

March 29, 2013

Curt Pendergrass, Ph.D.  
Supervisor, Radioactive Materials Section  
Kentucky Radiation Health Branch  
275 East Main Street  
Mail Stop HS-1CA  
Frankfort, KY 40621

SUBJECT: LEAK TEST REQUIREMENTS FOR BUNDLED EXEMPT-QUANTITY SEALED  
SOURCES

Dear Dr. Pendergrass,

This is a follow-up to the letter which Mr. Dewey F. Crawford, Radiation Control Program Administrator, Kentucky Radiation Health Branch, sent to Ms. Janet R. Schluter, Director, Division of Materials Safety and State Agreements/U.S. Nuclear Regulatory Commission (NRC), dated October 19, 2007, regarding the leak testing requirements for a device which contained ten exempt-quantity sources. Please note that the NRC position regarding the use of exempt-quantity sources in a device, a process called "bundling," has not changed.

Specifically, we understand that one of your licensees, Ronan Engineering Company (Ronan) is marketing a device which contains ten exempt-quantity sources, each with an activity level of 90  $\mu\text{Ci}$  of Cs-137, to a maximum of 900  $\mu\text{Ci}$  total, and that Ronan requested exemption from leak test requirements on the basis that these sources are exempt from leak testing when used discretely. The registration certificate of the device is KY-0576-D-113-B. We present the following specifics for consideration when determining the leak test requirements for such an application of exempt-quantity sources:

- The NRC regulations, under 10 CFR 32.210(g)(i), do not require sealed source and device (SS&D) registration for beta and gamma emitting sources under an activity level of 100  $\mu\text{Ci}$ . These quantities are called exempt quantities. Consequently, these sources are exempt from leak testing.

- The NRC has issued Generic Letter 99-01, entitled “Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities,” which stated that the NRC does not authorize the bundling of exempt quantities of byproduct material. The Generic Letter also stated that the exemption applies to users of such quantities and does not apply to manufacturers. The Generic Letter concluded, based on the NRC’s internal analysis and discussion with the Agreement States, that combining any exempt sources is inconsistent with the regulations and that the exemption provided in the regulations is applicable as long as no individual or discreet quantity of the byproduct material exceeds limits specified in 10 CFR 30.71, Schedule B. The Generic Letter is still in effect.
- Regarding bundling, the NRC has received only one request, in the last 15 years, for approval of a device which was to bundle a number of exempt-quantity sources. A moisture density gauge manufacturer wanted to bundle eight 10  $\mu$ Ci Cs-137 sources in a device and distribute it as an exempt product. The NRC granted an exemption from the requirements in 10 CFR 32.14 to the manufacturer. The NRC decision was published in the *Federal Register* on December 19, 2002 (see 67 FR 77818). For further information, the relevant documents are accessible in the NRC records under ML021350058 and ML021840743. To our knowledge, the device has not been commercially marketed.

Based on the above considerations, we conclude that exempt-quantity sources should not be bundled and the exemption from leak testing requirements, which applies to these sources when used individually, does not apply when bundled. However, the Kentucky Radiation Health Branch may exercise its regulatory authority to grant an exemption. Please note that, in your analysis to establish the basis for such an exemption, you could consider the historical performance of the devices which had been distributed and had been in commercial use previously. Consideration of good historical performance is used in other areas of SS&D safety evaluations, e.g., the guidance for SS&D registrations (Section 10.5, NUREG-1556, Vol. 3, Rev. 1, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration”) provides for, as one acceptable method for prototype testing, the operational history of the product.

If you wish to discuss these issues further, please contact Dr. John Jankovich of my staff at 301 415-7904 or email [john.jankovich@nrc.gov](mailto:john.jankovich@nrc.gov).

Sincerely,

**/RA/**

Margie Kotzalas Chief, Licensing Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

If you wish to discuss these issues further, please contact Dr. John Jankovich of my staff at: 301 415-7904 or email [john.jankovich@nrc.gov](mailto:john.jankovich@nrc.gov).

Sincerely,

**/RA/**

Margie Kotzalas Chief, Licensing Branch  
 Division of Materials Safety and State Agreements  
 Office of Federal and State Materials  
 and Environmental Management Programs

**DISTRIBUTION:** MSSA r/f

**ML13086A164**

<b>OFC</b>	MSSA/LB	MSSA/ASPB	MSSA/LB
<b>NAME</b>	JJankovich	DWhite	MKotzalas
<b>DATE</b>	03/27/2013	03/27/2013	03/29/2013

**OFFICIAL RECORD COPY**