

## Philips Medical Systems

May 22, 1985  
0317-85

MS 16  
P6

Nuclear Regulatory Commission  
Region 1  
631 Park Ave.  
King of Prussia, PA 19406

Attention: Laurence F. Friedman, Ph.D., C.H.P.  
Senior Radiation Specialist

REFERENCE: LICENSE NUMBER 06-10081-03  
DOCKET NUMBER 030-17244  
CONTROL NUMBER 18340

Dear Dr. Friedman:

As requested in your telcon of May 7 with Dr. S. Balter, we are providing a revised response to 15. of our renewal application.

Please let us know if we can be of any further assistance in this matter.

Sincerely,

*Robert F. Avrutik /jmg*

Robert F. Avrutik  
Director  
Regulatory Department

RFA/jmg  
Enclosure

8507030453 850610  
REG1 LIC30 PDR  
06-10081-03

"OFFICIAL RECORD COPY"

ML10

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15. The sources are kept in locked lead lined boxes. Only those persons authorized by this license to use the sources have access to them.

The attached copy of the Philips Medical Systems, Inc. Radiation Safety Manual is given to each monitored employee and explains our Radiation Safety Program. In addition, each monitored employee received a 1½ hour lecture on Radiation Safety and Biological Effects of Ionizing Radiation from the Company Radiation Safety Officer.

The leak test will be carried out by one of the following methods:

1. Philips Medical Systems, Inc. employees, who have been properly instructed by Nuclear Radiation Consultants, will make a wipe as instructed and send it to Nuclear Radiation Consultants for analysis. The wipe will be analyzed on a single gamma ray spectrometer through the use of a sodium iodide crystal "well detector". Nuclear Radiation Consultants will use a standard Cs 137 source for comparison and quantification. Nuclear Radiation Consultants will then send a certification to Philips Medical Systems, Inc. showing the results.
2. The wipe will be performed by Stephen Balter, Ph.D. according to the following procedure:

Material: Victoreen Thyac III GM Counter    Model 490  
Victoreen End Window GM Tube    Model 489-35  
Calibrated Co-60 Beta, Gamma Disk Source  
New England Nuclear NES-2000C

Procedure:

1. Turn on the Geiger Counter and allow a five-minute warm up period.
2. Switch to battery test position and verify adequate battery voltage.
3. Switch to XI scale, remove the protective cover from the end window of the GM tube, and verify gross performance of the instrument by use of the operational check source on the side of the instrument. A full scale deflection should be obtained.
4. Locate the instrument in a convenient location away from sources of radiation.

5. Calculate the present activity of the reference source (A).
6. Switch the instrument to long time constant.
7. Observe the background count rate in terms of CPM (B).
8. Place the reference source approximately 2 mm from the window of the GM tube. Observe the gross count rate (G).
9.  $S = (\text{CPM} / \text{nCi}) = (G - B) / A$
10.  $M = 5 * S$
11. If  $M > 2 * B$  the instrument may be used for evaluating wipes.

#### EVALUATION OF WIPES

1. Calibrate the GM counter using the attached procedure.
2. Set the instrument to long time constant.
3. Observe the background count rate in CPM (B).
4. Hold the wipe approximately 2 mm from the end window of the GM tube. The side used to wipe the surface should face the window. BE CAREFUL NOT TO TOUCH THE GM TUBE WITH THE WIPE.
5. After the count rate has stabilized (approximately 30 seconds), observe the count rate in CPM (T).
6. If  $T > 3 * B$  then the wipe may be contaminated. Set it aside and notify one of PMSI's Certified Radiological Physicists. The physicist will continue the evaluation of the wipe and the possibility of contamination of the source under test.

#### SAMPLE CALCULATION FOR GM CALIBRATION

##### Assumptions:

1. The activity of the reference source was 37 nCi on 1 Jan. 1982.
2. Today's date is 15 Apr. 1985.
3. The background count rate (B) is 50 CPM.
4. The gross count rate (G) is 1100 CPM.

Procedure:

1. The time interval between the calibration date of the reference source and today is 39.5 months.

2. The decay fraction is calculated by:

$$F = \exp - ((0.693 * 39.5) / 63)$$

$$F = 0.6475$$

3. The present activity of the source is:

$$A = 37 \text{ nCi} * 0.6475 = 24.0 \text{ nCi}$$

4. The sensitivity S is given by:

$$S = (1100 - 50) / 24.0$$

$$S = 44 \text{ CPM} / \text{nCi}$$

5. The net signal expected from a minimally contaminated wipe (5 nCi) M is therefore:

$$M = 5 * 44 = 220 \text{ CPM}$$

6. The background activity (B) is 50 CPM. Since  $M > 2 * B$  the instrument has sufficient sensitivity to detect a wipe contaminated with 5 nCi of Co-60.

# CERTIFICATE OF RADIOACTIVITY CALIBRATION

Cobalt-60 Reference Source  
NES-200C

Half-Life: 5.271 + 0.001 yrs.  
Lot Number: 200C083T82

The activity of Cobalt-60 was determined to be 0.036 microcuries on August 31, 1982.

## DESCRIPTION OF THE SOURCE

The activity was deposited in a 5mm diameter active area on a 0.25mm thick stainless steel planchet, covered with a 0.90 mg/cm<sup>2</sup> aluminized mylar window, and sealed into the aluminum mount. The overall dimensions of the source are 3.6mm in height and 25mm in diameter. The mass of the deposit was less than 0.01mg and self-absorption was considered negligible.

## DECAY SCHEME

$\beta^-$  0.318 MeV maximum  
0.096 average

Intensity (%)

99.92 (2 weak  $\beta^-$ 's  
omitted)

Reference: A Handbook of Radioactivity Measurements Procedures, NCRP Report No. 58,  
November 1978.

## METHOD OF CALIBRATION

The source was calibrated by measurement in a 2 $\pi$  internal proportional counter whose response for the radionuclide and geometry had been verified through the use of a secondary standard. The secondary standard was prepared from a solution whose activity was determined by measurement of the current produced in a 4 $\pi$  gamma ionization chamber. The response of the ionization chamber to Cobalt-60 had been determined using the National Bureau of Standards certified solution SRM 4915.

New England Nuclear Corporation participates in a National Bureau of Standards-Atomic Industrial Forum measurement assurance program in order to insure the continuing traceability of NEN's radioassays to the NBS.

## RADIOIMPURITIES

A random sampling of this production lot was examined for photon-emitting impurities with a Ge(Li) spectrometer system. The radioimpurities were determined to be <0.1% expressed as a percentage of the gamma-ray-emission rate of the 1332 keV gamma ray of Cobalt-60.

## ERRORS

Random Errors (99% confidence level)

Precision of the measurement of the source

+ 1.9%

Precision of the measurement of the NEN secondary standard

+ 1.2%

Systematic Errors

Accuracy of the NEN secondary standard (linear sum of the estimated  
upper limits of errors involved in its preparation)

+ 3.2%

Overall Error

$$[(1.9)^2 + (1.2)^2]^{1/2} + 3.2 = + 5.4\%$$

# CONVERSATION RECORD

TIME  
0830

DATE  
5/7/85

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☐ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT  
WITH YOU

Robert F. Aorutik

ORGANIZATION (Office, dept., bureau,  
etc.)

Philips Medical Systems

TELEPHONE NO.

SUBJECT

Deficiency in Leak Test Procedure

SUMMARY

I informed him his proposed leak test service was not licensed by NRC to perform leak tests.

I told him Philips could do own leak tests but I needed more detailed procedures, including make a model of instruments, and nature of calibration sources. (port, etc.)

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Lawrence F. Friedman

5/7/85

ACTION TAKEN

"OFFICIAL RECORD COPY"

ML10

SIGNATURE

TITLE

DATE

50271-101

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CONVERSATION RECORD

OPTIONAL FORM 271 (12-76)  
DEPARTMENT OF DEFENSE