

US Nuclear Regulatory Commission Region I Office
Division of Nuclear Material Safety
Industrial Branch
475 Allendale Road
King of Prussia, Pa. 19406-1415

MS-16
P-8

March 4, 2005

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RECEIVED
REGION 1

Attention: Donna Janda
Telephone: (610) 337-5371
Fax: (610) 337-5269

Licensee: American Red Cross Blood Services
License #: #37-30073-01 03033294
Subject: Amendment Request for Change in Leak Test Service
Control #: 136300

Dear Ms. Janda,

This letter is a follow-up to an amendment request filed by the above referenced licensee. The amendment was originally being handled by Judy Joustra, but through conversation with Judy, we understand that you have taken over the file in Ms. Joustra's absence.

In conversation with Ms. Joustra on March 2, 2005, she indicated that the following information was needed in order to approve the amendment request. This information is provided in the attachment.

- Verification of the action that will be taken if a leak test sample is positive (> 0.005 uCi)
- Verification that the consultant performing the leak test is not conducting the test as a commercial service for other licensees.
- Provide counting instrument information, the formula used for MDA, and efficiency information
- Identify the materials used

If there is anything else you need, or, if I did not answer the questions to your satisfaction, please do not hesitate to call or email me. We look forward to hearing from you as soon as possible.

Very sincerely yours,

Catherine M. Anderko

Catherine M. Anderko, M.S. CHP
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136300
NMSS/RGNI MATERIALS-002

Licensee: American Red Cross Blood Services
License #: #37-30073-01
Subject: Amendment Request for Change in Leak Test Service
Control #: 136300

Date: March 4, 2005

1. **Verification of the action that will be taken if a leak test sample is positive (> 0.05 uCi):**

- a. Samples taken at the irradiator will be immediately scanned with a GM survey meter set on its most sensitive scale. If a radiation level above background is detected with the GM, the samples will not be taken to the counting facility. The manufacturer will be notified and the unit taken out of service until it can be verified that the sources are not leaking.
- b. If no radiation level above background is detected with a GM, the samples will be taken to the counting facility using appropriately labeled transport media and promptly evaluated. If the sample analysis reveals contamination > 0.005 uCi/100 cm², the sample(s) will be immediately returned to the secure irradiator area, the manufacturer notified, and the unit taken out of service until it can be verified that the sources are not leaking. The samples will be handled and stored as radioactive material and properly disposed according to the manufacturers protocol.

2. **Verification that consultant is not a commercial leak tester:**

- a. The undersigned provides consulting services for the licensee, however, the leak test will be performed as a gratis service with no additional fees charged to the licensee. Leak testing is not performed by the undersigned for any other licensee.

3. **Provide counting instrument information, the formula used for MDA, and efficiency information:**

- a. The equipment used to count leak test samples will be a 3" x 3" NaI MCA with a well type detector system. The equipment is located either at Geisinger Wyoming Valley Medical Center in Wilkes Barre, Pa., or, at Geisinger Medical Center in Danville, Pa. The equipment is maintained by Health Physicists. The undersigned is the Radiation Safety Officer and Health Physics Department Director for this hospital system. Use of the equipment for this purpose is approved and authorized by senior management at Geisinger.
- b. The formula used to determine MDA is that provided by the NCRP and others:
$$MDA (dpm) = 2.71 + 4.66 \sqrt{BKG \text{ cpm} / \text{eff} (cpd) \times t (min)}$$
- c. The counting efficiency will be determined by counting a NIST-traceable standard of ⁶⁰Cobalt, determining net cpm, and dividing by the decay-corrected actual dpm certified by NIST to be present in the source standard. The efficiency will be verified at the time of the leak test analysis.
- d. Wipe test materials will include long handled q-tip swabs, a moistening agent such as alcohol preps or decontamination agent, envelopes or test tubes to serve as transport media, labeling materials, and GM survey meter.

4. **By: Catherine M. Anderko, CHP, Radiological Physics Consultant**

Catherine M. Anderko
3/4/05