

**From:** [Passo, Chuck](#)  
**To:** [Haines, Rick](#); [Struckmeyer, Richard](#)  
**Cc:** [jimh10@sbcglobal.net](#); [McCully, T.J.](#); [Hare, Jim](#); [Kralian, Mark A.](#); [Catalano, Anthony](#); [Farris, Virginia](#); [Zinger, Ed](#)  
**Subject:** RE: More concerning your letter of August 9, 2012  
**Date:** Thursday, September 13, 2012 10:32:09 AM

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Hi all

I will submitting a CIM form today to obsolete these. With a popup to instruct how to order multiples of lesser matched sets

Chuck Passo, LST

Associate Product Leader

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**From:** Haines, Rick  
**Sent:** Wednesday, September 12, 2012 3:41 PM  
**To:** Struckmeyer, Richard  
**Cc:** [jimh10@sbcglobal.net](#); Passo, Chuck; [McCully, T.J.](#); [Hare, Jim](#); [Kralian, Mark A.](#); [Catalano, Anthony](#); [Farris, Virginia](#); [Zinger, Ed](#)  
**Subject:** RE: More concerning your letter of August 9, 2012

Hi Richard,

I've reviewed this as much as possible, and no one can find error with your findings or exclusions to say otherwise, so by this email and on behalf of PerkinElmer, I request that you strike the following I125 and I129 part number multiple set quantities from the previously provided renewal submission list, because these will be obsoleted and no longer be ordered from our supplier, or distributed by our supplier or PerkinElmer to our customers - effective immediately.

Isotope Part Number	Activity	Status
5081025 (set of 10, I125 tubes)	$0.12 * 10 = 1.20\text{uCi}$	Obsolete, no longer saleable
5081225 (set of 12, I125 tubes)	$0.12 * 12 = 1.44\text{uCi}$	Obsolete, no longer saleable
5081525 (set of 15, I125 tubes)	$0.12 * 15 = 1.80\text{uCi}$	Obsolete, no longer saleable
5081625 (set of 16, I125 tubes)	$0.12 * 16 = 1.92\text{uCi}$	Obsolete, no longer saleable

5082025 (set of 20, I125 tubes)	$0.12 * 20 = 2.40\text{uCi}$	Obsolete, no longer saleable
5082525 (set of 25, I125 tubes)	$0.12 * 25 = 3.00\text{uCi}$	Obsolete, no longer saleable
5080229 (set of 2, I129 tubes)	$0.06 * 2 = 0.12\text{uCi}$	Obsolete, no longer saleable
5080329 (set of 3, I129 tubes)	$0.06 * 3 = 0.18\text{uCi}$	Obsolete, no longer saleable
5080429 (set of 4, I129 tubes)	$0.06 * 4 = 0.24\text{uCi}$	Obsolete, no longer saleable
5080529 (set of 5, I129 tubes)	$0.06 * 5 = 0.30\text{uCi}$	Obsolete, no longer saleable
5080629 (set of 6, I129 tubes)	$0.06 * 6 = 0.36\text{uCi}$	Obsolete, no longer saleable
5081029 (set of 10, I129 tubes)	$0.06 * 10 = 0.60\text{uCi}$	Obsolete, no longer saleable
5081229 (set of 12, I129 tubes)	$0.06 * 12 = 0.72\text{uCi}$	Obsolete, no longer saleable
5081529 (set of 15, I129 tubes)	$0.06 * 15 = 0.90\text{uCi}$	Obsolete, no longer saleable
5081629 (set of 16, I129 tubes)	$0.06 * 16 = 0.96\text{uCi}$	Obsolete, no longer saleable
5082029 (set of 20, I129 tubes)	$0.06 * 20 = 1.20\text{uCi}$	Obsolete, no longer saleable
5082429 (set of 24, I129 tubes)	$0.06 * 24 = 1.44\text{uCi}$	Obsolete, no longer saleable
5082529 (set of 25, I129 tubes)	$0.06 * 25 = 1.50\text{uCi}$	Obsolete, no longer saleable

Additionally, your observation regarding PerkinElmer Boston; yes, they will be distributing the exempt radioactive parts that are currently being distributed by Downers Grove, planned on being implemented/completed before the end of 2012, and we are currently in a state of transferring multiple manufacturing and our supplier base processes to them.

Hopefully, this email will suffice for what is intended, but if not let me know and I'll send it via PE letterhead.

Best regards,  
Rick

Rick Haines | QA/RA Mgr & RSO/LSO  
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**From:** Haines, Rick  
**Sent:** Monday, September 10, 2012 9:59 AM  
**To:** 'Struckmeyer, Richard'  
**Cc:** [jimh10@sbcbglobal.net](mailto:jimh10@sbcbglobal.net); Passo, Chuck  
**Subject:** RE: More concerning your letter of August 9, 2012

Hi Richard,

I've reviewed the below with our consultant, and so far, I cannot dispute. However, regarding the Downers Grove site distributing I125 vials for several past decades in sets of 1, 2, 3, 5, 10, 12, 15, 16, 20, and 25, I am a loss to determine why this wasn't brought to my attention during one or more of the past 11 years of NRC and IEMA audits.

Nonetheless, I must conclude it to be valid, since we cannot currently find any "exception" out there to allow continued distribution as in the past.

Give me a couple days to investigate, and if I can't find an exception, I will amend our renewal submission to read differently and within the 32.19 – i.e. this will include changing ours and our supplier's processes.

BRs,  
Rick

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**From:** Struckmeyer, Richard [<mailto:Richard.Struckmeyer@nrc.gov>]  
**Sent:** Friday, September 07, 2012 10:14 AM  
**To:** Haines, Rick  
**Subject:** More concerning your letter of August 9, 2012

Mr. Haines:

After taking a second look at the information you provided, I see that the sources that exceed the exempt-quantity limits in 10 CFR 30.71 for I-125 and I-129 are actually sets of sources.

However, 10 CFR 32.19(b) states, in part: "Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter."

Therefore it appears that some explanation is still needed.

I also have an amendment request from PerkinElmer, Inc., in Boston, that seems closely related to your letter. Does your facility in Downers Grove supply these source sets to PerkinElmer, Inc.? If so, is this in addition to distributing them to persons exempt from licensing?

I look forward to your response.

Thank you.

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**From:** Struckmeyer, Richard  
**Sent:** Thursday, September 06, 2012 8:57 AM  
**To:** 'Haines, Rick'  
**Subject:** Your letter of August 9, 2012

Mr. Haines:

I am writing in reference to your "Letter of Notification - re: Lic. No. 12-04933-06E, Exempt Radioactive Material Supplier Change" dated 8/9/12.

I would like to understand the meaning of the "Total Activity per P/N ( $\mu\text{Ci}$ )" for I-125 and I-129 in the table on page 2 of your letter. The exempt-quantity limits in 10 CFR 30.71 for these radionuclides are 1  $\mu\text{Ci}$  and 0.1  $\mu\text{Ci}$ , respectively. Most of the products in the table appear to exceed these limits. If you have documentation from a previous license application, amendment, or renewal that provides an explanation, I would appreciate your making this known.

Thank you,

Richard K. Struckmeyer  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials and Environmental Management Programs  
U.S. Nuclear Regulatory Commission  
301-415-5477