

From: [Emery-Howe, Tina M](#)
To: [Harris, Paul](#)
Subject: [External_Sender] Re: Blind question
Date: Thursday, September 17, 2015 12:15:41 PM
Attachments: [image001.png](#)
[image001.png](#)

Thanks Paul!!

Sent from my iPhone

On Sep 17, 2015, at 11:42 AM, Harris, Paul <Paul.Harris@nrc.gov> wrote:

If I understand the question correctly... and not to weigh in on audit findings or NRC inspection items, but...

The intent of blind performance testing to is ascertain whether the results from the lab are what are expected (positive, negative, dilute, adulterated, substituted, and valid); the intent is not to precisely assess quantitative results.

Note that by the NLCP, laboratories must have objective criteria for evaluating the results of QC samples. And the results must be within the laboratory's established acceptance range based on the sample's theoretical value or the supplier's stated value.

For qualitative assays including specimen validity tests (e.g., creatinine) and confirmatory drug tests, laboratories generally use a $\pm 20\%$ acceptance range for batch QC samples. However, laboratories must use more stringent qualitative criteria for calibrator verification, such as $\pm 10\%$ from the theoretical or supplies stated value. And for some laboratory processes, a $\pm 50\%$ range may be established. For the question below, laboratories may use a $\pm 20\%$ acceptance range for control verification. In other words, the verified concentration (e.g., the working mean) must be within 20% of the target value, not at the target value. These acceptance ranges (e.g., $\pm 20\%$) are not and never to be applied to the initial and confirmatory cutoffs in Part 26 and Federal workplace drug testing.

I hope this answers your question. Also, I thought others might have the same question, so I increased the scope of this email. I hope that is ok.

And the million dollar question is... who really believes that 26.168(g)(3) is doing what it is saying its doing? I sure don't. This will be fixed in Tech Issues rulemaking.

Please call or email if there is concern regarding this email.

R,
Paul

From: Emery-Howe, Tina M [<mailto:temeryh@entergy.com>]

Sent: Thursday, September 17, 2015 8:21 AM
To: Harris, Paul <Paul.Harris@nrc.gov>
Subject: [External_Sender] RE: Blind question

Do you agree with this?

<image001.png>

From: Harris, Paul [<mailto:Paul.Harris@nrc.gov>]
Sent: Thursday, September 17, 2015 7:57 AM
To: Emery-Howe, Tina M
Subject: RE: Blind question

Hi Tina,

Yes, because that is the purpose the blind testing program, 26.168. But perhaps I do not understand your question??

Paul

From: Emery-Howe, Tina M [<mailto:temeryh@entergy.com>]
Sent: Wednesday, September 16, 2015 2:41 PM
To: Harris, Paul <Paul.Harris@nrc.gov>
Subject: [External_Sender] Blind question

Paul –

When you purchase blinds they provide certification on the specimens with the qualitative amounts do you need to look at this to ensure it's still within the range when the results come back from the lab?

Thanks,
Tina Emery-Howe
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