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These are my comments after the first read through of this document.
More comments to follow.

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Comments regarding FR Doc 04-7984

Referencing subpart L – Point of Collection Test (POCT)

Section 12.8(b) requires each federal agency wishing to use the POCT to develop a standard operating procedures manual. Each Agency will write its own little quirks into the testing regulations. To simplify the process for the POCT collectors, a standardized set of operating procedures developed by DHHS, would make the use of these devices uniform.

Section 12.8(g) maintain records on those who have been SAMHSA-certified as POCT testers including records of their training. Where will the SAMHSA certifications be held? Will there be a cost associated with it? Who will do the training and certification of collectors? How much time will we have after this rule in order to get this certification? How does agency in Section 12.16, document training. Does each agency have to document collector's proficiency and training, or will documentation by one agency be good for all?

Section 12.9(a)(1) requires each collector to test the devices each day. The collector has already demonstrated proficiency in reading the devices. Why perform a negative, a single positive and a validity test for each person collecting POCT. Once the devices have reached the collection site, and are properly stored, they have a shelf life that indicates the product should produce valid results.
If I have three collectors who may do a POCT on a given day, I need to use 9 devices for what purpose? Finally I have one donor arrive to be tested with a POCT device. It has taken me 10 devices to perform one test. Not cost effective or reasonable. If I have only one collector, I still need to use 3 devices before I am allowed to run a test. This is excessive QC for a site.
When I do the positive control, do I need to test for all of the drugs the device is capable of reading or do I get to choose which drug to run a positive control on?
Who certifies my quality control samples, negative and positive and what adulterants do I need to run a QC with?

Section 12.26(a) prohibits the MRO from having any financial interest in a POCT. The vast majority of collection sites are medical facilities. The medical facilities that are currently using POCT for private industry use the MRO, on site, to review the tests. The MRO, on site, is usually a physician who works at and for the facility. Since the only test that will be released directly from the facility is a negative test, there is no problem with the MRO having a financial arrangement with the POCT site. Because the presumptive positive and adulterated samples are sent to the lab for confirmation testing, the MRO - Lab arrangement is much more important. The results reported from the lab could have adverse consequences for the donor, and a conflict of interest would have greater consequences.