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MRO Services Group

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Comments Re *Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing(69FR 19644, April 13, 2004, FR Doc #04-7985)*
Notice of Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69FR 19673, April 13, 2004, FR Doc #04-7984)

Dear Dr. Vogel:

The mandatory additions to validity testing appear quite reasonable (i.e. specific gravity refractometers accurate to 4 decimal places and colorimetric testing for 1 or more oxidizing adulterants).

However, from the MRO perspective, the proposed guidelines for confirmatory laboratory identification of adulterants are bound to fail because of economic realities. The various acceptable instrumentations required for confirmatory identification of adulterants are:

Multiwavelength Spectrophotometry
Ion Chromatography
Capillary Electrophoresis
Plasma Mass Spectrometry

These instruments are very expensive, and with the exception of capillary electrophoresis, would range for $100,000 to $150,000 in cost. They also require substantial maintenance. According to this same Federal Register entry (p 19653—left column par (4) there are about 7,096,000 Federal CCFs completed each year. The current number of detected adulterated or substituted specimens is three on-hundredths of one percent (Fed. Register same entry P19645 right column par (2)). This works out to be 2129 adulterated and/or substituted tests in the Federal Testing Program.

Assuming this newly approved technology picked up twice as many adulterated/substituted specimens, we are speaking of 4258 specimens per year. There are about 50 HHS approved labs, so each lab would average about 85 adulterated/substituted results per year.

No laboratory is going to expend the dollars for these instruments to find 85 adulterated/substituted results per year. Even <u>if only one lab</u> in the country <u>did all of the 4258 confirmation tests</u> per year, it wouldn't be economically feasible for that lab to invest in the instruments and their maintenance.

Simply because the proposed guidelines acknowledge the existence of this technology, does not mean any lab will make it available.

The first consequence of this policy will be an obvious increase in the number of invalid results presented to the MRO.

The second consequence of this policy will be a required discussion between the certifying scientist and the MRO to determine whether or not sending this invalid specimen to a second lab is likely to yield a confirmatory test, which will identify the adulterant. This conversation will be an exercise in futility since not any of the labs is likely to invest in confirmatory instrumentation for economic reasons mentioned previously.

These policies would waste a lot of time and money for the labs and MRO's, but would not increase the yield of adulterated specimens.

The proposed regulations were silent on the MRO response to dilute specimens, within the entire range of creatinine from 2 to 20 mgm/dl. The current interim rule is very useful in requiring immediate recollection under direct observation for creatinine 2 to 5 mgm/dl and optional recollection for creatinine 5 to 20 mgm/dl. Without the "Substituted" result required of labs for the 2 to 5 mgm/dl range; this split-up of the dilute range would probably continue to pick up a significant number of truly substituted specimens. We should not discard this concept.

Sincerely,

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Chief Medical Review Officer

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