From: Zaleski, Brian
To: sjwolf@aep.com
Cc: Harris, Paul; Mossman, Timothy
Subject: Question 1 - AEP audit of HHS-Certified Laboratory - LabCorp
Date: Friday, November 20, 2015 3:01:00 PM

Mr. Wolf,

We reviewed your question about the 10 CFR 26.167(h) requirement on the preparation of calibrators and controls. It is the NRC staff position that the current rule text is clear and more robust than the NLCP inspection program. An HHS-certified laboratory, when testing 10 CFR Part 26 urine specimens, cannot use the same stock solution to prepare both calibrators and controls (yellow highlighted text).

- 10 CFR 26.167(h) Calibrators and controls. "Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration."

We received no public comment on the HHS-certified laboratory calibrators and controls requirements in 10 CFR 26.167 that were included in the proposed 10 CFR Part 26 rule (70 FR 50442, August 26, 2005).

We also reviewed both the 2004 and 2008 HHS *Mandatory Guidelines for Federal Workplace Drug Testing Programs*.

- 2008 HHS Guidelines (73 FR 71858; November 25, 2008) which became effective on October 1, 2010.
- 2004 HHS Guidelines (69 FR 19658, April 13, 2004) which became effective on November 1, 2004.

While NRC has yet to issue rule changes to 10 CFR part 26 to incorporate changes in the 2008 HHS Guidelines, NRC does require our licensees and other entities to use HHS-certified laboratories to conduct specimen testing. Neither the 2004 nor the 2008 HHS Guidelines includes the NRC requirement in 10 CFR 26.167(h) on the preparation of standards and controls using different stock solutions.

- 2004 HHS Guidelines -- Section 2.4 Laboratory Analysis Procedures
  (q) Additional Requirements for Certified Laboratories. . . .
  (2) Laboratory calibrators and controls shall be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers. The calibrators and controls shall be properly labeled as to content and concentration. The standards (e.g., pure reference materials, stock standard solutions, purchased standards) shall be labeled with the following dates: when received (if applicable); when prepared or opened; when placed in service; and expiration date.

- 2008 HHS Guidelines. No longer included a specific provision on the preparation of laboratory calibrators and controls.

Finally, we reviewed the *Manual for Urine Laboratories, National Laboratory Certification Program* (effective 1 October 2010). We understand that a new version of this manual has been released in November of this year, but we have yet to receive a copy for review. The NLCP manual does include a statement regarding calibrators and controls for an assay. Specifically, that "at least one control (other than the drug-free control) must be from a separate source."

- Manual for Urine Laboratories, NLCP (effective 1 October 2010)
  - ***Question G-4**: For each drug and specimen validity test, is at least one control from a source separate from the calibrator(s)? (YES/NO)*

  - **Comment**: Controls containing the compound(s) of interest are used to check the validity of the calibration. If all calibrators and controls for an assay are derived from the same source, the laboratory may introduce an undetectable bias into its test results or may be unable to identify developing problems such as degradation or concentration of QC solutions. To monitor such problems, at least one control (other than the drug-free control) must be from a separate source.

    If all QC samples for an assay are obtained as prepared samples from a single supplier, the laboratory must have documentation that at least one control (other than the drug-free control) has been prepared from a separate source.

If you have additional questions or would like to discuss this further, please feel free to contact me.
Brian

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From: Sieg Wolf [mailto:sjwolf@aep.com]
Sent: Wednesday, November 18, 2015 3:55 PM
To: Zaleski, Brian
Subject: [External_Sender] FW: LabCorp Audit

Mr. Zaleski
Can you help us with this request?

It looks like Mr. Harris is out of the office this week.

Thank you,
Siegfried Wolf

From: Sieg Wolf
Sent: Wednesday, November 18, 2015 3:51 PM
To: 'Paul.Harris@nrc.gov'
Cc: lbrous@lsuhsc.edu
Subject: LabCorp Audit

Mr. Harris
I'm the NEI Audit team lead at the LabCorp facility in Durham North Carolina this week (November 17-19, 2015). Our Audit team ran into a question concerning calibrators and controls being prepared from the same stock solution. 10 CFR 26.167 (h) states the following (note the underlined portion).

Calibrators and controls. Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard

solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls **may not** be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

Is this a recommendation or a requirement (does this mean that they have to)? I have Dr. Larry Broussard as our team Technical Specialist. Feel free to contact him at his cell phone, (985)-703-0970 or myself (cell) at (269)-313-5912.

Thank you,
Siegfried Wolf

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