

To: U.S. Nuclear Regulatory Commission  
Washington D.C.

6/19/07

Attn: John Jankovich

From: Craig Caris

Subject: Clarification of wipe test requirements

Ronan Engineering is currently producing the RLL-1 source holder, Registry No. KY-576-D-113-B. The registry allows for the use of multiple special form capsules each containing less than 100 uCi of gamma emitting material or a single source with greater than 100 uCi of gamma emitting material, and a maximum activity of 900uCi per source holder. The current registry states that "Device users are subject to leak testing every three years for devices containing single sources of 100 microcuries or greater."

The RLL-1 Registry is currently under review by the Kentucky Radiation Health Branch and they have notified Ronan Engineering that they may have to change the registry making it mandatory for all RLL-1 source holders to be wipe tested. This determination is based on the wording in 10 CFR 31.5 stating that devices containing not more than 100 uCi do not require wipe testing. I have reviewed 10CFR and the use of the word devices in lieu of sealed sources in 10CFR31.5 appears to be the cause of this determination. The wording in all other sections is very clear that the sealed source activity is the determining factor not the source holder configuration. The following is quoted from 10CFR:

31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionizing atmosphere.

31.5 ( c )(2)(ii) Devices containing only tritium or not more than 100 microcuries of other beta or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

35.67 Requirements for possession of sealed sources and brachytherapy sources.

35.67(f) A licensee need not perform a leak test on the following sources:

35.67(f)(3) Sources containing 3.7MBq (100uCi) or less of beta or gamma emitting material or 0.37MBq (10 uCi) or less of alpha emitting material.

39.35 Leak testing of sealed sources

39.35(e) Exemptions from testing requirements. The following sealed sources are exempt from the periodic leak test requirements set out in paragraphs (a) through (d) of this section:

39.35(e)(4) Sources of beta or gamma emitting radioactive material with an activity of 3.7 MBq [100microcuies] or less;

When the RLL-1 source holder was originally approved in 1999 the NRC and the Kentucky Radiation Health Branch determined that the word "devices" in 31.5( c )(2)(ii) is referring to the sealed source capsule, as is clearly stated in 35.67 for medical sealed sources and in 39.35 for well logging sealed sources. The Kentucky Radiation Health Branch has requested that I obtain a written concurrence from the NRC.

I have reviewed several of our customer's specific licenses from both agreement states and NRC regions and they state that "sealed sources" containing less than 100uCi of gamma emitting material need not be wipe tested.

I am requesting that the NRC review 10CFR31.5 and direct Ronan Engineering and the Kentucky Radiation Health Branch as to the proper definition of the word "devices" as used in 10CFR31.5( c )(2)(ii). ie: Device means sealed source capsule.

Please contact me at 859-342-8500 or [ccaris@ronanmeasure.com](mailto:ccaris@ronanmeasure.com)

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Sincerely;

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