franklin regional medical center

July 11, 1985

John D. Kinneman, Chief
Nuclear Material Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

RE: License #37-11438-02
Docket #030-13111
Inspection #030-13111/85-01

Dear Mr. Kinneman:

Thank you for your letter of June 13, 1985 relative to the above noted inspection. We offer the following reply to the items noted in Appendix A, Notice of Violation:

A. The nuclear medicine technologists have been furnished with a copy of Guide 10.8 and the other items submitted as part of the license application. They have been made aware that these documents are conditions of the license.

B.1.a) Our records indicate a reading of 0.88 Mci for the daily constancy check of the dose calibrator on March 12, 1985. The permissible range (± 5%) for this reading was 0.7709 Mci to 0.9029 Mci. Our records indicate a reading of 2.82 Mci for the daily constancy check of the dose calibrator on December 12, 1985. The permissible range (± 5%) for this reading was 2.5046 Mci to 2.9335 Mci. Therefore, contrary to the stated violation, it would appear that we are well within the established limits. We will continue to monitor these readings carefully to assure continued compliance.

B.1.b) Guide 10.8 (and the NRC letter) uses the term, "all commonly used radio nuclide settings." In this Laboratory it is debatable whether or not I-131 and gallium 6% should be considered as commonly used nuclides. However, in the spirit of cooperation, these settings are now included in the daily dose calibrator checks.

B.1.c) Please refer to the Request for Amendment attached. We have also enclosed a check in the amount of $150.00 for the application amendment fee.

B.2.a&b) Wipe surveys are now being performed over designated areas of 100cm^2 each. The wipes are evaluated using the Picker - Pace I auto-gamma well counter, Model #630085. An I-125 well counter standard reference source is used to determine that the counting method is capable of detecting 200 dpm/100cm^2, or less. Records are made of all counts, including that of background and of the analyses. A diagram is enclosed of the wipe test survey areas.

C. Previously, I-125 was used by the Pathology Lab under a general license which permitted the possession of no more than 200uc. The Nuclear Medicine License #37-11438-02 (Amendment 8) has been amended to permit the possession of 3000uc of I-125 for invitro studies under the supervision of Dr. John Shonnard, Director of Laboratories.

D.1. Solid waste which may be contaminated with radioactive material is now examined using a Victoreen Model 490 portable survey instrument having a Model 489-35 (thin end window) GM detector. The examination is performed with the end window of the detector uncapped and the instrument set to its most sensitive range (X1). The instrument's response to background and the test source on its case are recorded for each survey event. Normal background count for this instrument in this lab is about 50 CPM. No solid waste will be discarded if it presents a gross count rate, including background, greater than 200 CPM. Written record is maintained of all such solid waste surveys and disposals.

D.2. While the amount of I-125, which has been flushed down the drain in the past, has been under the limits prescribed by 10 CFR 20.303 (by a factor of about 300), no written record of the permitted amount was maintained.

Based upon the estimated sewerage flow rate of this hospital (200 beds), (about 50,000 gallons/day), the limit of I-125 concentration permitted in this volume by 10 CFR 20.303 (at 4×10^{-5} uc/ml) is such that about 7600uc could be discarded daily

$$\frac{5 \times 10^4 \text{ gal}}{\text{day}} \times \frac{231 \text{ in}^3}{\text{gal}} \times \frac{(2.54 \text{ ml})^3}{\text{in}^3} \times \frac{4 \times 10^{-5} \text{ uc}}{\text{ml}} = 7571. \text{ uc/day, permitted I-125 disposal in sewer.}$$

All material disposed of in the sewer is readily soluble in water. Each disposal of I-125 in the sanitary sewer will be recorded. The record will show the date of disposal and the estimated amount, in microcuries. All such disposal will be done in the designated sink in the RIA lab and will not exceed prescribed limits.

A "Caution - Radioactive Materials" sign (accepted colors and symbol) has been posted at this sink and on the waste trap of the sink.

Sincerely,

John A. Stanton

John A. Stanton, Administrator

LINEARITY TESTS OF DOSE CALIBRATOR

July 11, 1985

Appendix D of Regulatory Guide 10.8, which is presently a condition of this license, requires that the quarterly linearity tests be performed using activities covering the entire range employed. It requires that the test be performed using the first elution of a new Tc-99m generator. It also pins the success of the test upon one certain reading (the 30 hour reading) rather than upon a scientific analysis of the data from all readings.

To use the first elution from a new generator in this laboratory would seriously deplete the available supply of Tc-99m for the day of the test. Patient testing would be at a minimum for that day.

Since the usual patient dose of Tc-99m is 20 mci, it is proposed that the linearity tests be performed using an initial activity of about 25 mci of Tc-99m.

It is further proposed that the readings be continued to at least 30 hours beyond the initial reading. This would give data covering 25 mci to about 0.8 mci, a reasonable range for clinical purposes. In contract, using the first elution of a new generator would, in this laboratory, involve an initial activity of about 1000 mci and a final activity (even at the 48 hours required by Guide 10.8) of about 4. mci. In other words, the method of Guide 10.8 neither covers the useful range of activities, nor is it observing the principles of ALARA.

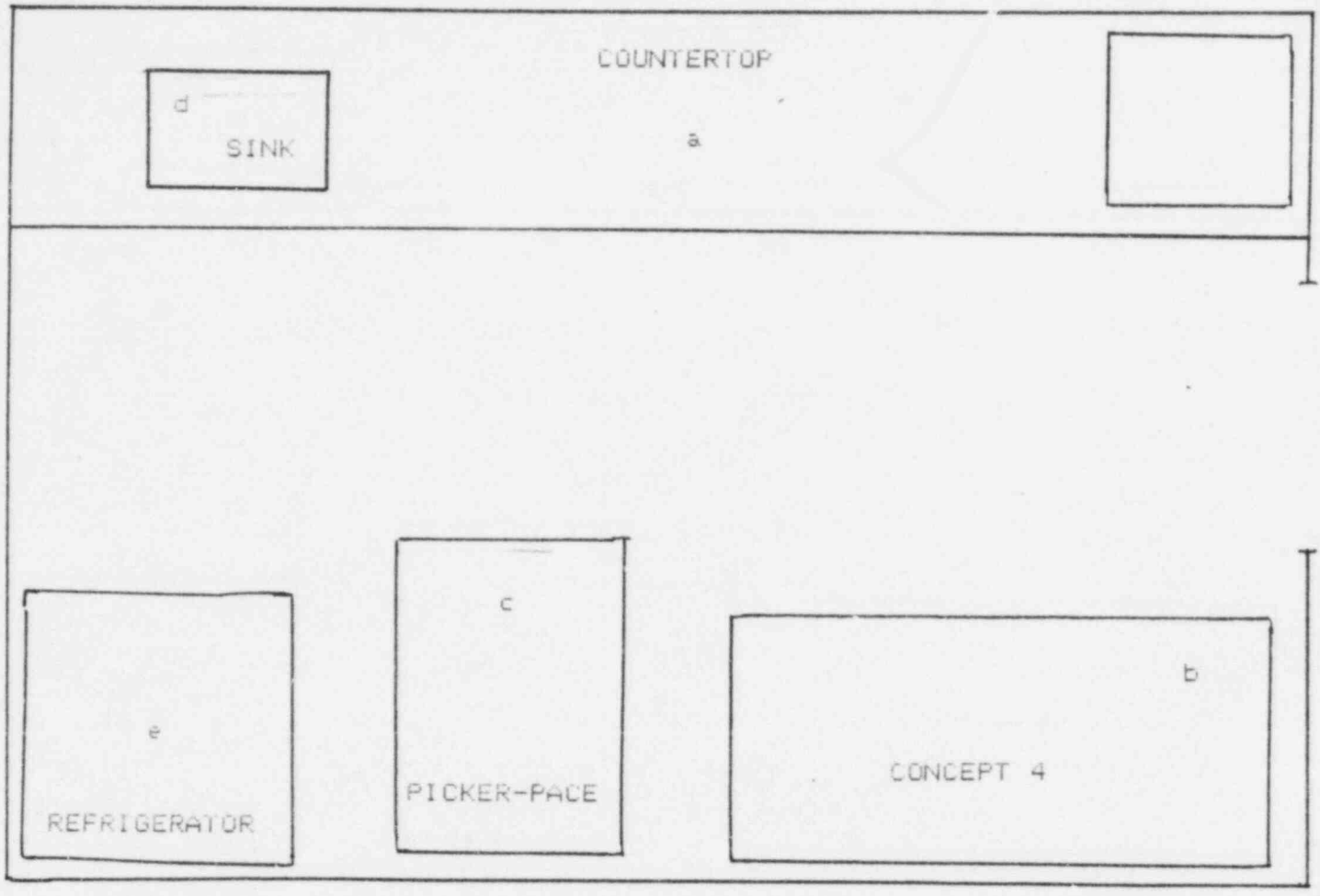
Rather than using the 30 hour activity measurement as required by Guide 10.8 for the calculation of the predicted Tc-99m activities at the other measurement times, it is proposed that all measurement data be plotted on semi-log graph paper and a "best-fit" straight line be drawn through the plotted points. This is a normal treatment of experimental data.

The apparent half-life of the Tc-99m will be calculated from the slope of the "best-fit" curve. The curve will be considered as acceptable if the calculated half-life is inside the range of 5.95 to 6.05 hours.

It is also proposed that the 30 hour activity as read from the "best-fit" curve will be used to calculate the predicted activities for the other reading times. If the predicted values as calculated by this method differ from the actual measured activities by more than 5%, the test will be repeated. If a difference of more than 5% persists, the dose calibrator repair facility will be requested to help determine remedial action.

Since the pressure of clinical work can easily delay a planned reading beyond the times specified by Guide 10.8, including the 30 hour reading, the 2, 4, 6, 24, & 30 hour reading times are only approximate.

RIA ROO[redacted] LOCATIONS FOR [redacted]PE TESTS



LOCATIONS FOR WIPE TESTS

Each area represents 100 square centimeters of surface.

a)Work countertop- Wipe area is located 4 feet to the right of the sink and 1 foot from tne back of the countertop.

b)Concept 4 filling station- Wipe the complete tracer filling station.

c)Picker-Pace counting well- Wipe area around the counting well on the Picker-Pace.

d)Sink- Wipe area is the far left corner floor and adjacent sides.

e)RIA Refrigerator bottom shelf- remove all reagents from the bottom shelf and place on a Chux that is plastic side up on the floor. Wipe area is 100 square centimenters in the center of the bottom shelf.

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Franklin Regional Medical Center

Application Dated: 7/11/85

Control No.: 04093

License No.: 37-11438-02

2. FEE ATTACHED

Amount: $150.00

Check No.: 01085

3. COMMENTS

Signed Brenda Platchek

Date 7/16/85

02120

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C - $120 ($30 refunded) 11/87

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed G Jackson

Date 8/8/85

REGION I FORM 213
(MARCH 1983)

"SECTION COPY"

INVOICE NUMBER	INVOICE AMOUNT	DISCOUNT	NET AMOUNT	INVOICE NUMBER	INVOICE AMOUNT	DISCOUNT	NET AMOUNT
Amendment of license			150.00				

01085 VENDOR NUMBER CHECK NUMBER CHECK DATE 7-11-85

franklin regional medical center

ONE SPRUCE STREET
FRANKLIN, PA 16323

60-71
433

01085

CHECK DATE	VENDOR NO.
7-11-85	

FIRST NATIONAL BANK
OF PENNSYLVANIA
FRANKLIN, PENNSYLVANIA

CHECK NUMBER
01085

TOTAL AMOUNT
$150.00

TO THE ORDER OF

United States Nuclear Regulatory Commission

⑈001085⑈ ⑆043300712⑆ 671⑈000110⑈