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CDRH/FDA**Fax**

P-7

19-07533-01

03004544

To: MR. TOM THOMPSON
From: PETRO SHANDRUK, RSO
MAIL CONTROL NO. 140402-
FDA/CDRH/OCER/DMQRP (HFZ-240)
Fax: 610/337-5269
Pages: One plus cover (2 total)
Phone: 610/337-5303
Date: MAY 29, 2007
Re: License Number 19-07538-01
cc:

☒ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Mr. Thompson,

Since you have been handling our license amendment request, I felt you would be the best person to assist me in this matter.

Earlier this spring, Buildings 1 & 2 of 12720 Twinbrook Parkway were vacated by the staff for their move to White Oak. In the course of their packing for the move, they uncovered an americium sealed source (a blue and yellow disk marked: NEN, Am-241, 7.3 microCi, dated 12/21/72). This source was quickly sequestered by me and a leak (wipe) test was performed on it, by a contractor, and the results were found to be at background.

While reviewing the NRC regulations concerning the source, I inquired with the researchers as to the origin of the source and determined that it had been used by an individual since its receipt until that person retired in 2001. I was also able to recover a "Certificate of Radioactivity Calibration" provided by NEN, a copy is attached. As a result of my inquiries, I have been approached by one of the Center's researchers who would want to use the source for the calibration of radiation detectors.

Am I correct in interpreting the NRC regulations that this source should be listed on our license? If so, should I submit another form 313 or is this fax request sufficient as an addendum to the pending amendment request.

I greatly appreciate your expeditious response to this inquiry.

Respectfully,



Petro Shandruk

140599

NMSS/RGN1 MATERIALS-002**REC'D IN LAT JUN - 5 2007**

Tom Farrell

CERTIFICATE OF RADIOACTIVITY CALIBRATION

Am-241 Standard
NES-128 S

Lot Number: 01-75-001
Half-Life: 458 years

The activity of Americium-241 was found to be,

7.3 microcuries on December 21, 1972

The 60 Kev gammas are assumed to be 0.38 of the decay rate.

DESCRIPTION OF THE STANDARD

The activity has been incorporated into an epoxy bead. The bead is then sealed in the center of a plastic disc $\frac{1}{4}$ " diameter by $\frac{1}{8}$ " thick.

METHOD OF CALIBRATION

The source was calibrated on a 4 π gamma ionization chamber against a source certified by the National Bureau of Standards.

ERRORS

Random Error (3 times the standard deviation)

a. Precision of the NENC measurement $\pm 1.0\%$

Systematic Error

a. Precision of the calibration of the
NENC ion chamber $\pm 1.5\%$

b. Precision of the NENC to National Bureau
of Standards comparison $\pm 2.0\%$

Overall Error

1.0% + 1.5% + 2.0% = $\pm 4.5\%$



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