

National Institutes of Health  
Bethesda, Maryland 20892

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July 16, 2013

Mr. Scott Wilson, Health Physicist  
Division of Nuclear Materials Safety  
Region 1  
U.S. Nuclear Regulatory Commission  
2100 Renaissance Blvd.  
King of Prussia, PA 19406

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Dear Mr Wilson:

03008478

Please consider this response to your email notice of July 10, 2013. This is in reference to the renewal of License 19-00296-17 and addresses all of the remaining deficiencies that you brought to my attention regarding our leak-test procedures. Specifically:

- 1) Specify the personnel training required for personnel taking leak test samples  
Individuals who collect leak test samples from the sealed source irradiator devices will have met the training requirements as specified in Appendix P to NUREG-1556, Vol. 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," dated October 1998. As a minimum, these individuals will have completed the NIH "Radiation Safety in the Laboratory" training class as described in broad scope License 19-00296-10, and will have received on-the-job training consisting of observing more experienced individuals collecting and analyzing leak test samples, and collecting and analyzing leak test samples under the supervision and in the physical presence of a more experienced individual who has already met full training requirements for performing leak tests at NIH.
- 2) Specify that the counting equipment must be of sufficient sensitivity to determine that sample activity is less than 0.005 uCi  
The counting equipment on which leak test samples are analyzed will be of sufficient sensitivity to determine that sample activity is less than 0.005 uCi.
- 3) Provide instruction on how to determine the minimum detectable activity  
The counting equipment on which leak test samples are counted is located in a low-background area, with a calibrated and operable survey instrument available to check samples for gross contamination before they are analyzed. The counting equipment has a known sensitivity across the range of expected energies and has a Lower Limit of Detection (LLD) calculation performed each day that samples are counted. Since the Analytical Lab is utilized to count hundreds of samples every day, including leak test samples, the MDA is not an appropriate daily calculation to use since the anticipated radionuclides (and therefore the applicable counter efficiency) will differ with each sample. Thus, the LLD is calculated, which is a simplified MDA calculation without the "E" term for detector efficiency and with slight formula differences. Only a leak test sample with a

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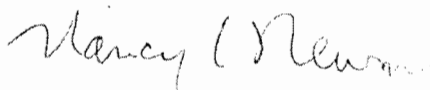
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detectable net count above LLD will be re-counted for activity and have an efficiency for the counter applied at that time.

- 4) Provide that leak test samples of gamma emitting isotopes (Co-60) will be counted using gamma sensitive counting equipment (NaI(Tl) well counter system with a single or multi-channel analyzer) A NaI(Tl) well counter system with a single or multi-channel analyzer typically will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60). Alternatively, a high resolution intrinsic germanium detector with associated computerized gamma spectroscopy capability may be used to count these samples.
- 5) Provide that leak test samples of beta emitting isotopes (Sr-90) will be counted using beta particle sensitive counting equipment (liquid scintillation or gas-flow proportional counting system) A liquid scintillation counter system will be used to count samples of beta-emitting isotopes.

If you have any additional questions, please feel free to reach me at 301-496-2254 or via email at [newmann@mail.nih.gov](mailto:newmann@mail.nih.gov).

Sincerely,



Nancy E. Newman  
Radiation Safety Officer,  
National Institutes of Health

cc: Ms. Cathy Ribaudo, Irradiator Security Manager, DRS, NIH

## DRS Procedures for Leak Testing Irradiators

- ♦ For each irradiator, list identifying information such as location, make, model number, serial number, radionuclide, and activity.
- ♦ Measure exposure rates in the vicinity of the irradiator, and indicate the results on a diagram of the irradiator.
  - If the irradiator is the type in which the source moves to the sample, measure exposure rates both when the irradiator is on and when it is off.
  - If any of the exposure rate measurements is  $>5$  mR/hour at 30 centimeters, ensure that the facility is posted as a Radiation Area.
- ♦ Use a cotton swab or filter paper to leak test the most accessible area(s) where contamination would be present if the sealed source were leaking.
- ♦ Indicate the leak testing location(s) on the diagram of the irradiator.
- ♦ Submit the leak test sample(s) to the DRS Analytical Laboratory or other NRC- or Agreement State-authorized laboratory for analysis.
- ♦ The laboratory will count and record background count rate on the liquid scintillation or gamma counter which will be used to analyze the wipe(s).
- ♦ The laboratory will check the instrument's counting efficiency using a NIST-traceable standard source with similar energy characteristics to the source being leak tested.
- ♦ The laboratory will verify that the accuracy of the counts of the standard source is within  $\pm 2$  and 3 sigma of the stated value.
- ♦ The laboratory will count each leak test sample; determine net count rate; record activity in microcuries; and notify the person who performed the leak test.
- ♦ If the activity on any leak test sample is 0.005 microcurie or greater:
  - Immediately withdraw the source from use.
  - Notify the RSO.
  - Notify the NRC per 10 CFR 30.50 (c)(2).

- Notify the manufacturer or other authorized service company to decontaminate, repair, or dispose of the source properly.
- ◆ Sign and date the leak test record.
- ◆ Submit leak test records to the designated reviewer
- ◆ The designated reviewer will ensure that the records are accurate and complete.
- ◆ The designated reviewer will file the records.
- ◆ Leak test records shall be retained (in hard copy or electronic format) for 3 years.