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To: "'wvogl@samhsa.gov'" <wvogl@samhsa.gov>
Date: 6/14/04 5:30PM
Subject: 69 FR 19644 Revised Mandatory Guidelines

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Re: 69 FR 19644, Revised Mandatory Guidelines

Dear Dr. Vogl:

The validity test guidelines are very thorough and necessary. I understand the added level of accuracy desired for specific gravity measurement on non-negative specimens. Actions are taken based on a specific gravity (SG) result of 1.001 and the fourth decimal place is significant. We have similar considerations for all the other non-negative results we report. However, I question the necessity of requiring four decimal place SG results for dilute specimens as described in paragraph 2.4(g)(6). We result several dilute specimens per day. Many laboratories, in response to the new guidelines, are purchasing two digital refractometers in order to have a reserve should one refractometer fail. Repairs are expected to take only a day or two, but in this industry, that is a long delay for a dilute specimen. In addition, no specific action is taken with a negative dilute specimen, so added accuracy on dilute specimens doesn't seem necessary.

We average about 1.5 substituted and creatinine-invalid specimens per month. The digital refractometers cost about $10,000.00 each. It is not efficient to spend an additional $10,000.00 for 1.5 non-negative SG specimens per month. If dilute specimens were not held to the same stringent standard as non-negative specimens, laboratories could use the manual refractometers for backup for dilute specimens if and when a digital refractometer failed. The fact is that most laboratories will use the four-decimal-place refractometer on dilute specimens, but why regulate the test at a stricter level than necessary. Please consider removing the requirement to use a four-decimal-place refractometer on anything but a non-negative specimen.

I am also concerned that laboratories will find it difficult to meet the +/- 0.0003 PT criteria for specific gravity as stated in paragraph 3.19(a)(7)(iii) and paragraph 3.19(b)(8)(iii). In paragraph 3.19(a)(8), +/- 0.0006 from the calculated reference mean is described as a disqualifying condition for SG. As this technology is new to all the certified laboratories, this seems a bit too stringent for the initial application of this technology. +/- 0.0006 seems to be a smaller relative error than a 50% quantitative error for a drug confirmation, yet they have the same consequences.

The requirement that we have a digital refractometer in place for the July PT set is unreasonable. It has taken several years to issue guidelines on validity testing and now the laboratories have three months to digest the

changes, evaluate the equipment, petition our owners for $10,000.00 to $20,000.00 to buy unbudgeted equipment and perform the validation studies. Please consider delaying the implementation of the new guidelines to April 2005, to help the laboratories with the process of complying with these new guidelines.

Sincerely

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