) in an effort to reduce the number of identified POCT "failures". This requirement represents one of the few examples in the proposed guidelines that institutes a check and balance on POCT - and even this attempt is flawed without additional details and guidance.

- 1) It is well known by defendants that require drug surveillance in the criminal justice system, that by using an insulin syringe and injecting bleach (or other high pH solutions) through the outer membrane of the patch into the cellulose collection pad the results of drug testing can be altered. Because the needle is small and the puncture site miniscule, the tampering is often missed by collection staff removing the sweat patch and therefore the adulteration goes undetected. Similarly, there is already a commercially available lozenge (Quick Fizz™, Spectrum Labs, www.urineluck.com) which alters the pH of saliva in an effort to thwart the drug testing of oral fluids. Despite these schemes there is no requirement in the proposed guidelines to measure the pH of every saliva and sweat sample. This requirement should be incorporated and studies evaluating the actual effects of non-physiological pHs on saliva and sweat should be conducted.
- 1) Subpart F does not make it clear whether the CCFs for the alternative samples even exist. The CCFs are a fundamental component of the drug collection and testing process. Their development also brings to light problematic issues associated with the handling and processing of forensic samples. To proceed without these documents is to repeat past mistakes and missteps (that occurred with urine testing). Section 16.2 describes briefly the criteria for rejecting an alternative specimen for testing based upon CCF flaws. However, it is clear that because the CCFs appear not to exist that this list is abbreviated and incomplete. It is not advisable to attempt to finalize rules without knowing and understanding the format details of these documents.
- 1) The confirmation of nitrite by certified laboratories needs to be re-visited and further evaluated. Recent statistics indicated that nitrite adulteration occurs in less than 3 tenths of one percent of all federally-regulated samples. Under the current (and proposed) guidelines, in order for a laboratory to report a sample as adulterated for nitrite, a sample must have a nitrite concentration of equal to or greater than 500 mcg/mL on two separate aliquots AND be confirmed by a different test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis). The current guidelines raise several issues. The confirmation technologies listed as examples are costly - tens of thousands of dollars. Few laboratories have the resources to devote that amount of money to a very seldom-used procedure. Second, the nitrite confirmation methodologies provided as examples (while familiar to toxicology) are generally not utilized in most drug testing laboratories. Therefore, most drug testing facilities have little, if any, expertise in the use of this instrumentation. Third, there currently exists no alternative guidance for laboratories without these nitrite confirmation techniques

to submit potentially adulterated samples to another laboratory (Lab B) for the purpose of confirming nitrite. These same issues affect the confirmation of other compounds such as chromium, halogen, glutaraldehyde and other adulterants.

It is recommended that the Department develop guidelines that will allow a laboratory to submit potentially nitrite adulterated samples to a second laboratory that has been certified to perform nitrite confirmations (or confirmations for other adulterants). It would be unwise and unnecessary to require that *all* laboratories maintain these confirmation capabilities based upon their very limited use and significant expense - not to mention that such requirements would make it nearly impossible for smaller laboratories to meet minimal program criteria. However, without an alternative adulteration confirmation strategy, laboratories will continue to report samples as "invalid" (because they are unable to confirm the presence of the adulterant by a different test) rather than "adulterated". The reporting of samples as "invalid" rather than "adulterated" may not provide all of the information a MRO or employer needs to make appropriate employment decisions and also results in significantly different consequences (invalid result - canceled test, observed collection; adulterated result - potential immediate termination or removal and return to duty process). Given the discrepancy between the employment sanctions associated with invalid versus adulterated results, the Department is urged to develop a mechanism for laboratories without adulteration confirmation capabilities to submit "suspected" samples to a second laboratory for confirmation.

- 1) Sections 3.12 - 3.14. These sections underscore the total lack of scientific understanding associated with adulteration testing in alternative specimens. These one-sentence sections are devoid of any detail or specifics, which may accurately reflect the state of the science, but do little to advance the development of meaningful practices. These sections are an invitation to confusion and misapplication. Problems with the specimen validity testing of urine exposed the federal drug testing program to significant legal challenges. No one wants a repeat of that situation. The lack of clarity associated with alternative specimen validity testing further illustrates the knowledge gap associated with the use of alternative specimens for employee drug testing and reinforces the necessity for additional research prior to finalizing these rules.
- 2) Section 8-4. The instructions for skin preparation prior to sweat patch application are inadequate. Of all of the alternative specimens, the experience base associated with the sweat patch is the most extensive. The manufacturer's guidance regarding sweat patch application is detailed and specific. The guidance in this draft is 60 words in length - wholly inadequate. The most problematic aspect of sweat patch testing (associated with contamination-related issues) involves the application and removal of the patch itself. This section requires much greater detail with specific instructions to collectors.
- 3) Section 12.4 defines a non-instrumented device as one that requires "visual

evaluation (i.e. read by human eye)". Yet nowhere in the proposed guidelines are there any requirements for the visual acuity of POCT testers to be evaluated prior to performing non-instrumented testing. Is poor vision detrimental to the performance of POCT? What about persons with color-blindness? If the devil is in the details, this is another example where additional fine print is required.

- 4) The guidance provided in the proposal regarding standard operating procedures highlights the double standard being created between laboratories and POCT sites (with POCT having to meet a *lower* standard). SOPs represent the operational framework for a drug testing facility. Section 11.1 lists the SOP requirements for certified laboratories, which includes numerous requirements and specific details. For POCT, Section 12.8 (b) contains 11 words of guidance - basically, "develop a SOP". Equity issues aside, this guidance is entirely inadequate.
- 5) Section 11.4 (a) This commenter is very appreciative that the Department has included a provision that "extremely small certified laboratories" may request a waiver from the Secretary to the requirement that all HHS-certified laboratories must have multiple RPs or an alternate RP. It is unclear if the Department has, in the past, evaluated the impact of its rulemaking on small laboratories. If not, then this particular proposal is an important recognition (heretofore not provided) that small laboratories have a place in the federal workplace testing program. The Department needs to be aware that it can be very difficult for small laboratories to comply with the many provisions of this program due to their finite resources. Currently, most HHS-certified laboratory testing is performed in huge, factory-style facilities. While economies of scale are often required for profitable ventures, quantity (number of samples tested) is not, nor should not, be the *only* way of doing business. It is the hope of this commenter, that the Department will pursue suitable guidelines in the future that will allow small laboratories to continue to participate in federally-regulated testing.

Concluding Remarks:

The Department and those that assisted in the development of the **Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs** (Federal Register / Vol. 69, No. 71 / Tuesday, April 13, 2004) are to be commended for their efforts and their hard work. Those of us who struggle on a daily basis with the complexities of workplace drug testing issues understand and appreciate the effort that was required to formulate these proposals. While the majority of this commenter's responses have been critical of the proposed guidelines, this in no way diminishes the admiration toward those that have labored to produce this proposal.

This commenter has taken great pains to limit any editorial remarks associated with the proposed guidelines. However, it seems apparent to this reviewer that commercial and manufacturing interests have applied pressure to the Department and that pressure has

driven aspects of this proposal. This commenter is also aware of complaints of "unacceptable delays" (associated with the inclusion of alternative drug tests in the federal program) voiced by members of Congress who undoubtedly have constituency groups with vested interests in these proposed rules. While these numerous lobbying efforts do not appear to have corrupted the ruling making process, in this reviewer's opinion, an unnecessary sense of urgency (where none exists) has accelerated the process into premature proposals; particularly with regards to alternative specimens and POCT. This is both regrettable and troubling.

Regarding alternative specimens - without doubt, this document consolidates and advances the understanding and knowledge base associated with alternative matrices; but it also raises false expectations that sufficient data is available to establish hair, sweat and oral fluid on an equivalent footing with urine testing. That is clearly not the case. It is understood that the Department cannot simply create scientific knowledge to address all of the unanswered questions, but nor can it abrogate its responsibility to ensure that sufficient scientific facts and technical expertise exists BEFORE attempting to codify far-reaching rules. Regarding POCT - it strains credibility to suggest (as the Department has) that the need to develop a complex, multifaceted program (that includes POCT device validation, an evolving list of POCT certified devices, a continuous quality assurance effort to identify and track POCT "failures", the certification of POCT sites and personnel and the on-going inspection of POCT sites and personnel) is based upon the necessity to test federal employees "located in remote areas of the country" or "overseas". In this commenter's opinion, once again, the hand of commercial POCT device manufactures seems evident. It is not difficult to understand why these business interests are eager to see these rules reach finalized status despite the limited number of employees that might actually be tested under these guidelines - it is because DHHS is the foot in the door. Acceptance of POCT by the Department legitimizes these products and establishes POCT as the next gold standard. Using the Department's "seal of approval", these devices have limitless sales potential for use in all drug testing applications. The Department should and must be keenly aware of the sweeping and lasting impact of its decisions on the entire drug testing industry. Whether a truly unintended consequence or not, a ruling by the Department is often seen by the broader drug testing industry (non-regulated employment, criminal justice, sports, etc.) as "gospel" and as a result gains nearly unquestioned acceptance. "If it's good enough for federal workplace testing, it's good enough our testing." Not to be misinterpreted, POCT drug testing manufactures have every right to aggressively market their products and pursue new opportunities - just as those of us reviewing these proposals have the obligation to question whether these devices are appropriate for their intended use. As in the case of alternative specimens, it is this commenter's position that the pressure applied by manufactures and marketers of POCT and Congress has resulted in proposals that do not meet the requisite forensic benchmarks for federal employee drug testing and therefore must be withdrawn until such time as they do.

Sweat, hair and oral fluids as alternative specimens and on-site testing with POCT devices hold great promise to enhance the practice of drug testing. Significant advances in these technologies seem to occur almost daily and there is little doubt that these technologies will re-shape the employment testing landscape. Unfortunately, our

mutual goal is to establish forensic practice standards utilizing the *current* state-of-the-science knowledge and expertise. Based upon an inadequate scientific and technical foundation on which to build procedural guidance for the use of alternative specimens and on the inability of POCT to demonstrate this technology can produce forensically defensible results, the proposals to test alternative specimens (hair, sweat and oral fluids) and the proposals to utilize POCT for federal workplace drug testing both should be withdrawn from consideration at this time.

The proposed guidelines utilizing alternative specimens and POCT do not meet the "gold standard" that has been established by the current urine-based program for federal workplace drug testing. This benchmark is exceedingly high for a very important reason - the employment ramifications associated with a positive drug test. Clearly, more research and study is required on alternative specimens and POCT prior to the re-introduction of rules that will mandate such testing. An oft-cited comment in the Mandatory Guideline used by the Department to justify its own decisions reads as follows:

"This action is consistent with the Federal Workplace Drug Testing Program goal of ensuring an accurate and reliable result on every specimen tested, whether the result is positive or negative for drugs, adulterated, substituted, or invalid."

Based upon the Departments *own* standard of expectation, it is clear that these proposals must be withdrawn.

appreciate the opportunity to comment on these proposed rules.

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