From: Zaleski, Brian
To: Sieg Wolf
Cc: Harris, Paul; Mossman, Timothy
Subject: Question 2 - AEP audit of HHS-Certified Laboratory - LabCorp
Date: Friday, November 20, 2015 4:00:00 PM

Mr. Wolf,

We reviewed your second question about the labeling of quality control material and reagents in 10 CFR 26.167(h). It is the NRC staff position that the laboratory practice, as described in your email on November 19, 2015 (included below), meets the intent of the 10 CFR 26.167(h) requirement.

> 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."

NRC requires each licensee that performs 10 CFR Part 26 testing to use HHS-certified laboratories. To receive and maintain HHS certification, a laboratory must pass each National Laboratory Certification Program (NLCP) inspection. The NLCP inspection manual and associated checklist include specific procedures to ensure to the sufficiency of identifying information on "internal standards and test materials".

Given that the laboratory is preparing the materials in house, the "received" date is the date the material was "prepared". This distinction should be described in their procedures.

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

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From: Sieg Wolf [mailto:sjwolf@aep.com]
Sent: Thursday, November 19, 2015 10:36 AM
To: Zaleski, Brian
Subject: [External_Sender] LabCorp Audit - second question

We have another question for you.

Labeling of quality control material and reagents
During the audit it was noted that quality control material prepared in-house and transferred to the testing area did not contain date received labels.

The relevant statement in 10 CFR 26.167 (h) is:
"….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."

Laboratory practice is to label purchased quality control material with the date received but not to do so for material prepared in house. This policy meets the NLCP checklist question concerning the labeling of QC material copied below (Source: November 2015 Revision of Manual for Urine Laboratories. NLCP Program Document):

Question G-6: Does the laboratory label all QC materials with sufficient identifying information? (YES/NO)
Comment: Labels on QC materials (e.g., stock standards, calibrators, controls, certified negative urine) must include sufficient information for the analysts to enable their proper use. The information on the labels must be consistent with QC records.
It is acceptable to label working containers with minimal information (i.e., QC sample identifier, analyte/measurand, lot number, expiration date) provided the information is readily cross-referenced to preparation and verification records. Individual tubes of a pooled QC sample may be labeled with only a unique identifier, if analysts retrieve them from a rack labeled with the unique identifier as well as the other required information. Laboratory staff should label purchased QC materials with the date opened/placed into service and expiration date. The manufacturer label is not sufficient (e.g., the manufacturer's expiration date may not be appropriate for opened bottles). QC materials that have not been placed into service should be inaccessible to analysts or should be clearly labeled to distinguish them from current QC materials, to prevent their inadvertent use.

Comments by Technical Specialist:
The NLCP checklist question provides a detailed interpretation of the identifying information required for labeling of QC material. In fact the Comment provided with the question specifically states that purchased QC should be labeled with the date opened/placed into service and the laboratory follows that practice. The Comment does not specifically address QC material prepared in-house but question G-14 (copied below) includes date of preparation (date of receipt and/or preparation) as an alternative for the labeling of internal standards and test materials. This implies that NLCP accepts date of preparation as an alternative to date received when considering material prepared in-house.

Question G-14: Does the laboratory label internal standards and test materials with the date of receipt and/or preparation, date placed into service, and an expiration date? (YES/NO)
Comment: At a minimum, laboratories must label internal standards and test materials with the date of receipt and/or preparation (with initials of the preparer), date placed into service, and the expiration date. The information on labels must be consistent with and easily linked to the preparation and verification records. Labels on working containers must contain the name, expiration date, and sufficient information (e.g., lot number) to link the working container to the stock container.

Thank you,

Siegfried Wolf

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