



November 1, 2007

Janet R. Schluter, Director
Division of Materials Safety and State Agreements
United States Nuclear Regulatory Commission
Washington D.C. 20555-0001

RE: Letter from Kentucky Radiation Health Branch dated October 19, 2007

Dear Ms. Schluter:

I am the Radiation Safety Officer for Ronan Engineering and want to clarify our amendment request for the RLL-1 source holder. The RLL-1 source holder with multiple 90uCi capsules has never required leak testing since being approved in 1999. The leak testing exemption was granted after rigorous testing and prototype evaluation by the Kentucky Radiation Health Branch and the N.R.C. The source containment is two stainless steel tubes with end pieces continuously welded, essentially double encapsulating the special form sources within. This assembly is then welded into a housing to provide shielding and further protect the source assembly.

Our amendment request to the Kentucky Radiation Health Branch was to simply clarify and move the leak testing requirements from page 6 of the registry to page 1. Our proposed wording is:

Source holders containing source capsules not exceeding 90uCi each do not require leak testing

Source holders containing a single source capsule exceeding 100uCi require leak testing
See caution label on device.

Their letter referencing 10CFR35.67(f)(3) leak testing for Brachytherapy sources is not applicable to this device.

10CFR 31.5 (c)(2) states that leak testing shall be conducted at 6 month intervals or as specified in the label. The 100uCi exemption in 31.5 is not the issue nor is the bundling of exempt quantities (less than 10uCi sources). The source holder does not require leak testing due to prototype testing and evaluation conducted in accordance with 10CFR32.51(a)(4)(b) and approved by the regulating authorities authorizing distribution to general licensees.

RONAN ENGINEERING COMPANY
MEASUREMENTS DIVISION

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Ronan understands that a general statement as to leak testing can not be issued dependent on source size. Each device must be evaluated for its inherit safety features, operating experience and the environmental conditions where it will be used to determine the leak testing frequency. Ronan currently distributes devices requiring leak testing every 6 months, every 36 months and no leak testing required.

Our request to the N.R.C. is to formally respond to Kentucky Radiation Control so that this issue is not raised again with the next change in personnel. The safety of the device has never been questioned the only issue is the interpretation of the regulations.

Again I want to emphasize that Ronan Engineering is not requesting any changes to the device or usage requirements, only to format the registry properly to avoid confusion.

Thank you.

Respectfully;

A handwritten signature in black ink, appearing to read "Craig A. Caris", is written over a horizontal line.

Craig A. Caris
Radiation Safety Officer
Ronan Engineering Co.
ccaris@ronanmeasure.com

cc: John Jankovich ✓
Thomas Herrera