030-02672

ST. VINCENT HOSPITAL AND MEDICAL CENTER

TOLEDO, OHIO 43608
August 21, 1981

John E. Bowyer
Nuclear Regulatory Commission
Region III
Licensing Division
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Byproducts Materials License No.
34-01216-03
St. Vincent Hospital and
Medical Center
2213 Cherry Street
Toledo, Ohio 43606

Aug 21, 1981

Dear Mr. Bowyer:

St. Vincent Hospital and Medical Center would like to amend its Byproducts Materials License as per Attachments A through D to this letter.

Also enclosed please find the $40.00 amendment fee.

Sincerely,

Allen Johnson

Allen Johnson
Executive Administrator
St. Vincent Hospital and Medical Center

RECEIVED BY LSMB
Date 9/8/81
Log Sept. Pg 6 Reg. III
By Brown
Orig. To
Action Compl.

Applicant
Check No. 064032
Amount Paid $40.00
Type of Fee Amendment
Date Check Rec'd 9/8/81
Received By Brown

AUG 20 1981

AJ/jfp
Enclosures

8506100047 850517
REG3 LIC30
34-01216-03 PDR

CONTROL NO. 05281

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

Attachment A. Amendment to add an authorized user to the license

St. Vincent Hospital and Medical Center wishes to add Peter Royen, M.D. to its license as an authorized user. Supplements A and B for this physician are attached.

Attachment A

8-21-81

CONTROL NO. 05281

AUG 20 1981

FORM NRC-313M-SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
PETER ROYEN, M.D.	OH

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C.
DIAGNOSTIC RADIOLOGY		JUNE, 1975

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	HARTFORD HOSP (CONN) 7/71 - 6/74	60	
b. RADIATION PROTECTION	"	20	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	20	
d. RADIATION BIOLOGY	"	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	"	20	

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc^{99} I^{131} I^{125} Xe^{133}		ABOVE AND ST VINCENT HOSP TOLEDO, OH	9 years	clinical

CONTROL NO. 05281

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: PETER MARK ROYEN

STREET ADDRESS: 421 MICHIGAN

CITY: TOLEDO | STATE: OH | ZIP CODE: 43624

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	50	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	25	
	LIVER FUNCTION STUDIES	~~500~~	
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	25	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS	10	
I-131	THYROID IMAGING	100	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING	25	
Yb-169	CISTERNOGRAPHY	25	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	200	
OTHER			
Tc-99m	BRAIN IMAGING	300	
	CARDIAC IMAGING	25	
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	200	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	300	
	LUNG IMAGING	250	
	BONE IMAGING	250	
OTHER			

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PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	10	
	TREATMENT OF HYPERTHYROIDISM	10	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

7/71-6/74 600 "

7/74-12/80 600 "

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
S.T. PINSKY, M.D.

b. NAME OF INSTITUTION
ST VINCENT HOSP

c. MAILING ADDRESS
2213 CHERRY ST

d. CITY
TOLEDO, OH

e. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
(See letter on following page)

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

FORM NRC-313M-SUPPLEMENT B
(8-78)

CONTROL NO. 05281

Hartford Hospital

To whom it may concern:

This is to certify that Peter Royen, M. D. spent three full months (520 hours) in Nuclear Medicine training under my preceptorship from April 1, 1972 through June 30, 1972 as part of his Radiology residency. The time included training in radiation safety and handling, radiation physics and instrumentation, radiopharmaceutical chemistry and clinical training in diagnostic uptake, dilution and imaging procedures. He supervised or observed approximately 950 patient diagnostic studies during this time.

I am board certified by the American Board of Nuclear Medicine (number 01134), May 5, 1972. The Nuclear Regulatory Commission License Number of Hartford Hospital is 06-00253-04.

Sincerely,

John J. Sziklas

John J. Sziklas, M. D.
Director
Clinical Nuclear Medicine

JJS:dpr

CONTROL NO. 05281

HARTFORD, CONNECTICUT 06115 • TELEPHONE: (203) 524-3011

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

Attachment B.

Amendment to Xenon-133 Amendment to Byproduct Materials License
(Amendment No. 32 to License Number 34-01216-03, February 5, 1980)

Amendments to the following sections listed in Amendment No. 32 are requested:

1. Section F. Dosage Employed

   Amend in entirety to
   "15 mCi per patient, however, higher or lower doses may be used when professional medical judgement indicates the necessity."

2. Section I. Imaging Equipments

   Substitute "Technicare Radioisotope Camera, Model No. 438-3" for "Searle Pho Gamma IV" in Imaging Room #2.

3. Section K. Dose Calibration

   Amend in entirety to

   All doses for patient use will be checked immediately prior to administration with a Capintec Dose Calibrator CRC-30 described in Addendum 1. to this Attachment. The Mediac Dose Calibrator described in our original license submission will be used only as a back-up calibrator.

4. Section N. Description of Storage Area

   a) Amend first two sentences to: Xenon-133 gas will be stored in its 1/8" thick lead shipping container within the fume hood until required. The storage area within the fume hood is covered lead cylinder with the following dimensions: 5 1/2" high, 8 1/2" diameter, and 3/4" thick.
   b) Delete the last sentence:
      "The Xenalert detection system as describe in Attachment #3 will monitor the room air in the area when it is not being used during a patient procedure in the Imaging Room."

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ATTACHMENT B
8-21-81

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

5. Section O. Description of Procedure

Amend the first sentence by deleting "Mediac". The sentence will therefore read: "The Xenon-133 gas will be used in the following manner: the dose will be measured in a dose calibrator."

6. Section P. Description Utilizati -ea (Imaging Room)

a) Amend this section by deletion of the third sentence: "Upon completion of this procedure, the monitor will again be placed in the storage area room containing the fume hood, as described previously".
b) Add the following sentence to the end of this section "The Xenalert Room air monitor will remain in Imaging Room #1 unless needed in other areas as dictated by circumstances."

7. Section Q. Disposal Phase

Amend the third sentence to: " To insure that the trap is working efficiently, the exhausted air from the trap may be monitored using the following procedure:..."

8. Section R. Equipment Operation and Monitoring of Leakage

Subsection C. Amend in its entirety to:

c) The Xenon leakage from the Xenon traps may be monitored as described above. Other leakage tests will be performed as the xenon is exhausted following a patient study. This exhaust will be fed into the Xenalert detection system in the port provided for this purpose. The resulting monitored leakage measurement will be recorded and compared with a standard value. A replacement filter trap will be installed whenever this standard value is exceeded. All traps will be tested within every ten uses.

ATTACHMENT B
8-21-81

Attachment B.

CAPINTEC

CAPINTEC RADIOISOTOPE CALIBRATORS

SECTION 1

INTRODUCTION

1.1 GENERAL DESCRIPTION

The CRC-30 Radioisotope Calibrator provides a fast and very accurate method of measuring radioisotope activity at the time and place of its application. It also provides for the automation of many of the chores involved in patient safety, calculations, record keeping and inventory control.

Activity measurements are performed by state of the art electronic circuits in conjunction with an ionization chamber possessing extremely high sensitivity and stability.

Eight preset isotope pushbuttons are provided for quick calibration setting of the most often used radioisotopes. In addition, the half-life and name of each of these eight radioisotopes is preset into the computer's memory for automatic decay correction with time and for printout identification.

Confirmation of instrument functioning and all required adjustments can be made with finger-tip operation.

1.2 Functions and Capabilities

This section describes the functions and capabilities of the CRC-30 instrument.

1.2.1 Measurement (calibration) of the activity of seven preset radioisotopes and measurement by manual setting of over 100 "other" radioisotopes (using the calibration charts provided).

1.2.2 Storage of initial specific activity information within a self-contained memory for up to 19 different samples of any of the radionuclides normally used in Nuclear Medicine.

1.2.3 Automatic decay correction with time for the specific activity of eight of the more commonly used

radionuclides in accordance with their half-lives.

1.2.4 Calculation of the required volume for a given dose with decay correction, if the radionuclide being used is one of the eight for which half-life information has been preset into the computer.

1.2.5 Printing of a permanent record of the dose computation and measurement on a three copy form.

1.2.6 Printing of the activity concentration and the required volume to deliver a given dose for the samples as a function of time.

1.2.7 Measurement and printing of calculated results of radiochemical purity analysis performed using paper chromatography.

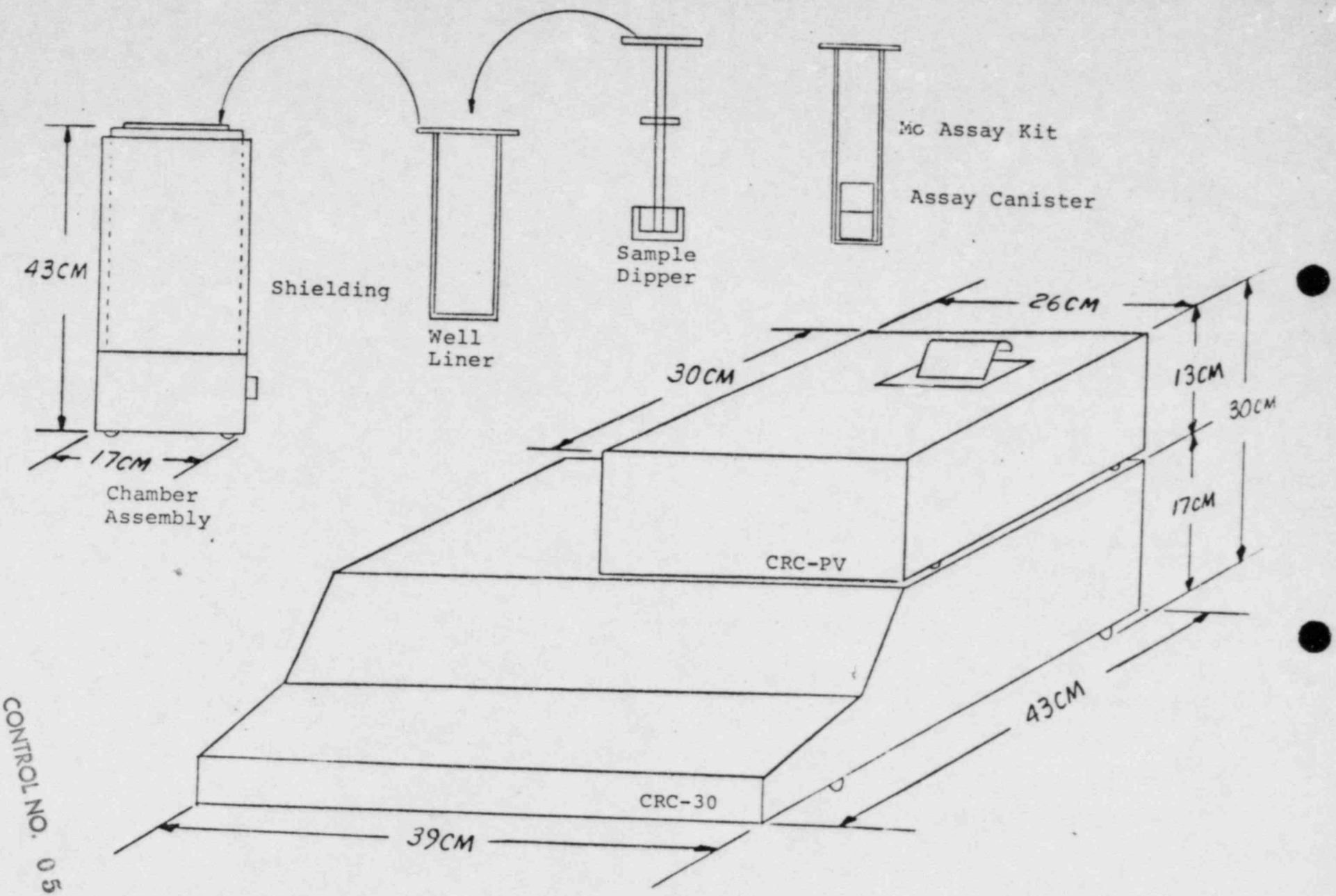
1.2.8 Maintain a running inventory of the remaining isotope in a given sample.

1.2.9 Measurement and calculation of Molybdenum 99 content of ^{99m}TC.

1.3 SPECIFICATIONS AND REQUIREMENTS

1.3.1 ENVIRONMENTAL REQUIREMENTS

1. The calibrator should be located where the level of the background radiation is as low, and as constant, as possible.
2. The calibrator should be placed on a steady table in a clean and dry location.
3. Avoid placing the calibrator in direct sunlight or in a close proximity to a heater or air conditioner.
4. For maximum reliability and accuracy the instrument should be located where the temperature range is from 50°F to 85°F (10°C to 30°C) and maximum relative humidity is 60%.



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DIMENSIONS OF CRC-30 AND CRC-PV

NOTE: The calibrator may be used safely to temperatures as high as 100° F (40° C) and relative humidities as high as 95% as long as no condensation forms anywhere on the unit.

1.3.2 DIMENSIONS(see fig. 1-1)

	CRC-30	CRC-PV	Chamber Assay
length	43cm	30cm	-
width	39cm	26cm	17cm dia
height	17cm	13cm	43cm
weight	9.3kg	7.3kg	14kg

1.3.3 POWER REQUIREMENTS

Line Voltage:

115±20 VAC @ 1 Ampere
230±35 VAC @ 0.5 Ampere

Frequency:

60 Hz (50 Hz optional)

- CAUTION -

In the event of a power failure the memory is protected by battery for up to 3 weeks. However, stock information is not protected and must be re-entered.

1.3.4 Performance specifications

Activity Range
Five automatic ranges
0.1 - 199.9 μ Ci
199.9 - 1999 μ Ci
.1999 - 19.99 μ Ci
19.99 - 199.9 μ Ci
199.9 - 1999 μ Ci
(overrange - indicated by HELP 2 or 10)

Detector Linearity (to activity)
±1% (chamber saturation less than 2% up to 2 Ci ^{99m}Tc)

CONTROL NO. 05481

Detector Response (to radiation)
Within ± 2% of mean for radioisotopes with major photon radiation over 0.1 MeV (when chamber response is normalized for ^{60}Co and ^{57}Co radiations)

Iometer Accuracy (low impedance electrometer)
± 2% of reading

Digital Panel Meter

The digital panel meter is a 4 digit, seven segment (13 mm. high) LED display with floating decimal point. Over-range is set for 2000 milliCuries and is indicated by blinking center segment.

±0.05% of full scale
±0.1% of reading
±1 on the last digit

1.3.5 Overall Accuracy

Overall accuracy of the calibrator is determined by the accuracy of:

(a) specific source calibration accuracy
(b) chamber linearity and response
(c) Iometer accuracy
(d) digital readout accuracy

1.3.6 Repeatability

Measurements will repeat to within ±1% for a period of 24 hours during which time the instrument is maintained under constant temperature, humidity, and background radiation conditions, and is powered at all times.

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ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

Attachment C. Amendment to Application for Byproducts Material License Submitted on October 17, 1978.

The amendments are to be made to the following attachments contained in the October 17, 1978 submission:

1. Attachment B-4 (Item No. 7 11-1-77)
   a) Amend "Physicist Chairman" to Kathryn (Schroader) Williford, M.S.
   b) Amend "Radiation Safety Officers" to
      Kathryn Schroader Williford, M.S.
      E.P. Ho, M.D.

2. Attachment C. Item 8,b. (Item No. 8, November 1, 1978)
   Amend to "Two Radiation Safety Officers are appointed:
      E.P.Ho, physician
      K.J, (Schroader) Williford, M.S., physicist

3. Attachment D. Item 9,a. Survey Instruments (Item No.9, Nov. 1, 1978)
   Add a new survey instrument
   4. Manufacturer's Name: Kiethley
      Manufacturer's Model Number: 36100
      Number of Instruments Available: 1
      Maximum Range: 0 R/hr to 20 R/hr
      Minimum Range: 0 mR/hr to 200 mR/hr

4. Attachment D. Item 9,b. Dose Calibrator (Item No.9, Nov. 1, 1978)
   Add a new Dose Calibrator:

      Manufacturer's Name: Capintec
      Manufacturer's Model: CRC-30
      Number of Instruments Available: 1

5. Attachment D. Item 9,c. Diagnostic Instruments (Item No.9, Nov. 1, 1978)

   a) Delete
      Gamma camera Searle (Nuclear Chicago) Pho Gamma HP
   b) Add
      Gamma camera Technicare 438-3

6. Calibration of Survey Instruments

   Amend in entirety to:
   1. Survey instruments will be calibrated at least annually and following repair.

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Attachment C
8-21-81

2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

   The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ∓ 10 percent of the calcuiated or known values for each point checked. Readings within ∓ 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ∓ 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated
   a. At the licensee's facility
      1) Calibration source

         Manufacturer's name: J.L. Shepherd, and Associates
         Model no. 28-6A
         Activity in millicuries: 1000
         or
         Exposure rate at a specified distance: 315 mR/hr
         Accuracy: 5%
         Traceability to primary standard: Direct traceability to N.B.S. (See Addendum 1 to Attachment C of this Amendment Request).

      2) The calibration procedures in Section I of Appendix D will be used.

   Appropriate Radiation safety precautions will be taken during the calibration of survey instruments. These precautions include the use of time, distance and shielding techniques by those performing the calibration, and the performance of the calibrations only in Restricted Areas with appropriate caution signs properly displayed.

7. Attachment K. Emergency Procedures, Including Names and Telephone Numbers of Personnel to be Notified.

   Amend page 2. Radiation Safety Officers to

   K.J. Williford, M.S.
   Office Phone: 259-4127
   Home Phone: 537-9948

   E.P. Ho, M.D.
   Office Phone: 259-4572
   Home Phone: 882-1340

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Attachment C
8-21-81

J L SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

CALIBRATION CERTIFICATE

TO: St. Vincent Medical Hospital (Victoreen) P.O.#: 14050 Release #10

SOURCE: 1Ci ^{137}Cs 3M 4P6E S.N. 769

MOUNTING: J.L. Shepherd & Associates Model 28-6A S.N. 10007

INSTRUMENT: Landsverk-64 Roentgen Meter, S.N. 438. This roentgen meter is calibrated by Dosimeters Incorporated and its calibration is directly traceable to National Bureau of Standards.

POSITION: Centered in Beam Port

DISTANCE: 1 Meter

OUTPUT: 315mR/hr

DATE: November 5, 1980

J.L. Shepherd

CONTROL NO. 05281

L SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

OPERATING MANUAL FOR

SERIES 28 CALIBRATION FACILITIES

S.N. 10007
Model # 28-6A
Control #

A. RADIATION SAFETY

1. The calibrator emits an intense beam of radiation in the area subtended by the beam port (cone). A much lower level of scattered radiation extends in a penumbra surrounding the primary beam. THE OPERATOR SHOULD NEVER STAND IN THE DIRECT BEAM WHILE OPERATING THE UNIT. He should also avoid standing in the penumbra adjacent to the primary beam. THE UNIT MUST BE OPERATED AT ALL TIMES FROM A POSITION BEHIND THE CALIBRATOR, ON THE SIDE OPPOSITE THE BEAM PORT. The user should set up exclusion lines for personnel using this calibrator as well as limited room access. This information is ordinarily included as part of the facility operation regulations and is required as part of the users' license to possess the calibrator.

2. At intervals not exceeding six months, leak tests should be made on the calibrator by taking wipes at the nearest accessible surface of the source when it is in the "off" position. This surface would be at the top of the calibrator where the operating rod extends through the top plate. These wipes should be measured on an instrument capable of measuring 0.005 uCi of 60 Cobalt or 137 Cesium, dependant on which isotope is used in the calibrator. Use of the calibrator should be stopped immediately if contamination is detected and the manufacturer should be notified. NOTE: The 0.005 uCi level is that generally prescribed by regulatory authorities; individual institutions may require more stringent standards.

B. INSTALLATION

Series 28 Calibrators are normally shipped in two parts--the source-shield and the stand. To install, bolt the source-shield to the stand in the location where the calibrator is to be used. Plug the cord into a 115V. 1 phase socket.

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C. OPERATION

1. Remove the padlock which locks the source in the "off" position during shipment, using the key provided. NOTE: This padlock may be used to lock the source in the "off" position at any time that the calibrator is not being used.

2. To expose the source, grasp the black operating knob (while standing behind the calibrator, opposite the beam port) and raise it until the spring loaded detent engages the depression on the operating shaft. The source is now exposed.

3. To return the source to the "off" position, push the operating knob down until the pin on the shaft strikes the stop on the calibrator top. The source is now fully shielded.

D. SAFETY FEATURES

The shield provides for full shielding in all directions at all times except out the beam port when the source is in the "on" position.

Position indicating lights (green="OFF", red="ON") at the top of the calibrator show source position at all times. The "ON" light is activated whenever the source is not fully "OFF".

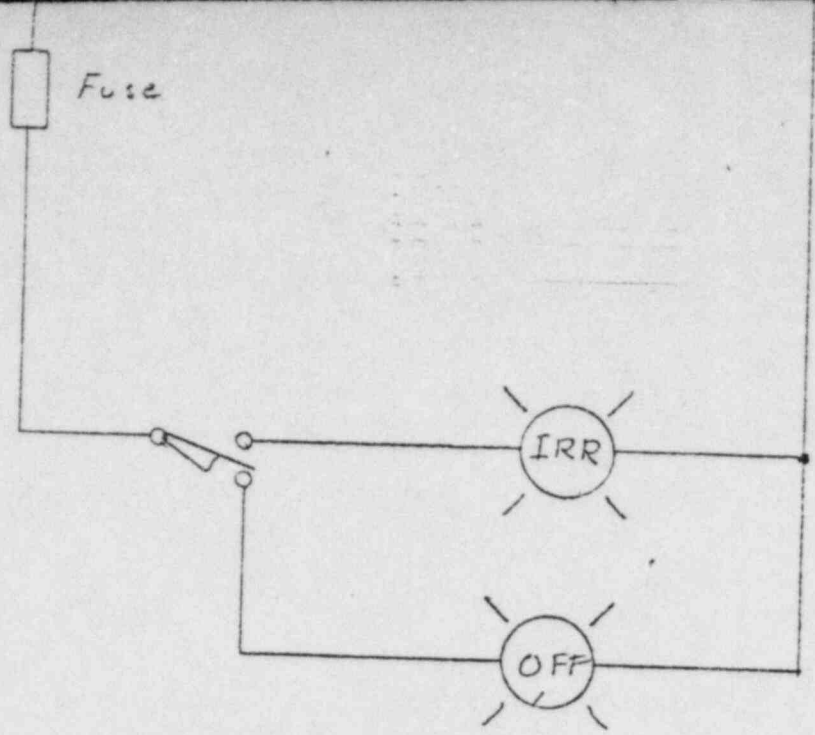
E. EMERGENCY PROCEDURES

If at any time the operation of the source rod becomes difficult, the calibrator should be removed from service. It should be taken to a hot cell, the source rod removed and both the source rod and the tube through which it slides should be cleaned. Difficult operation will be caused by dirt or foreign particles falling into the source tube.

F. MAINTENANCE

1. Do NOT lubricate the source rod at any time in any way. LUBRICATION OF ANY KIND WILL VOID THE WARRANTY.

2. Operate the unit in a clean atmosphere. Do not permit dirt or other particles to fall in the hole at the top of the unit. When not in operation, it is recommended that the calibrator be covered, i.e., by a plastic bag.



J. L. SHEPHERD and Associates

SCALE:	APPROVED BY:	DRAWN BY
DATE:		REVISED

ELECTRICAL - SCHEMATIC for SERIES

DRAWING NUMBER

CONTROL NO. 05281

J L SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

CALIBRATION CERTIFICATE

TO: St. Vincent Medical Hospital (Victoreen) P.O.#: 14050 Release #10

SOURCE: 1Ci ^{137}Cs 3M 4P6E S.N. 769

MOUNTING: J.L. Shepherd & Associates Model 28-6A S.N. 10007

INSTRUMENT: Landsverk-64 Roentgen Meter, S.N. 438. This roentgen meter is calibrated by Dosimeters Incorporated and its calibration is directly traceable to National Bureau of Standards.

POSITION: Centered in Beam Port

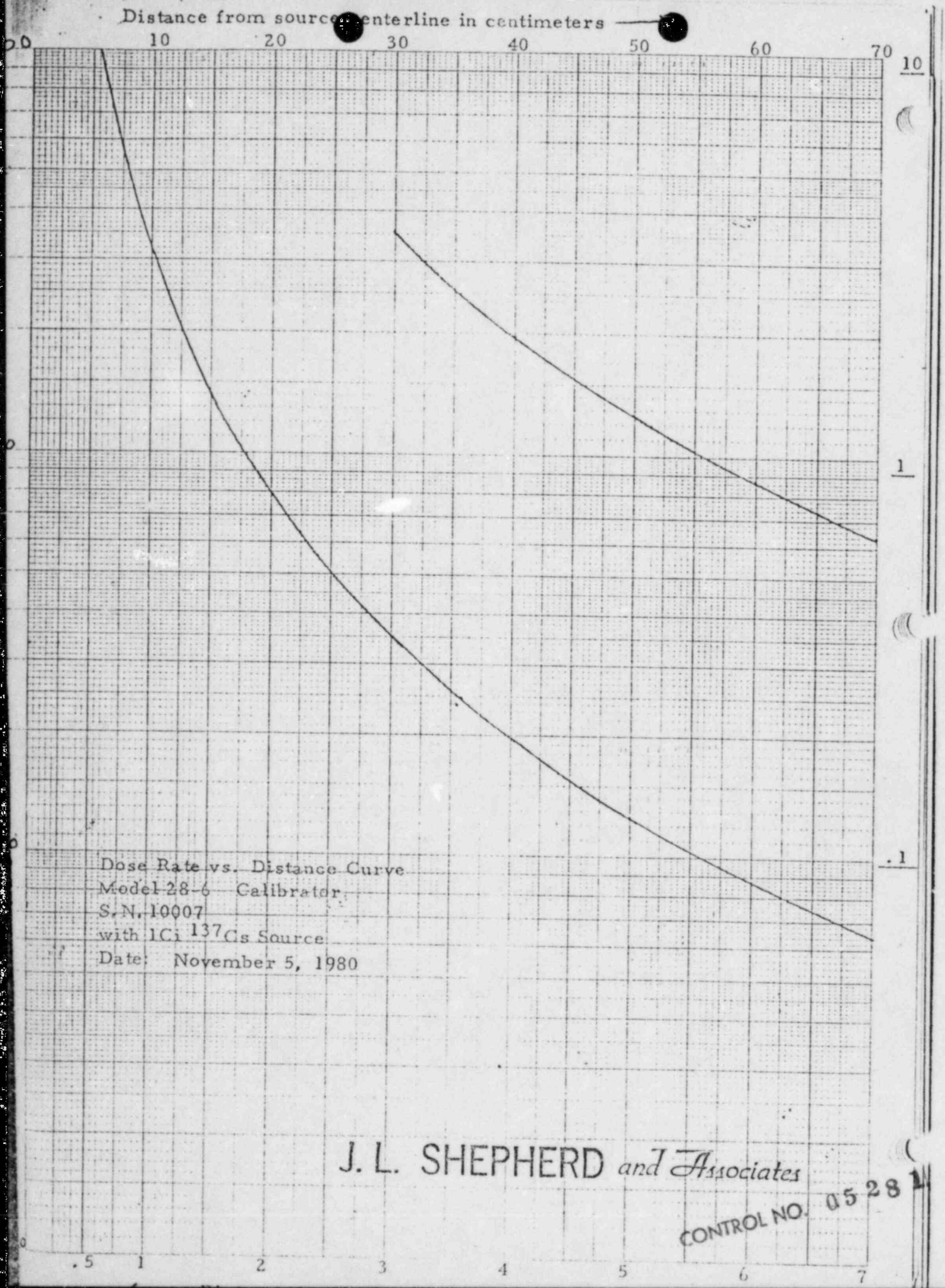
DISTANCE: 1 Meter

OUTPUT: 315mR/hr

DATE: November 5, 1980

J.L. Shepherd

CONTROL NO. 05281



Dose Rate vs. Distance Curve
Model 28-6 Calibrator
S.N. 10007
with 1Ci ^{137}Cs Source
Date: November 5, 1980

J. L. SHEPHERD and Associates

CONTROL NO. 05 28 1

J.L. SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

EXTERNAL RADIATION LEVELS

TO: St. Vincent Medical Hospital (Victoreen)

DEVICE: J. L. Shepherd & Associates Model 28-6A, S. N. 10007 with 1Ci ^{137}Cs 3M 4P6E S. N. 769

SOURCE IN "OFF" POSITION:

≤2mR/hr at 12" from surface

SOURCE IN "ON" POSITION:

≤2mR/hr at 12" from surface through 180° angle opposite beam port

DATE: November 5, 1980

J. L. Shepherd & Associates

CONTROL NO. 05281

J L SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

LEAK TEST CERTIFICATE

TO: St. Vincent Medical Hospital (Victoreen)

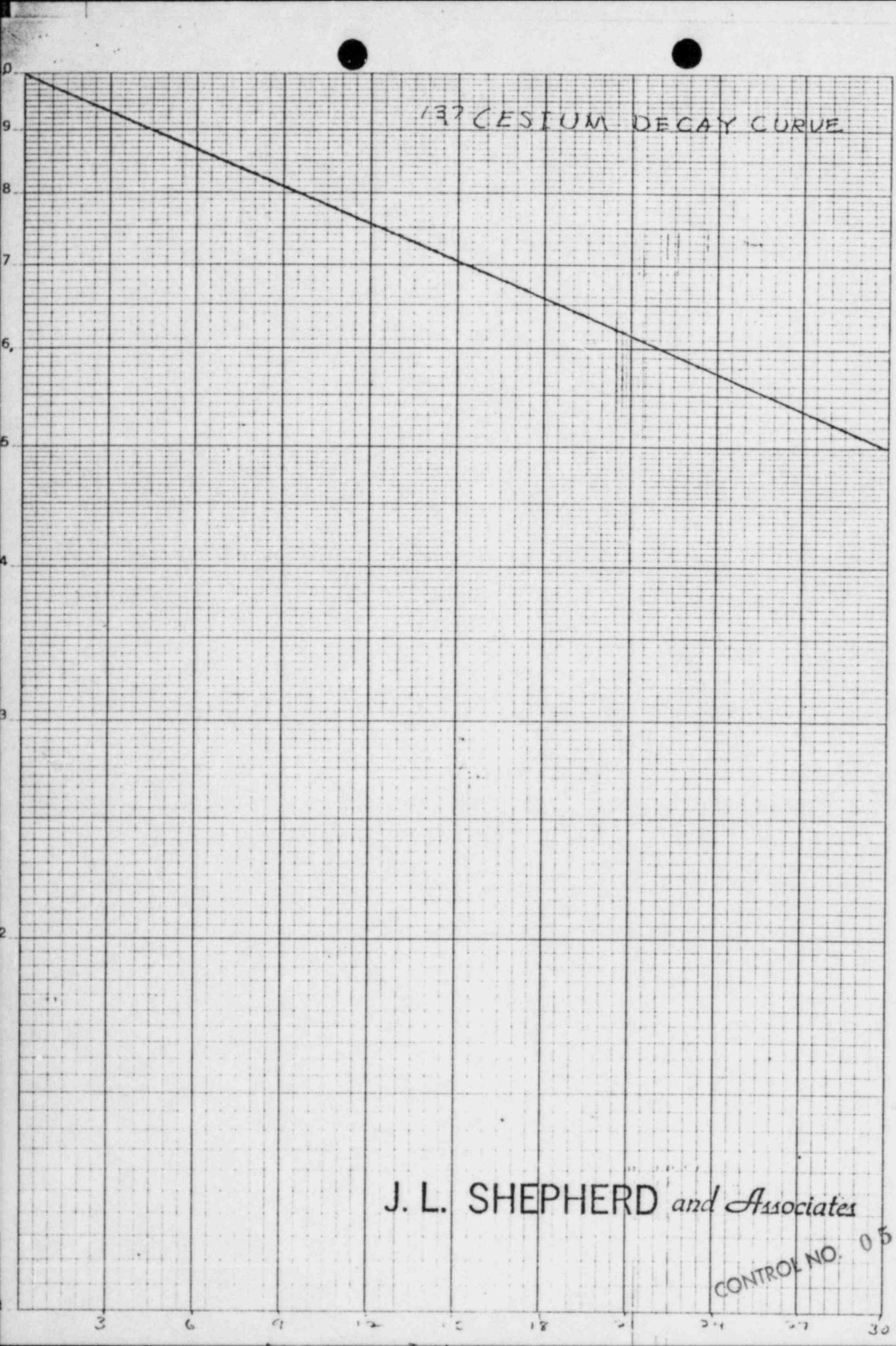
SOURCE: 1Ci ^{137}Cs 3M 4P6E S. N. 769 mounted in J. L. Shepherd & Associates Model 28-6A S. N. 10007

LEAK TEST: $\leq 5 \times 10^{-5}$ microcuries

DATE: November 5, 1980

J. L. Shepherd & Associates

CONTROL NO. 05281



J. L. SHEPHERD and Associates

CONTROL NO. 05281

J L SHEPHERD and Associates

740 Salem Street, Glendale, California 91203 • 213/245-0187

Irradiation & Calibration Equipment • Lead Shielding • Nuclear Applications

WARRANTY

FREE PARTS AND SERVICE WILL BE ALLOWED FOR THREE MONTHS FOLLOWING INSTALLATION, WITH REPLACEMENT OF FAULTY COMPONENTS FOR AN ADDITIONAL NINE MONTHS.

THIS IS TO CERTIFY THAT THIS UNIT MEETS ALL APPLICABLE D.O.T. SHIPPING REGULATIONS RELATED TO EXTERNAL RADIATION LEVELS FOR CONTAINERS OF RADIOACTIVE MATERIALS.

THIS UNIT MEETS ALL UNDERWRITER'S LABORATORY SPECIFICATIONS, INCLUDING FIRE CODE REGULATIONS.

THIS UNIT MEETS REQUIREMENTS FOR A STANDARD INDUSTRIAL FIRE WITHOUT RELEASING RADIATION OF RADIOACTIVE MATERIALS TO ENVIRONS.

CONTROL NO. 05281

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

Attachment D. Addition of ALARA Program

See Addendum I to Attachment D. for ALARA Program Model incorporated as policy at St. Vincent Hospital and Medical Center, Toledo, Ohio.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

St. Vincent Hospital and Medical Center

(Licensee's Name)

August 21, 1981

(Date)

1. **Management Commitment**

   a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

   c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. **Radiation Safety Committee (RSC)[2]**

   a. Review of Proposed Users and Uses

      (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

      (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

      (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

   b. Delegation of Authority

      (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

      (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

      (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

[1] Private practice physician licenses do not include an RSC.

[2] The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

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c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).[3]

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. **Radiation Safety Officer (RSO)**

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. **Authorized Users**

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

[3] The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

   a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

   b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures**

   This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	*Level II*
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by §20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 0-1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

   In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

   The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official**[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

Allen Johnson

Signature

Allen Johnson

Name (print or type)

Executive Administrator

Title

Institution (or Private Practice) Name and Address:

[4]The person who is authorized to make commitments for the dministration of the institution (e.g., hospital administrator) or, n the case of a private practice, the licensed physician.

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