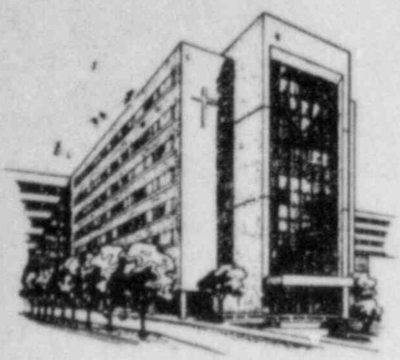

ST. ELIZABETH HOSPITAL MEDICAL CENTER

A MAJOR TEACHING HOSPITAL ASSOCIATED WITH
The Northeastern Ohio Universities College Of Medicine

DEPARTMENT OF RADIOLOGY

1044 Belmont Avenue
P.O. Box 1790
Youngstown, Ohio 44501-1790

(216) 746-7211
Extension 3666

030-02670

'83 OCT 21 P2:23
RECEIVED
U.S. N.R.C.
LIC. FEE MGMT BRANCH

N. R. C. License # 34-01131-01

12 October, 1983

RECEIVED BY LFMB
Date 10/21/83
Log 001 1204
By CAP
Orig. To R/III
Action Compl. CAP 11/22/83

United States Nuclear Regulatory Commission
Material Licensing Branch
Region III
799 Roosevelt Road
Glenn Ellyn, Illinois 60137

Dear Sir:

Please amend our N. R. C. License # 34-01131-01 in three (3) areas as stated below.

1. Due to the increase in the volume of Nuclear Cardiology procedures, (3,000 procedures in 1982), please amend our current possesion limit of Mo 99 generators from 2 Ci to 3 Ci.

2. We presently place our Mo99 generators in storage until radiation levels reach background. We wish to amend our license as to return spent generators to the manufacturer. Guide lines for this procedure will be followed according to N. R. C., Department of Transporation and Manufactures regulations.

3. Test for instrument linearity is presently being done on our dose calibrator in accordance with attachment No.#6., sub-stem E, of our original license application. (enclosure)

As an alternative to our present procedure, the dose calibrator can be checked for activity linearity with use of a device called "calicheck" form Calcorp, Inc. The manufacturers instructions for use as revised on March 2, 1982, will be followed. Test results will be recorded and retained for inspection. Corrective action will be taken if unacceptable linearity is demonstrated.

Thank you for your co-operation.

Sincerely,

Clayton A. Hixson

Clayton A. Hixson, M. D.
Medical Director--Division of Nuclear Medicine

Applicant
Check No. 119303
Amount/Fee Category $40.00
Type of Fee amend
Control No. 75749
Date Check Rec'd 10/18/83
Received By CAP

RECEIVED
OCT 17 1983
REGION III

OCT 17 1983

A. Test for the following:

1. Instrument linearity (at installation and annually thereafter).

2. Geometrical variation (at installation).

3. Instrument accuracy (at installation and annually thereafter).

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Daily or before each use of the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment, or recalibration.

2. Measure and record the apparent activity of a long-lived clinical radionuclide such as Cs-137 or Ra-226. Choose a source with activity in the 100 uCi range.

F. Inspect the instrument on a quarterly basis to ascertain that the instrument chamber liner is in place and that instrument zero is proper (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a unit of high-level activity (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.

2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

Control No. 75749

Using the 30-hour activity measurement as a standard, calculate the predicted activities at 0, 6, 24, and 48 hours using the following scale:

Assay Time (hr)	Correction Factor
0	32
6	4
24	2
30	1
48	0.125

Example: If the 30 hour activity measured was 1.025 mCi, the predicted activity for 0 and 48 hours would be: 0 = 250 mCi and 48 = 0.125 x 1.05 mCi = 0.13 mCi.

4. Plot the measured and predicted activities for each time interval versus the predicted activity on log-log graph paper.

5. The activities plotted should be within ± 5% of the predicted if the instrument is linear and functioning properly. Errors greater than ± 5% indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the bulk sample accurately measured or to use the graph constructed to convert measured activities to true activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measurements as a function of sample volume or configuration, depending on the well size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be established for commonly used radionuclides and appropriate correction factors computed if variation is significant, i.e., greater than ± 2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be verified).

To measure variation with volume of liquid, a 10-cc aliquot of a solution of Co-57 or other appropriate radionuclide (in a volume of 1 ml or less) is

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.