

From: [Reber, Eric](#)
To: Monica.king@hyh.com
Subject: Clarification of Licensing Requirements; Halyard Health, Inc.; License No. 10-23980-01E
Date: Tuesday, March 15, 2016 7:26:00 AM

Dear Ms. King,

I've reviewed your exempt distribution report dated March 3, 2016 for the 2015 reporting period. Your report meets the reporting requirements for your license; however, based on the format of your report, some clarification is necessary concerning the specific requirements of your license.

Your license authorizes two main things:

- Distribution under 10 CFR 32.18 of liquid scintillation standards containing less than 100 microcuries of carbon-14 for use by persons exempt from licensing under 10 CFR 30.18.
- Distribution under 10 CFR 32.21 of carbon-14 contained un urea capsules for use by persons exempt from licensing under 10 CFR 30.21.

In the "License #" column of the table in your report, you wrote "N/A" in the third row, which implies that your license (i.e., License No. 10-23980-01E) does not apply to the distribution of urea capsules; however, as I wrote previously, one of the two main things your license authorizes is the distribution under 10 CFR 32.21 of carbon-14 contained in urea capsules.

Your report contains the statement, "All materials are transferred for use under §30.18 or equivalent regulations of an agreement state in accordance with §30.41." This statement would only apply to liquid scintillation standards containing less than 100 microcuries of carbon-14 that were transferred under 10 CFR 32.18 (i.e., it would not apply to the distribution of carbon-14 contained in urea capsules). Since you apparently only transferred products under 10 CFR 32.21 (i.e., carbon-14 contained in urea capsules), these products were transferred for use by persons exempt from licensing under 10 CFR 30.21.

In future reports, you should revise the format of your report to make these distinctions clear.

Further information about the requirements that apply to annual reports of exempt distribution can be found in the attached Regulatory Issue Summary.

If you have any questions, please feel free to contact me.

Regards,
Eric

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