



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-001

April 22, 2013

Mr. Ronald Como  
Radiation Safety Officer  
Canberra Industries, Inc.  
800 Research Parkway  
Meriden, CT 06450

Mail Control No. 579625

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Como:

This letter is in response to your application dated December 18, 2012, for a renewal of your exempt distribution license and to your March 13, 2013, response to our questions dated February 14, 2013. We still do not have sufficient information to complete the review of your application. We have summarized the issues that need to be addressed in an enclosure to this letter. Please submit the information within 30 days from the date on this letter.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions regarding your application, please contact me at 301-415-5619 or [lymari.sepulveda@nrc.gov](mailto:lymari.sepulveda@nrc.gov). Any correspondence regarding the application should reference the mail control number specified above.

Sincerely,  
*/RA/*

Lymari Sepulveda  
Licensing Branch  
Division of Materials Safety and State Agreements  
Office of Federal & State Materials &  
Environmental Management Programs

Docket No. 030-36154  
Enclosure: As stated

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DISTRIBUTION: MKotzalas TKime RJones LFARB Region I/DNMS/LAS MSSA r/f

OFFICE:	FSME:MSSA:LB	FSME:MSSA:LB	FSME:MSSA:LB	
NAME:	LSepulveda	SXu	MKotzalas	
DATE:	4/22/2013	4/18/2013	4/22/2013	

**OFFICIAL RECORD COPY**

## Request for Additional Information

### Questions regarding renewal application of NRC exempt distribution license 06-15099-03E

1. Please indicate which byproduct material listed in your license will be distributed under 10 CFR 32.18.
2. Per the requirements in 10 CFR 32.18(c), please confirm that the byproduct material is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.
3. In your application dated December 18, 2013, you indicated that the sources listed in item 5 will be procured from a source manufacturer. Please provide the manufacturer and model number of the sealed sources.
4. In your application dated December 18, 2013, Attachment #2, you provided copies of the labels. Please note that the labels do not contain information regarding the manufacturer and/or distributor. Please provide copies of the label identifying the manufacturer and/or distributor.
5. In item 6 of your application you stated that the sources will be distributed to person exempt from licensing pursuant to 10 CFR 30.15. Please indicate under which category as specified in 10 CFR 30.15 the devices belong.
6. The requirements in 10 CFR 32.14(b)(4) states that the applicant must submit information concerning the procedures for and results of prototype testing to demonstrate the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product. Your application did not contain information which confirms that the product will maintain its integrity in conditions likely to be encounter in normal use of the product. Please provide the required information.

In your March 13, 2013, response to our questions of February 14, 2013, you stated that the manufacturer does not performed testing on sources of 30 microcuries or less. Please note that if you intend to incorporate byproduct material into a device, you need to provide results and procedures for prototype testing for your devices to demonstrate that the material will not become detached from the product.

### Questions regarding the addition of activities under exempt distribution license 41-14168-01E to exempt distribution license 06-15099-03E

1. In your application dated December 18, 2013, you asked that the location at 107 Union Valley Road, Oak Ridge, Tennessee be added to your license. On March 21, 2013 we had a conference call with Canberra's facilities in Connecticut and Oak Ridge. During the call you informed us that the intent of adding the Oak Ridge facility to your 06-15099-03E license was to terminate license 41-14168-01E and to continue the activities under license 06-15099-03E. Please indicate what activities will be performed at the Oak Ridge facilities and provide the list of byproduct materials to be used at the Oak Ridge facilities and the purposes for which licensed materials will be used.
2. Per the requirements of 10 CFR 32.18 (b) please confirm that the byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

Enclosure

3. Per the requirements in 10 CFR 32.18(c), please confirm that the byproduct material is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.
4. Per the requirements in 10 CFR 32.18(d), please submit copies of prototype labels and brochures.
5. Per the requirements in 10 CFR 32.19(a), please confirm that no more than 10 exempt quantities as set forth in 10 CFR 30.71, Schedule B shall be sold or transferred in any single transaction.
6. Per the requirements in 10 CFR 32.19(b), please confirm that each quantity of byproduct material set forth in 10 CFR 30.71 Schedule B shall be separately and individually package.
7. Per the requirements in 10 CFR 32.19(c), please confirm that the immediate container of each quantity of byproduct material bears a durable, legible label which (1) identifies the isotope, (2) lists the quantity of radioactivity, and (3) bears the words "Radioactive Material."
8. Please confirm that the label affixed to the immediate container, or an accompanying brochure, contains the information required by 10 CFR 32.19(d)