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To: Zaleski, Brian; Harris, Paul
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Subject: [External_Sender] NRC Open Meeting Comments 11-7-19
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NRC Open Meeting Comments 11-7-19.docx

Attached are the comments you requested for the three questions I asked about/made comments about.

Hopefully we can chat more next week in DC.

John

Additional comments for Proposed Part 26 Rulemaking

Submitted by John Nielsen, INPO

Hydration monitor. I already provided some comments to NEI about this, but wanted to be clear on what I offered at the Public Meeting.

I believe the changes are largely unnecessary because provisions already exist for having a third party involved in the collection process. Both §26.31 and §26.115 provide the means in which a person may be trained and used to ensure significant portions of the collection process are in compliance. Since these have been successful for at least 11 years without having to be FFD Program personnel, it appears to be unnecessary that another type of monitor would now require so much more.

It is suggested that the hydration monitor be added to the text in §26.31 and the provisions for training be clearly stated.

Validity testing/ Invalid result due to pH. This was not addressed in my comments to NEI. After the discussion for the Public Meeting, it appears that one of the most suspected causes for a specimen being out of normal range is the manner in which a specimen is handled - from time of receipt to time of delivery at the lab. “Sitting in a hot truck” was an example that was used a number of times, which would be the time that the laboratory’s courier has possession and time that we have no control over.

My comment is not about the out of range instruction, it is about the classification “Protecting the Donor.” There is current instruction in §26.117(j) that may be a significant contributor to the cause of the pH issue – potential mishandling of the donor’s specimen:

> Specimens must be shipped from the collection site to the HHS-certified laboratory or the licensee testing facility as soon as reasonably practical but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days.

Allowing the courier to hold a specimen for up to 2 business days provides a much higher possibility that specimens could sit in an uncontrolled environment (hot truck) that would cause the questionable validity results. Nationally, we continue to hear examples where children or pets are dying in a hot vehicle, often exceeding 140° in a short period of time.

> Possible scenario – Courier picks up specimens on Wednesday before Thanksgiving but can’t make it to the lab on Wednesday. Since Thanksgiving is a holiday, Black Friday is often a holiday as well, and Saturday and Sunday are not business days, the 2 business days would be on Tuesday.
>
> This may be allowable by Part 26, but is it meeting intent and couldn’t this time frame cause the out of range readings?

Indirectly, is this long duration for shipping causing the donor to be suspected and additional work to be done by the MRO and FFD Staff? When questionable results arise, the donor is suspected and subject to additional testing, an MRO must interview the donor and make an assessment, and additional work is required by the FFD staff.

Rather than limiting this rule change to how the test results will be handled, I suggest the change also include the specimen handling by the courier. Shipping should be completed within 24 hours.

[Contractually, we can add a requirement that the courier service advise the client whenever this is exceeded, so I am not proposing that notification be included in the revision to §26.117(j).]

Blind Lots. – I did not provide comments to NEI for this item.

I believe there was an error on the slide presented. §26.168(h)(1) doesn't limit a blind provider to certifying a lot for only 6 months; it requires that any lot they certify be for a period of no more than 6 months.

In actuality, they do not certify the lot one time; they certify the lot each time they sell specimens from that lot, which could be on a daily or weekly basis. While sufficient quantity exists to conduct their certification testing, the controlled & numbered batch is considered to be an "open" lot; when no more of the batch is available for certification testing it is considered to be a "closed" lot.

The challenge that comes up is when a blind is not submitted within the two months of receipt and the open lot number must be re-verified. The first thing that must be verified is if it is still an open lot. If no longer an open lot, the blind cannot be used.

Once it is established to still be an open lot, the provider must provide evidence to the client that any time they tested the numbered lot, it was within NRC parameters. Therefore, that lot could be certified from the test date for another six months. Additional testing can be done for the open lot to establish a new certification date for the blind specimen.

It should be noted that neither "Lot" or "Open Lot" is defined in Part 26, so I suggest the following be added to §26.5 to minimize confusion:

> Lot (blind specimen) – A controlled and numbered batch prepared by a provider of Blind Specimens that meets specific Part 26 testing parameters for a drug type, metabolite, adulterant, etc. that must be tested and confirmed by an HHS-certified lab as part of the provider's specimen certification process.
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> - Open Lot – A controlled and numbered batch that meets specific Part 26 testing parameters, and sufficient quantity remains to be tested and confirmed by an HHS-certified lab as part of the provider's specimen certification process.
> - Closed Lot - A controlled and numbered batch that previously met specific Part 26 testing parameters, but there is no longer sufficient quantity to support the provider's specimen certification process.