EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved GAO R0557

INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (Institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE

Tri-State Cardiac Imaging, Inc.
611 Harriet Street
Evansville, IN 47710

TELEPHONE NO. AREA CODE 812 423 - 7878

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE

Same as 1.a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Thomas Roger White, M.D.

TELEPHONE NO. AREA CODE 812 423-7878

3. THIS IS AN APPLICATION FOR: (Check appropriate item)

a. ☒ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)

Thomas Roger White, M.D.

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)

Thomas Roger White, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Tc 99m - MAY 98	Pertechnetate	100	Human use (N. Cardiology)
	PYP	100	Human use (N. Cardiology)
	HSA	100	Human use (N. Cardiology)
Mo 99 Generator	Generator	1,000	Preparation of Tc 99m
Cs 137	Sealed	0.200	Quality Control and
Ba 133	Sealed	0.250	Calibration

FORM NRC 313M (8-78)

License Fee Information on p. 3.

CONTROL NO. 81246

RECEIVED MAY 07 1986

CONTROL NO. 81246

REGION II MAY 7 1986

8710070581 870611
REG3 LIC30
13-24706-01 PDR

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☒ Equivalent Rules Attached
☒ Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	☐ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	☒ Equivalent Procedures Attached
☒ Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	☒ Equivalent Procedures Attached
☒ List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☐ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☒ Equivalent Information Attached
☒ Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** N/A *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
☒ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES** N/A
☒ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☒ Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)** N/A
☒ Detailed Information Attached	☐ Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS** N/A
☐ Appendix F Procedures Followed; or	☐ Detailed Information Attached
☒ Equivalent Procedures Attached	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
	☒ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer, Inc.	1 X per month at the first of the month
		TLD	NA	
		OTHER (Specify)	NA	
b. FINGER		FILM	NA	
	X	TLD	R. S. Landauer, Inc.	1 X per month at the first of the month
		OTHER (Specify)	NA	
c. WRIST		FILM	NA	
		TLD	NA	
		OTHER (Specify)	NA	

d. OTHER (Specify)

Log May 10 III
Remitter Tri State Cardiology Consultants
Check No. 2158
Amount $580
Fee Category 7C
Type of Fee Application
Date Check Rec'd. 5/9/86
Date Completed
By: Mussin

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: Deaconess Hospital

MAILING ADDRESS: 600 Mary Street

CITY: Evansville | STATE: IN | ZIP CODE: 47747

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE
(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7c

(2) LICENSE FEE ENCLOSED $: 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: Thomas R White MD

(1) NAME *(Type or Print)*: Thomas Roger White, M.D.

(2) TITLE: Applicant

c. DATE: 18 April, 1986

FORM NRC-313M (8-78)

A T T A C H M E N T S

ORDER OF ENCLOSURE	DESCRIPTION	ITEM #
1.	Radiation Safety Committee	7.
2.	Training and Experience	8.
3.	Instrumentation	9.
4.	Calibration of Survey Instruments	10.
5.	Calibration of Dose Calibrator	10.
6.	Monitoring of Imaging Equipment	10.
7.	Facilities and Equipment	11.
8.	Employee Training	12.
9.	Ordering and Receiving Material	13.
10.	Opening Packages	14.
11.	Safe use of Radiopharmaceuticals	15.
12.	Records of Use	15.
13.	Leak Testing	15.
14.	External Exposure	15.
15.	A L A R A	15.
16.	Spill (Emergency) Procedures	16.
17.	Area Surveys	17.
18.	Waste Disposal	18.
19.	Hospital Letter	25.

A T T A C H M E N T 1

NRC 313M Item 6.b.

This application is for nuclear cardiology only. The procedures will be limited to those studies considered to be cardiovascular in nature.

The Tc99m in the form of pertechnetate, PYP and HSA will be purchased, prepared, from a radiopharmaceutical company and/or a central radiopharmacy.

The technetium generator, less than 500 mCi per generator, will be used for the preparation of technetium pertechnetate should the radiopharmacy and/or radiopharmaceutical company not continue to be a practical and/or reliable source.

The generator elution will also be used to prepare Tc99m labeled PYP and HSA from commercially available kits, FDA approved. We will follow the manufacturer's instructions in preparation of the kits and will keep all sources behind our shield and all sources shielded during the preparations.

RADIATION SAFETY COMMITTEE

The applicant will not establish a radiation safety committee because this is a private practice. All of the professional members of the practice will be kept fully informed, through the practice's routine monthly meetings, of all radiation safety and procedural developments. The RSO will be responsible for radiation safety in the facility.

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FORM NRC-313M-SUPPLEMENT A (6-78) — 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
Thomas Roger White, M.D.	IN

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
American Board of Internal Medicine		October 19, 1977
Cardiovascular Disease		October 19, 1977

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)	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D)
a. RADIATION PHYSICS AND INSTRUMENTATION	~~Chicago, Illinois~~ National Inst. for Prof. Educ. June 21, 1984 to November 15, 1984	100	
b. RADIATION PROTECTION	Chicago, Illinois October 18 - November 11, 1984	30	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Chicago, Illinois September 27, 1984 - Oct.1	20	
d. RADIATION BIOLOGY	Chicago, Illinois Oct. 18 - Nov. 11, 1984	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	Chicago, Illinois Nov. 15 - Dec. 19, 1984	30	

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 99m	25 mCi MUGA	See Attached Preceptor	900 hours	Medical -
T1 201	5 mCi	Statement		Nuclear Cardiology

FORM NRC-313M-SUPPLEMENT B
(5-78)

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
Thomas Roger White, M.D.

STREET ADDRESS
611 Harriet

CITY | STATE | ZIP CODE
Evansville IN 47710

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		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Sr-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING (MUGA)	30	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

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		
	TREATMENT OF HYPERTHYROIDISM		
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 T1-201	Myocardial Imaging	655	

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

1981 - 1982 300 hours (estimated)
1983 - 1986 600 hours
900 hours

NOTE: Handling techniques were 300 hours of the 900 total.

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

a. NAME OF SUPERVISOR
David J. Carlson, M.D.

b. NAME OF INSTITUTION
Deaconess Hospital

c. MAILING ADDRESS
600 Mary Street

d. CITY
Evansville, IN 47747

e. MATERIALS LICENSE NUMBER(S)
13-00142-2

5. PRECEPTOR'S SIGNATURE
Please see Dr Carlson's letter
dated Jan. 16, 1986
David J Carlson, MD

7. PRECEPTOR'S NAME *(Please type or print)*
David J. Carlson, M.D.

8. DATE

I am aware that Dr. [illegible] attended his experience at Deaconess, but was not his supervisor

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

* U.S. GOVERNMENT PRINTING OFFICE 1981 - 341 742 1180

January 16, 1986

re: Thomas R. White, M.D., F.A.C.C.

To Whom It May Concern:

According to our records, Dr. White has obtained more than 600 hours of clinical experience in Nuclear Cardiology from January 1981 to January of 1986.

During these hours he has performed nuclear examinations on more than 679 patients who had MUGA and Thallium stress and resting procedures.

I am enclosing summaries of Dr. White's clinical experience with nuclear cardiology and I am also enclosing a summary of the 200 hours of didactic teaching in Nuclear Physics that Dr. White obtained.

Sincerely,

David J. Carlson, MD

David J. Carlson, M.D.
President, Medical Staff
Deaconess Hospital, Evansville, Indiana

424-8231

[illegible] MARY ST EVANSVILLE, INDIANA 47747 TELEPHONE (812) 426-3000

FORM NRC - 313M - SUPPLEMENT A
MODIFIED SUBSTITUTE - TRAINING ONLY

NATIONAL INSTITUTES FOR PROFESSIONAL EDUCATION
4880 RIVERBEND ROAD
BOULDER, CO 80301

TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

TRAINEE:

Thomas White	M.D.	
NAME	TITLE	
611 Harriet Street		
ADDRESS		
Evansville	Indiana	47710
CITY	STATE	ZIP

COURSE TITLE:	BASIC MEDICAL RADIATION PHYSICS	LOCATION	Chicago, Illinois
DATE: COMMENCED	June 21, 1984	COMPLETED	July 29, 1984
COURSE TITLE:	RADIATION PHYSICS OF NUCLEAR MEDICINE	LOCATION	Chicago, Illinois
DATE: COMMENCED	September 27, 1984	COMPLETED	October 19, 1984
COURSE TITLE:	RADIATION BIOLOGY AND RADIATION SAFETY	LOCATION	Chicago, Illinois
DATE: COMMENCED	October 18, 1984	COMPLETED	November 11, 1984
COURSE TITLE:	RADIATION CHEMISTRY AND RADIOPHARMACEUTICALS	LOCATION	Chicago, Illinois
DATE: COMMENCED	November 15, 1984	COMPLETED	December 19, 1984

SUMMARY OF FIELD OF TRAINING HOURS DISTRIBUTION

FIELD OF TRAINING (A)	LECTURE/LABORATORY (HOURS) (C)
a. Radiation Physics and Instrumentation	100
b. Radiation Protection	30
c. Mathematics Pertaining to the use and measurement of Radioactivity	20
d. Radiation Biology	20
e. Radiopharmaceutical Chemistry	30
TOTAL HOURS OF LECTURE/LABORATORY	200

VALID ONLY IF SEALED

AUTHORIZATION: This document is valid for the individual, dates and hours as stated above and supported by the seal. If validation, records or other information is required by the Regulatory Agency, contact the undersigned.

Charles Herbert Rose, MA, MSPH, D(ABSNM)
Telephone (303) 449-4621

HOSPITAL

JAN 2 [illegible]

January 16, 1986

re: Thomas R. White, M.D., F.A.C.C.

To Whom It May Concern:

Thomas R. White, M.D., F.A.C.C. has full admitting privileges at Deaconess Hospital in Evansville, Indiana, for the treatment and management of patients containing diagnostic radiopharmaceuticals.

Sincerely,

David J. Carlson, M.D.
President, Medical Staff
Deaconess Hospital, Evansville, Indiana

600 MARY ST. EVANSVILLE, INDIANA 47747 TELEPHONE (812) 426-3000

RADIATION DETECTION EQUIPMENT*

TYPE	NUMBER	RADIATION DETECTED	SENSITIVITY mR/hr	USE
Gamma Camera Dyna Camera 5 (Picker)	1	Gamma	N.A.	Imaging
Cutie Pie Survey Atomic Products 069-740	1	Alpha, Beta Gamma	0 - 25,000	Surveys
G-M Survey Atomic Products 069-701	1	Beta	0 - 50	Surveys
Pocket Dosimeters Atomic Products 019-200	2	Gamma	0 - 200	Monitoring

* See NRC 313M Item 11 for additional information

4

NRC 313M
Item 10

PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

The applicant will calibrate survey instruments using the following procedure or will hire a contractor to calibrate the instruments. If a contractor is hired, the applicant will determine, in writing, that the contractor will follow this procedure in making calibrations. The applicant will also determine, in writing, that the contractor has a State or Federal byproduct material license to calibrate survey meters or has been approved by a state to do such calibrations. Because posession of sources sufficient to perform the calibrtions are not being requested by the applicant at this time, an amendment will be obtained before the applicant performs his own calibrations.

Radiation Survey meters will be calibrated with a radioactive source. Electronic calibrations are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing".)

Model Procedure

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

Procedure for calibrating survey instrument - Continued

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137, 21 millicuries of Co-60, and 34 millicuries of Ra-226.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. The following two kinds of scales are frequency used on the survey meters requested by the applicant.

   a) Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b) Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

Procedure for calibrating survey instruments - Continued

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

    a) The owner or user of the instrument;

    b) A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

    c) A description of the calibration source, including exposure rate at a specified distance on a specified date.

    d) For each calibration point, the calculated exposure rate, the indicted exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

    e) The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

Procedures for calibrating survey instruments - Continued

f) The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

g) For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h) The apparent exposure rate from the check source; and

i) The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

a) The source that was used to calibrate the instrument;

b) The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c) For each scale or decade, one of the following as appropriate:

Procedures for calibrating survey instruments - Continued

1) The average correction factor,

2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d) The angle between the radiation flux and the detector during the calibration; and

e) The apparent exposure rate from the check source.

NOTE: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

Attached: Survey Meter Calibration Report

SURVEY METER CALIBRATION REPORT

Owner: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ License #: _____

Contact: _____ Telephone: _____

Survey Meter: Mfg: _____

Model: _____

Type: GM _____ Ion _____ Other _____

Probe: Model _____ Serial # _____

Calibration Source: _____ mCi of _____ Ref. # _____

Calibrated: _____, 19__ at mR/hr at _____ in-cm

Output Today: _____, 19__ at mR/hr at _____ in-cm

Instrument Checks: Last Calibrated: Date: _____

Last Service: Date: _____

Battery Check: _____ mR/hr or _____

Integral Check Source indicated _____ mR/hr

Calibration Geometry

Window: _____ open _____ closed _____ fixed

SURVEY METER CALIBRATION REPORT

Calibration Source	Scale: _____ Reading	Corfac	Scale: _____ Reading	Corfac	Scale: _____ Reading	Corfac	Scale: _____ Reading	Corfac
Distance	mR/hr							

Correction Factors _____ _____ _____ _____

Correction Comments: _____

_____

_____

Certification: By: _____

Company: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ License# _____

Expiration Date: _____

CALIBRATION STICKER

Calibrated On _____, 19_____

With _____ Window _____

Scale	CorFac	Battery Ck _____ mR/hr
_____	_____	Ck Source _____ mR/hr
_____	_____	By _____
_____	_____	Company _____
_____	_____	Telephone _____

The company listed below will be performing linearity tests on the dose calibrator as well as accuracy tests. (every 3 months). They will also be responsible for analyizing wipes.

Mr. Robert Anger
5230 North Washington Blvd.
Indianapolis, IN 46220

(317) 253-0443 or (317) 929-3572

Materials License # 13-02063-01

5

NRC 313M
Item 10

PROCEDURE FOR CALIBRATING THE DOSE CALIBRATOR

The applicant will establish and implement this procedure for calibrating the dose calibrator.

CALIBRATION PROCEDURE

1. Frequency - We will test for the following at the indicated frequency and for the suggested tolerance:

   a) Constancy at least once each day prior to assay of patient dosages (+/- 5 percent).
   b) Linearity at installation and at least quarterly thereafter (+/- 5 percent).
   c) Geometry dependence at installation (+/- 2 percent).
   d) Accuracy at installation and at least annually thereafter (+/- 5 percent).

2. After repair or adjustment, we will repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. We will assay at least one relatively long-lived source, 57 Co*, using a reproducible geometry each day before using the calibrator. Because we will only use low energy radionuclides, it will be sufficient to only use this single source. We will use the following procedure:

Procedure for calibrating the dose calibrator - Continued

a) Assay the reference source using the appropriate dose calibrator setting (i.e. Co 57 using the Co 57 setting).

b) Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

c) Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d) Repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e) Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator.

Procedure for calibrating the dose calibrator - Continued

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

* 5 mCi Co 57 from New England Nuclear, Catalog No. 369 as listed in the BRH/FDA Radioactive Materials reference manual.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test will be done using a vial or syringe of Tc99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, or in a unit dosage syringe, whichever is largest.

DECAY METHOD

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Attached). This first assay should be done in the morning at, for example, 8 a.m.

Procedure for calibrating the dose calibrator - Continued

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper (see Attached), label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date, model number, and serial number of the dose calibrator. Then plot the data.

e. Pick a data point that falls near a millicurie value that you frequently use for patient dosages. Draw a letter "O" around that point on the graph. Multiply the millicurie value of the data point by 16. Subtract 24.1 hours from the time associated with the data point you chose. Plot a new point for the time and activity you have calculated, and draw a letter "C" around that point.

Procedure for calibrating the dose calibrator - Continued

f. Draw a solid straight line through the two pints "O" and "C" on the graph.

g. Multiply the millicurie value at point "O" by 1.05, and plot that point directly above point "O". Draw a dashed line through this point parallel to the sold line.

h. Multiply the millicurie value at pint "O" by 0.95, and plot that point directly below point "O". Draw a second dashed line through this point also parallel to the solid line.

i. If any data points fall outside the dashed lines, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity".

j. The regulations require that the dose calibrator be tested for linearity between the range of the highest dosage administered and 10 microcuries. If more than 70 hours is needed to cover this range, continue decaying the vial, and record the data on a second worksheet and graph.

Procedure for calibrating the dose calibrator - Continued

k. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

We may decide to use a set of "sleeves" of various thicknesses to test for linearity, (Atomic Products Corporation "Lineator" Catalog #086-507) but it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve A in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve A and put in sleeve B. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through i above.

Procedure for calibrating the dose calibrator - Continued

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in lace. This is the "equivalent decay time" for sleeve A. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve B in place. This is the "equivalent decay time" for sleeve B. Record that time with the data recorded in step c.

h. Continue for sleeve C.

i. The table os sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

Procedure for calibrating the dose calibrator - Continued

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve A in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve A and put in sleeve B. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on the sample form (see attached) label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date, model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Pick a data point that falls near a millicurie value that you frequently use. Draw a letter "O" around that point on the graph. Multiply the millicurie value of the data point by 16. Subtract 24.1 hours from the time associated with the data point you chose. Plot a new point for the time and activity you have calculated, and draw a letter "C" around that point.

Procedure for calibrating the dose calibrator - Continued

6. Geometry Independence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

   a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

   b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see attached).

   c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

Procedure for calibrating the dose calibrator - Continued

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".

f. If any correction factors are greater than 1.05 or less than 0-.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "True Activity". If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Procedure for calibrating the dose calibrator - Continued

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".

Procedure for calibrating the dose calibrator - Continued

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to true activity". If this is necessary, be sure to label the table or graph "vial geometry dependence,", and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. The activity of at least one reference source should be within the range of activities normally assayed. At least three sources with different principal photon energies (such as Co-57, Ba-133, and Cs-137) will be used.

NOTE: Ba 133, 356 KEV, 250 uCi
Cs 137, 662 KEV, 200 uCi; and
Co 57, 122 KEV, 5.0 mCi

Procedure for calibrating the dose calibrator - Continued

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background form the indicated activity to obtain the net activity. Record this measurement on the Dose Calibrator Geometry and Accuracy Form (see attached). Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the calibrator will be repaired or adjusted.

Procedure for calibrating the dose calibrator - Continued

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

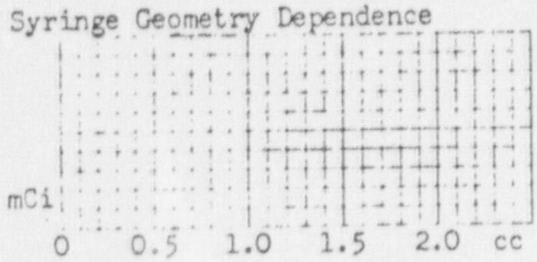
8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

See the attached forms for the type of form we will use.

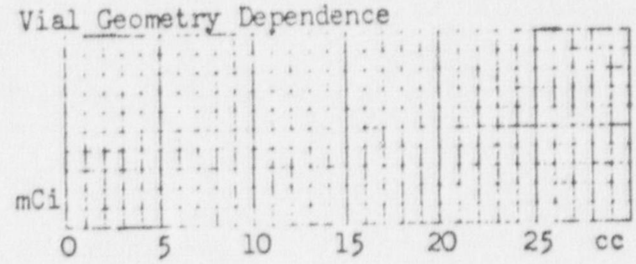
Dose Calibrator Geometry and Accuracy

Manufacturer:__________________ Model:____________ S/N:____________

Syringe Geometry Dependence



Vial Geometry Dependence



Date:__________ Name:______________

Accuracy Sources	19__	19__
_____mCi of _____ Model:__________ S/N:__________ Calibration date: ______________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi
_____mCi of _____ Model:__________ S/N:__________ Calibration date: ______________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi
_____mCi of _____ Model:__________ S/N:__________ Calibration date: ______________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi

Name: ______________ ______________

Date: __________ __________

Dose Calibrator Linearity Test

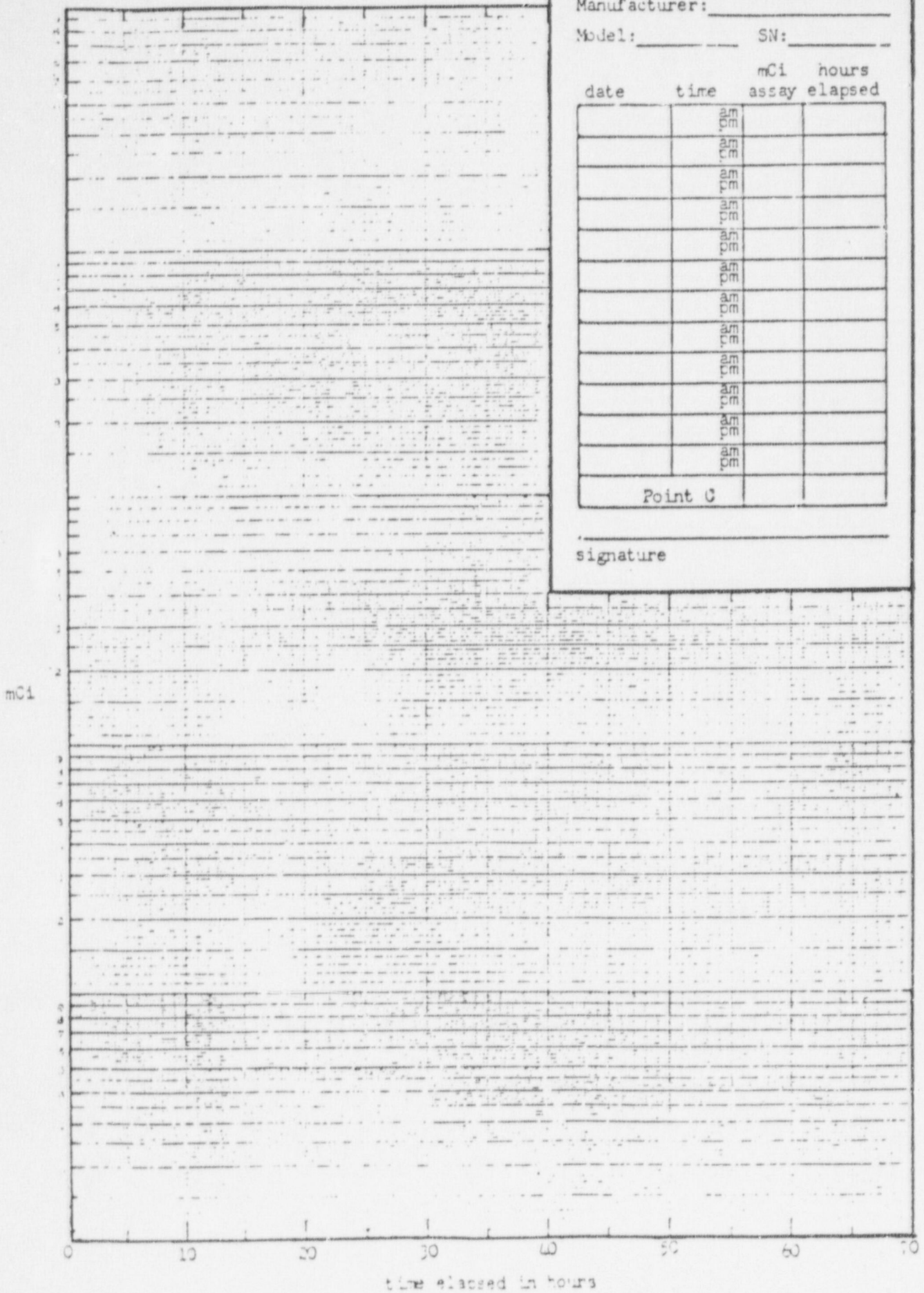
Manufacturer: _____

Model: _____ SN: _____

date	time	mCi assay	hours elapsed
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
	am pm		
Point C			

_____

signature



PROCEDURE FOR MONITORING PERFORMANCE OF IMAGING EQUIPMENT

The applicant will voluntarily establish and implement the following procedure for monitoring the performance of stationary imaging equipment. All technical and professional workers will receive a copy of these procedures.

Procedure

1. We will perform the following checks on equipment each day before administering byproduct material:

   a) Peak each camera according to the manufacturer's instructions.

   b) With a frequently used collimator in place, image a flood field of either Tc-99m or Co-57. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.

   c) Do not administer material until an authorized user or a designated technologist approves the camera for use.

   d) We will make record of these checks.

2. We will perform the following checks weekly:

   a) With the same frequently used collimator in place, image a quadrant phantom with the flood field as a source.

Procedure for monitoring performance of imaging equipment - Continued

b) Rotate the resolution quadrant phantom so that each quadrant is imaged in each quadrant of the crystal. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

c) Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.

d) Retain the images for 2 years.

3. We will perform the following safety checks after repairs and quarterly:

a) Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

b) Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release

Procedure for monitoring performance of imaging equipment - Continued

just the dead-man switch. Test all motion switches and all directions in the manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. We will set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for 2 years.

5. Because delivery has not been made on the equipment, it is impossible to list the manufacturer's recommendations for monitoring performance. The manufacturer's instructions will also be followed.

7

NRC 313M
ITem 11

FACILITIES

AND

EQUIPMENT

1. Radioisotope Receipt & manipulation
2. Radioisotope Storage
3. Disposal, below counter
4. Camera
5. Cart

TRI-STATE CARDIAC IMAGING, INC.

EQUIPMENT

Gamma Camera - Dyna Camera 5 (Picker)

Computer - PSC 512 (Picker)

Imaging Table (Atomic Products)

Syringe Shields - 1 cc
- 3 cc
- 5 cc

Tourniquet

Lead Lined Storage Container

Bar Phantom - standard bar

Flood Phantom Source

Flood Source - 5 mCi 57-Co

Dose Calibrator with Intergral Chamber (see attached)

Q.C. Sources		
	137 Cs	200 uCi
	57 Co	5 mCi
	133 Ba	250 uCi

Lineator (see attached)

Cutie Pie Survey Meter (see attached)

Portable Survey Meter (see attached)

G-M Probe B-Gamma

Pocket Dosimeters (2)

Charger

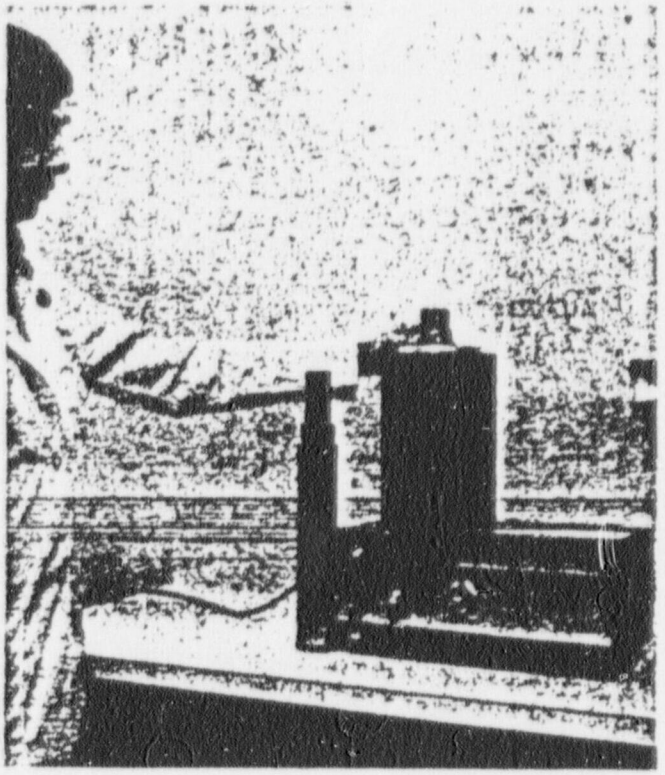
Lead Glass Barrier Shield (see attached)

Caution Radioactive Materials Sign

Caution Radiation Area Sign

Label Tape - Radioactive Materials

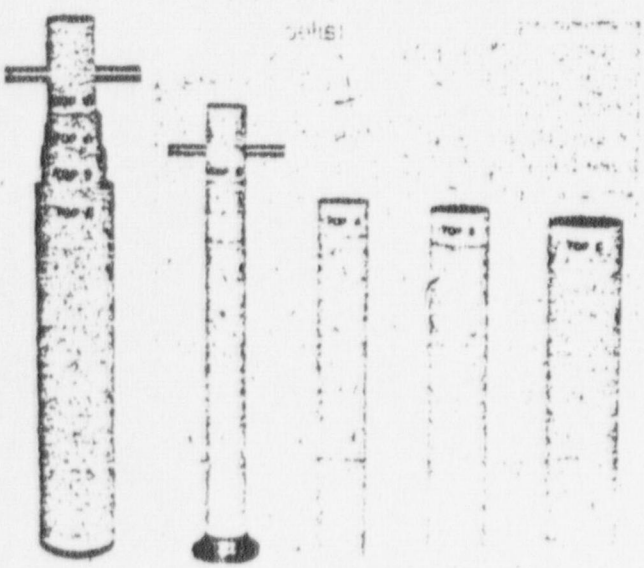
The Lineator



Tests Linearity of Dose Calibrators Over a Wide Dynamic Range

- **Simple**
- **Effective**
- **Economical**

The Lineator is a simple device for testing linearity and dynamic range of isotope calibrator instruments. It simplifies compliance with the Nuclear Regulatory Commission regulatory guide 10.8 and various state requirements.



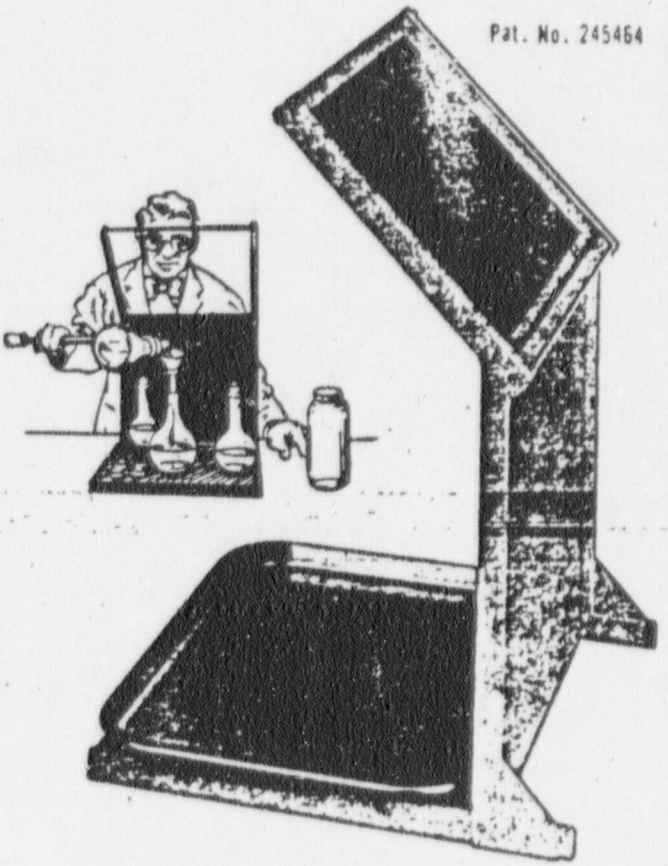
The Lineator consists of four tubes, three are lead lined and can be arranged concentrically. The smallest diameter tube is labeled O and is used to contain and position a source of Technetium 99m of the maximum activity to be measured in the dose calibrator in normal service. The lead lined tubes, labeled A, B, & C, slide over the central tube, and are used singly, or in a combination. Each of these outer tubes absorbs some of the radiation from the source and reduces the effective source activity seen by the dose calibrator. Use of the Lineator allows the operator to simulate a total of eight different source strengths with only one source. The effective reduction increases from tubes A to B to C, and is affected slightly by the shape of the source used, and by the characteristics of the isotope calibrator.

The principal of operation of the Lineator is reproducibility over a wide dynamic range, rather than absolute calibration. Initially the linearity of the dose calibrator must be established by conventional means, such as dilution or decay of a Technetium source. The initial calibration using the Lineator then establishes the effective reductions in activity (ratios of activity with lead tube(s) inserted relative to source in central tubes alone). All subsequent use of the Lineator will show the same effective ratios unless the dose calibrator becomes defective, at which time it must be repaired.

086-507 Lineator $275.00

Table Top Lead Barrier Shields

Protect head and body from radiation when working with radioactive material.



■ *Two model sizes available*

MINI TABLE TOP SHIELD for small jobs in limited working areas.

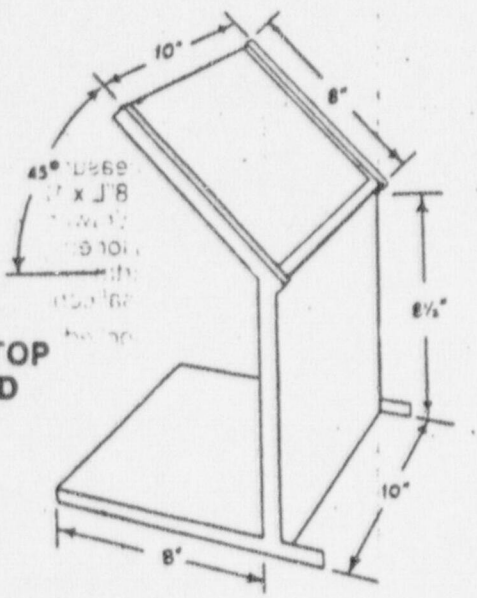
STANDARD TABLE TOP SHIELD for all routine work requiring protection against exposure to radiation.

Select the shield most suited to your workload. Both units provide exceptional protection to the clinician when setting up technetium generators, filling syringes, performing radium loading procedures, etc.

½" thick lead wall protects the torso while solid lead base provides ample working surface and balance against tipping. Face shielding is optically clear ¼" thick lead glass (1 or 2 pieces may be specified when ordering), cantilevered for unimpaired viewing or work area. The lead equivalent of each thickness of glass is 2.00mm.

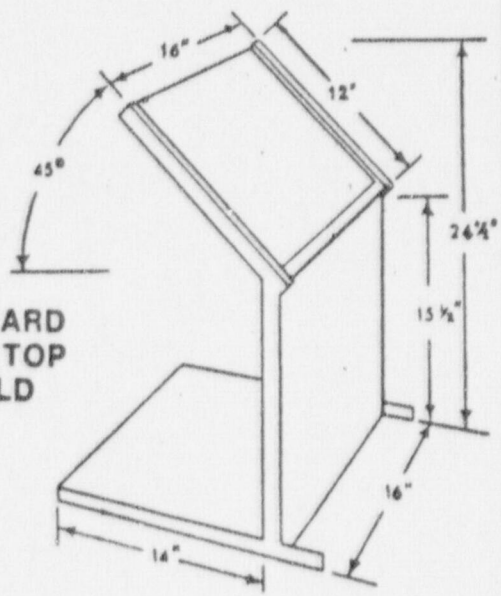
Both units can be moved with little effort to any convenient location, allowing total flexibility in choice of work area.

MINI TABLE TOP SHIELD



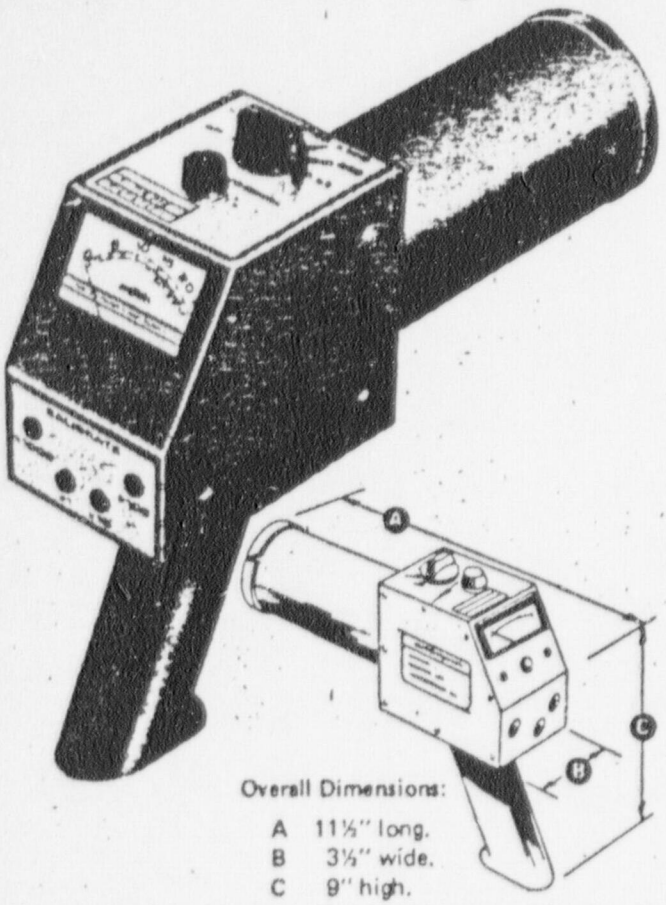
042-016	Mini Table Top Shield (one piece lead glass)	$230.00
042-116	Mini Table Top Shield (two pieces lead glass)	$290.00

STANDARD TABLE TOP SHIELD



042-216	Standard Table Top Shield (one piece lead glass)	$400.00
042-316	Standard Table Top Shield (two pieces lead glass)	$500.00

Cutie Pie Survey Meter



Overall Dimensions:

A 11½" long.
B 3½" wide.
C 9" high.

CUTIE PIE has achieved popularity as a low-cost, general purpose alpha-beta-gamma survey instrument. The gun type design of Cutie Pie, which is based on original requirements of the health physics group at ORNL, provides operational simplicity and ease of portability.

ECONOMICAL, LOW-COST MONITORING of alpha-beta-gamma radiations.

Net Weight: 3¾ pounds.

Shipping Weight and Volume: 8 pounds; 2.5 cu. ft.

Radiation Detected: Alpha, beta and gamma.

Ranges: Model 740F – 0-25, 0-250, 0-2500, 0-25000 mR/hr.

Minimum Energy Detected: Alpha, over 3.5 Mev; Beta, 40 Kev (approximately); Gamma and X-ray, 7 Kev to 2 Mev.

Energy Dependence: Within ±15% for gamma or X-rays from approximately 40 Kev to 2 Mev.

Detector: Air ionization chamber with 0.00025" thick mylar end window. Chamber volume 580 cc.

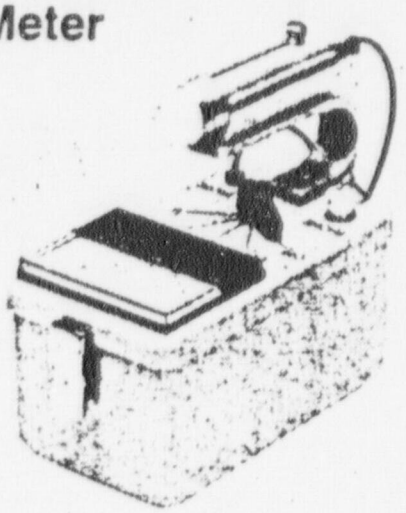
Accuracy: Maximum instrument inaccuracy, exclusive of energy dependence, is less than ±10% of fullscale indication.

Battery Complement: Four 22.5 volt batteries. One 1.3 volt battery.

Battery Life: Over 200 hours.

051-740 ..... $995.00

Beta-Gamma Survey Meter



- **Portable, lightweight, battery operated, transistorized.**

This solid-state survey meter is recommended for checking radioactive contamintion of instruments, personnel, work areas, food, clothing, etc., for locating spilled radiochemicals, and for detecting stray radiation from apparatus, containers, etc.

Radioactivity is indicated by clicking sounds in a headphone and by a 3-range meter that is graduated from 0 to 50 mR/hr and from 0 to 30,000 cpm. One knob turns on the unit, selects the proper range and checks the batteries.

The probe consists of a side-wall halogen quenched geiger tube located in a shield with a telescoping metal holder. When the GM tube is shielded only gammas are detected. When the GM tube is exposed, betas above 175 keV are detected. Ideal for ^{131}I, ^{32}P and higher-energy beta radiation.

The survey meter is extremely stable and should require very little maintenance or readjustments.

Meter Ranges: 0-0.5, 0-5, 0-50 mR/hr, 0-300, 0-3000, 0-30,000 cpm
GM Detector: Side-Wall (069-993)
Controls: Selector switch for power on-off, bat. check and ranges (×1, ×10, ×100). Internal calibration adjust pot for each range.
Audio Indication: Clicks in headphone or audible speaker.
Meter Accuracy: ±2% of full scale.
Batteries: Two "D" cells, 1½V.
Cable: 33 inch length.
Equipment Included: Batteries, manual, probe/detector.
Size: 7⅛" long × 4¼" wide × 7⅜" high.
Shipping Weight: 2 lb. 11 oz.

069-701	Survey Meter, Beta-Gamma	$355.00
069-993	GM Detector, Side-Wall (M). Stainless steel, halogen quenched	40.00
069-888	Headphones	25.00
069-877	Audible Speaker	50.00
101-103	^{137}Cs check source, 10 μCi, Flat Disc, 1" D	25.00

CAL/RAD™ II
Isotope Calibrator

FACTORY-CALIBRATED FOR ALL WIDELY USED RADIONUCLIDES. OTHERS CAN BE ADDED EASILY

- *AUTOMATIC RANGING FROM 1 μc TO 1 Ci.*
- *4-DIGIT, SOLID STATE READOUT.*
- *FULLY-SHIELDED CHAMBER.*
- *MOLYBDENUM BREAKTHROUGH SHIELD.*

The CAL/RAD II Isotope Calibrator provides the budget-conscious laboratory with an economical, reliable system that incorporates many of the performance characteristics of more expensive instruments.

Five most-commonly used isotopes may be instantly switch-selected: Technetium-99m, Xenon-133, Gallium-67, Iodine-131, and Molybdenum-99. Other gamma emitters from 50 keV to 1.2 MeV can be assayed by switching the selector to the "Dial" position and adjusting the ten-turn potentiometer to the proper value. A calibration sheet for 12 radionuclides is supplied; others are available upon request.

Standard measurements for the calibrated positions on the switch have a least-significant-digit value of 10 μCi (except Mo-99 which has 1 μCi). High-sensitivity determinations (least-significant-digit value of 1 μCi) may be performed by using the ten-turn potentiometer for the isotope measurement.

A sample is placed in the plastic holder, lowered into the shielded chamber and the selector switch or potentiometer is set for the isotope being calibrated. The "Start" button is depressed and the sample activity appears on the large digital display. The system automatically ranges to the correct scale, displaying values from 1.0 μCi to 1 Ci with automatic decimal placement. If the sample is over 1 curie, the display automatically blanks.

The detector well is 6" high x 2" diameter and will accept multi-dose collection vials, syringes and containers of almost any configuration without applying a correction factor. A selection of vial and syringe holders is available. An internal 1/4" lead shield surrounds the sensitive portion of the chamber and provides protection against the radiation from the radionuclide being measured. Dose rates at the surface of an unshielded chamber can be as high as 900 mR/hr for approximately 100 mCi of ^{99m}Tc. The shielded chamber reduces this to acceptable limits.

A convenient ^{99}Mo Breakthrough Shield is included. It provides a simple means of determining the amount of ^{99}Mo contamination in the eluate from a ^{99m}Tc generator. The shield's lead thickness absorbs most of the ^{99m}Tc gammas while permitting most of the ^{99}Mo activity to enter the counting chamber.

SPECIFICATIONS

Overall Size: 8¾" long x 11" wide x 7" high.
Well Size: 6" high x 2" diam.
Detector: Incorporated into control unit.
Chamber: Has a ¼" lead shield. A standard holder accommodates all major radiopharmaceutical vials.
Energy Range: 50 keV to 1.2 MeV.
Operating Range: Auto-ranging. Approx. 1.0 μCi to 1.0 Ci. Over-range indication whenever the activity exceeds the instrument's range.
Accuracy: ±10% overall. Less than ±2% error due to vial volume 0-30 ml, or point source position within normal measurement volume.
Numerical Display: 4-digit LED plus decimal points.
Isotope Selector: Factory calibrated for 6 isotopes. Others may be assayed by using the 10-turn potentiometer.
Power: 115V/60 Hz, 10W (230V/50 Hz, 10W available on request).
Molybdenum Breakthrough Shield: Included.
Shipping Weight: Net 30 lbs. Gross 40 lbs.

086-061	"Cal/Rad II" Isotope Calibrator	$1750.00
086-094	Optional Holder for 3M vials	40.00
086-095	Optional Holder for 2½-5cc syringes	37.00
063-261	Technetium-99m Calibration Standard (5nCi of cobalt-57)	600.00*
086-201	Extra Moly Breakthrough Shield	85.00
087-220	Power Converter for 220V	30.00

** NRC or Agreement State license is required.*

8

EMPLOYEE TRAINING PROGRAM

This document describes the training program to be implemented by the applicant upon receipt of the license.

I. Who Will Be Instructed:

All persons, professional/technical and ancillary, will be instructed. The professional/technical workers include:

- Technologists
- Medical Physicists
- Authorized Users
- Other Physicians* and any other persons who may use be present when byproduct material is being used.

The ancillary personnel include:

- Nursing
- Clerical
- Housekeeping
- Aids/Porters

Employee Training Program - Continued

* Other than the authorized users who may be present for medical care of the patient (i.e. supervising the stress test)

II. Instruction Frequency:

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

III. Topics Of Instruction:

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions

2. Areas where radioactive materials is used or stored

3. Potential hazards associated with radioactive materials in each area where the employees will work

Employee Training Program - Continued

4. Appropriate radiation safety procedures

5. Licensee's in-house work rules

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer

7. Appropriate response to emergencies or unsafe conditions

IV. Method Of Instruction

Instruction will be lecture with all of the employees receiving copies of appropriate documents including but not limited to:

- Personnel External Exposure monitoring Programs
- Program for ALARA
- Rules for Site Use of Radiopharmaceuticals
- Spill Procedures
- A floor plan of the facility showing storage and use areas
- A tour of the facility, to familiarize all employees with the location of all national safety devices and the scope of operations present

Employee Training Program - Continued

In addition, technical and professional employees who will work with or around the byproduct materials, non-ancillary personnel, will receive copies of

- Procedures for monitoring performance of imaging equipment
- Procedures for ordering and receiving radioactive material
- Procedures for safely opening packages containing radioactive material
- Records for byproduct material use
- Procedure for area surveys
- Rules for safe use of radiopharmaceuitcals
- Procedure for waste disposal
- Spill procedures

PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

The applicant will establish and implement the following procedure for ordering and receiving radioactive material. All technical and professional workers will receive a copy of these procedures (see Employee Training Program).

Procedure

1. The Radiation Safety Officer (RSO) or a sole designate must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a) For routinely used materials:

      1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      2) The above records will be checked to confirm that material received was ordered through proper channels.

Procedure for ordering and receiving
radioactive material - Continued

b) For occasionally used materials:

1) The authorized user who will perform the procedure will make a written request that indicates the isotope, compound, activity, and supplier.

2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. There will be no deliveries during off-duty hours.

RADIOPHARMACEUTICAL ORDER AND RECEIPT RECORD

ORDER					RECEIPT*					MONITORING			Rec./ Monit.
Date	P.O.#	Act. mCi	Isotope/ Chem.	Supplier	Pack. Slip #	Act. mCi	Isotope	Chem.	Supplier	Pkg. OK?	mR/hr Surf.	Notes	Init.

* Follow procedure for ordering and receiving radioactive material.

NOTE: Upon completion of the receipt procedure and of this record, log the radioactive material into the appropriate distribution record.

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

The applicant will establish and implement the following procedure for opening packages containing radioactive material. All technical and professional workers will receive a copy of these procedures (see Employee Training Program).

No possession in excess of 20 Curies has been requested by the applicant, thus the procedure for opening packages is as follows:

Procedure

1. The applicant will make arrangements to receive all packages when they are offered for delivery by the carrier. By prior arrangement, they will only be delivered during working hours.

2. No packages will be received except as delivered by the commercial carrier or the central radiopharmacy.

3. The packages will be placed on an absorbant, plastic backed, pad in the area marked "receipt" on the floor plan.

4. Within 2 hours after the receipt, the package will be opened using the following procedure:

   a) Put on gloves to prevent hand contamination.

Procedure for safely opening packages
containing radioactive material - Continued

b) Visually inspect the package for any sign of damage (e.g. wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

c) Measure the exposure rate from the package. If it is higher than usual, stop and notify the RSO. *

d) Open the package with the following precautionary steps:

1) Remove the packing slip.

2) Open the outer package following the supplier's instructions, if provided.

3) Open the inner package and verify that the contents agree with the packing slip.

4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

5) If anything is other than expected, stop and notify the RSO.

* Measure the exposure rate from the package at the surface and at three (3) feet. If the specific action level is greater than the radiation package label allows, stop and notify the RSO immediately.

Procedure for safely opening packages
containing radioactive material - Continued

e) If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe to determine if there is any removable radioactivity by using the GM survey meter sensitive for this measurement. Take precautions against the potential spread of contamination.

f) Check the user request form to ensure that the material received is the material that was ordered.

g) Monitor the packing material and the empty packages for contamination with the low-range GM survey meter before discarding.

   1) If contaminated, treat this material as radioactive waste.

   2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h) Make a record of the receipt.

See Exhibit 1 for a sample of the record form we will use.

RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

The applicant will establish and implement the following rules for safe use of radiopharmaceuticals. The applicant will also post these rules and give all workers, technical and professional, a copy of the rules (see Employee Training Program).

Rules

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area with a crystal probe or camera.*

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such a remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

* We will use our gamma camera for monitoring hands and clothing.

Rules for safe use of radiopharmaceuticals - Continued

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With the low-range GM survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

Rules for safe use of radiopharmaceuticals - Continued

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or patient's name and identification number.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescriptions of less than 10 microcuries. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive materials in shielded containers.

16. Use a cart, or wheelchair or specially designed tray, to move flood sources, syringes, waste, and other radioactive material.

RECORDS OF BYPRODUCT MATERIAL USE

The applicant will establish and implement the following rules for use of byproduct materials. A copy of these records will be posted and given to all workers, technical and professional (see Employee Training Program).

Records of Unit Dosage Use

We will use the following model procedure to keep a record of unit dosage use.

Procedure

For each unit dosage received from a supplier, make a record of the:

1. radionuclide;
2. chemical form or its abbreviation or trade name;
3. date of receipt;
4. activity n millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
5. supplier;
6. lot number or control number if assigned;
7. date of administration or disposal;

Records of byproduct
material use - Continued

8. If administered,

   a) time of administration,

   b) measured activity in millicuries or microcuries,

   c) patient name, and

   d) patient ID number if one has been assigned;

9. if discarded, the method of disposal; and

10. initials of the person who made the record

    (See Unit Dose Record form attached)

Records of Multidose Vial Use

We will use the following model procedure to keep a record of multidose vial use.

Procedure

For each multidose vial that we receive from a supplier or that we prepare, we will make a record of the:

1. radionuclide;

2. chemical form or its abbreviation or trade name;

3. date of receipt or preparation;

Records of byproduct
material use - Continued

4. date and time of initial activity assay and activity in millicuries and volume;

5. supplier or kit manufacturer;

6. if administered, or withdrawn for any other use (i.e. quality control):

   a) date and time dosage was drawn,

   b) prescribed dosage,

   c) calculated inverse concentration (mCi/cc) at time of dosage measurement,

   d) calculated volume that is needed for the prescribed dosage,

   e) measured activity in millicuries,

   f) patient name and identification number if one has been assigned;

7. if discarded, the method of disposal and date; and

8. initials of the individual who made the record.
   (see Multidose Record form attached)

Records of byproduct
material use - Continued

Measuring and Recording Molybdenum Concentration

We will test each elution or extraction of the generator for its molybdenum concentration. (This will not have to be done when using prepared radiopharmaceuticals from a distributor.) This measurement will be made with the dose calibrator.

This procedure is based on the use of a "molybdenum breakthrough pig." The dose calibrator manufacturer will supply, as an option, a Molybdenum breakthrough pig made of lead. The pig is thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure will be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution.

Model Procedure

For each generator elution, make a record of the:

1. date the generator was received;

2. date and time of elution;

3. measured Mo-99 activity in microcuries;

Records of byproduct
material use - Continued

4. product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. measured Tc 99m activity in millicuries;

6. ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO.) [The 0.07 action level allows for the quicker decay of the Tc through the day of use.]

7. initials of the person who made the record.

UNIT DOSE RECORD

Label

RECEIPT

Date: _____, 19___ Supplier: _____ Lot #: _____

Isotope: _____ Form: _____ Units: _____ Assay Date: _____ Time: _____

Assay Dosage/Unit: _____ __ Ci Total Possesion: _____ __ Ci

DISTRIBUTION Administration Date	Time	Assay Dosage mCi	Decay Factor	Calc. Dosage mCi	Measured Dosage mCi	Patient Name Last, Init.	I.D. #	Prep/ Admin. Init.

DISPOSAL

Removed for disposal

Date: _____, 19___ Time: _____ By: _____ Route: _____

Disposal identification and disposition: _____

_____ By: _____

MULTIDOSE RECORD

RECEIPT

Isotope: _____ Supplier/Source: _____ Lot #: _____

Assay: Date: _____, 19__ Time: _____ Activity: _____mCi Volume:___cc

Kit: Supplier: _____ Lot #: _____ Prep. Init.: _____

Radiopharmaceutical: _____

Assay Activity: _____mCi Volume: _____cc Concentration: _____mCi/cc

Label

DISTRIBUTION

Administration Date	Time	Assay Concent. mCi/cc	Decay Factor	Calc. Concent. mCi/cc	Dosage Activity mCi	Volume cc	Measured Dosage mCi	Patient Name Last, Initial	I.D. #	Prep. Adm. Init.

DISPOSAL

Removed for disposal: Date: _____, 19__ Time: _____ By: _____ Route: _____

Disposal identification and disposition: _____

_____ By: _____

Label

TECHNETIUM 99m/MOLYBDENUM 99 GENERATOR RECORD

RECEIPT:
Date: _____, 19___ Supplier: _____ Lot #: _____

Assay Date: _____, 19___ Time: _____ am/pm Mo 99 _____ mCi

ELUTION ASSAY		99m Technetium			99 Molybdenum			Assay
Date	Time	Activity mCi	Volume cc	Concentration mCi/cc	Activity mCi	CorFac	Ratio* 99/99mTc	Init.

DISTRIBUTION		Assay	Decay	Calc.	Activity Prep.		Measured	Distribution Discrip.	Prep.
Date	Time	Concent. mCi/cc	Factor	Concent. mCi/cc	Activity, mCi	Volume, cc	Dosage, mCi	of Transfer	Init.

DISPOSAL
BALANCE OF ELUTION (Daily)
Removed for disposal Date: _____, 19___ Time: _____ By: _____ Route: _____

GENERATOR
Removed from service for DIS Date: _____, 19___ By: _____

Dismantled:** Date: _____, 19___ By: _____

* As determined by mCi 99Mo - mCi 99mTc NOTE: The maximum acceptable concentration is 0.07 mCi 99Mo/mCi 99mTc

** It must be at least 60 days after assay date, see Procedure For Waste Disposal

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LEAK TESTING SEALED SOURCES

The applicant will establish and implement the following procedure for leak-testing sealed sources. All sealed sources, i.e. 57Co, 137Cs and 133Ba, that require an NRC/State license will be leak tested.

All sources will be leak tested not less than every 3 months.

Procedure

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. Set out a survey meter so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   a. For small sealed sources, it is easiest to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

Leak testing sealed sources - Continued

b. If testing radium sources at the same time your are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

a. Select a suitable detector that is sufficiently sensitive to detect 0.005 microcuries. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter will be appropriate.

b. Assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be nece sary to use a certified check source with a different isotope that has a similar spectrum in order to estimate the detection efficiency of the analyzer used to assay the wipe samples.

c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

Leak testing sealed sources - Continued

d. Calculate the estimated activity in microcuries on the wipe sample.

e. Continue same analysis procedure for all wipe samples.

f. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC and the agreement state will be notified.

g. Record the wipe sample results on the list of sources, and sign and date the list.

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PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

The applicant will establish and implement the following personnel external exposure monitoring program. All whole body film badges and TLD finger dosimeters will be supplied by R. S. Landauer and will be changed on a monthly basis.

The Program

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. All exposure reports will be posted on a monthly basis where all workers involved can review their records. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or TLD.

2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who handle radioactive material on a regular basis will be issued a TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses and aids, will be issued a whole body monitor.

Personnel external exposure monitoring program - Continued

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

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A L A R A

The applicant will implement a voluntary ALARA program even though it isn't required because this is a private practice application. This voluntary ALARA program will consist of those actions necessary to maintain occupational radiation exposure as low as reasonably achievable. To do this, the RSO will:

1. Perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections,e tc., and consultations with the radiation safety staff or outside consultants.

2. See that modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in the RSO's judgement, is considered to be unjustified.

3. See that 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.

4. Encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA program.

A L A R A - Continued

5. Perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 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.

TABLE 1
Investigational Levels

		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

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

6. Evaluate overall efforts for maintaining exposures ALARA on an annual basis.

A L A R A - Continued

7. Perform an annual review of the radiation safety program for adherance to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

8. Review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA.

9. Review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

10. Will schedule briefings and educational sessions to inform workers of ALARA program efforts (see instruction to workers).

11. Will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and that the RSO is committed to implementing the ALARA concept.

12. See that radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

A L A R A - Continued

13. Be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

14. Establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

15. 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.

16. Will consult with the RSO before using radioactive materials for a new method of use.

17. Will evaluate all methods of use before using radioactive materials to ensure that exposures will be kept ALARA.

18. Will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

A L A R A - Continued

19. Will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

20. See that workers are instructed in the ALARA concept and its relationship to work procedures and work conditions.

21. See that workers will know what recourses are available if they feel that ALARA is not being promoted n the job.

22. Establish Investigational Levels in order to monitor individual occupational external radiation Exposures (see Table 1).

23. Review and record "Current Occupational External Radiation Exposures", results of personnel monitoring not less than once in any calendar quarter as required by the regulations.

The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose 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 dose is less than Table 1 values for the Investigational Level I.

A L A R A - Continued

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

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action.

A L A R A - Continued

d. Reestablishment of Investigational Level II to a level above that listed in Table 1.

In cases where a worker's or a group of workers doses 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.

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SPILL PROCEDURES

The applicant will establish and implement the following procedures for handling spills of radioactive materials. The applicant will also post these rules and give all workers, technical and professional, a copy of these procedrues (see Employee Training Program).

Procedures

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with the low-range, GM survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey (see attached).

Spill procedures - Continued

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Check your hands, clothing and shoes for contamination.

3. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

4. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

5. Close the room and lock or otherwise secure the area to prevent entry.

6. Notify the RSO immediately.

7. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

8. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey (see attached).

RADIOACTIVE SPILL KIT (SUGGESTED CONFIGURATION)

From a Radiological Supplier:

2 - Disposable lab coats	032-100	4.00
2 - Pair re-usable gloves	034-005	1.50
1 Bx disposable gloves (1 Box of 100)	037-125	6.50
1 Bx disposable boots (1 Box of 100)	038-300	12.00
1 Roll absorbant paper (20"x300')	033-300	40.00
100' Rope (Yellow & Magenta)	121-072	20.00
1 Pkg radioactive material signs (20)	025-002	4.75
1 Roll radioactive material tape	026-013	6.50

From An Office Supply Store:

1 Clipboard
2 Chinamarkers (red)
2 Black markers (Permanent)
2 Red markers (water soluble)
2 Pencils (sharpened)

From A Hardware Store:

1 Roll garbage bags - large - with twist ties
1 Roll masking tape - 1" wide
1 Small plastic garbage can with cover

From A Grocery Store:

2 Rolls paper towels
1 Jar of liquid (hand) soap
1 Small bottle of liquid dish soap
1 Bar lava soap
1 Soft brush
1 Small box of tide or other detergent
1 Small box of corn meal
1 Small jar of hand lotion

From Your License Materials

1 Copy "Spill Procedures"
1 Copy "Radioactive Spill Report"
1 Copy "Emergency Notification Numbers"

Radioactive Spill Contamination Survey

The spill occurred at ___:___ am pm on ___-___-___ in room _____. Decontamination was completed at ___:___ am pm.

Sketch of spill area

loc	pre-clean mR/hr	post-clean beta cpm	post-clean gamma cpm

Name: _____

Date: _____

Radioactive Spill Report

The spill occurred at ___:___ am/pm on ___-___-___ in room _____.

Instrument used to check for personnel contamination:
Meter model: _____ Meter S/N: _____ Probe model: _____ Probe S/N: _____

Personnel present	Personnel contamination results*

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Instrument used to survey spill area before cleanup:
Meter model: _____ Meter S/N: _____ Probe model: _____ Probe S/N: _____
Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

_____mCi of _____ as _____
_____mCi of _____ as _____
_____mCi of _____ as _____

Give a brief description of the accident: _____

Give a brief description of followup actions taken to prevent recurrence:

Name: _____
Date: _____

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PROCEDURE FOR AREA SURVEYS

The applicant will establish and implement the following procedure for area surveys. All area surveys will be made with our low level survey meter, Atomic Products #069-701 and #069-993 GM Probe, capable of full scale readings 0.5, 5.0 and 50 mR/hr. We will use a Cs-137 10 uCi check source (Atomic Products #101-103) to detect the presence of 200 dpm for the level of removable contamination.

Calculation of Efficiency: (The actual numbers of cpm will have to be determined when the survey instrument and the check sources are obtained). The actual number of uCi will have to be calculated.

10 uCi = 2.22×10^7 dpm (as calculated)

2.22×10^7 dpm = X cpm (as measured)

Efficiency = cpm (as measured)/dpm (as calculated)

Application:

cpm X Efficiency = dpm

The surveys, Ambient Exposure Rate and Removable Contamination, will be supplemented, at least annually, by exposure surveys of the uncontrolled areas adjacent to the areas where the radioisotopes are stored.

Procedure for area surveys - Continued

Ambient Exposure Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with our low-range survey meter. If diagnostic administrations are occasionally made in other areas (i.e. patient/examination rooms), and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with our low-range survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a low-range survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with an ionization chamber survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Procedure for area surveys - Continued

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 200 dpm 100 cm^2 of removable contamination. We will use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute) to dpm. (see preceding example of calculation).

Procedure for area surveys - Continued

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of exposure rate and contamination survey results. It will include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed and contamination and exposure rate action levels as established by the RSO*.

   d. Measured exposure rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive exposure rates or contamination and follow-up survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

* NRC Regulatory Guide 8.23, "Radiation Safety Surveys At Medical Institutions" will be used as a guide. However, any detectable, removable contamination above 200 dpm will be cause for decontamination.

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PROCEDURE FOR WASTE DISPOSAL

The following are the rules for byproduct waste disposal that will be established and implemented by the applicant.

General Rules

1. All radioactivity labels will be defaced or removed from all containers and packages prior to disposal in in-house waste. Waste will not be compacted.

2. Procedures will be established to ensure that nonradioactive waste such as leftover reagents, boxes, and packing materials are not mixed with radioactive waste.

3. All procedures will occasionally be monitored to ensure that radioactive waste is not created unnecessarily. All new procedures will be reviewed to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, we will consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

Procedure for waste disposal - Continued

Two methods of disposal will be used by the applicant.

I. Transfer For Disposal - Syringes and other containers received from a central radiopharmacy may be transferred, returned, to the same radiopharmacy for disposal. This transfer will only occur by direct pick-up by the radiopharmacy and upon receiving written proof that the radiopharmacy is authorized to receive such material for disposal.

Complete records will be maintained showing the:

date and time of the transfer;

who received the material;

what and how much wa transferred.

The recipient of the transfer, from the radiopharmacy, will sign for receipt of the material.

II. Procedure For Disposal By Decay-In-Storage (DIS)

1. We will use two separate containers, double lined garbage cans, for containment of all waste. Because we will have no waste with a half life of over 65 days, it will not be necessary to separate the material by half life.

Procedure for waste disposal - Continued

The material will be placed in double plastic gags, in the large and appropriately labeled, container. Each bag will contain no more than 2 weeks accumulation of waste. The bag will not provide any radiation shielding for the material.

2. When the bag is full, or at the end of the week, we will seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the bag. The bag will be transferred to the other container for DIS.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your low-range GM survey meter for proper operation.

   b. Monitor in a low-level (less than 0.05 mR/hr) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

Procedure for waste disposal - Continued

e. Discard in in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of materials (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. Mo-99/Tc-99m generators will be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a low-range GM survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with a low-level survey instrument in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

WASTE DISPOSAL RECORD FORMS

The following information will be maintained in the licensees records of disposal.

TRANSFER TO RADIOPHARMACY RECORD

Radiopharmacy: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ License #: _____

Date	Time	Amount	Form	Transferred By	Received By

DECAY IN STORAGE RECORDS (DIS)

Container/Bag	Date	Radionuclide	Amount	Form	By Initial

Date Sealed: _____ By: _____

Disposal Date: _____ Exposure Level: _____ mR/hr

Type of Material: _____ Labels Defaced Or Removed: _____

Disposal Route: _____

Monitored And Disposed By: _____

External Contamination Levels: _____

Removable Contamination Levels: _____

Mo99/Tc99m GENERATOR DISPOSAL RECORDS

Generator: Mfg _____ Lot # _____ Assay Date: _____

Removed from Service: Date _____ (a)

Earliest Date for Dismantlement For Disposal: Date _____ (b)

Dismantling Date: _____ By: _____

Disposal Date: _____ Exposure Level _____ mR/hr

Route: _____ By: _____

Labels Defaced or Removed: _____

(a) beginning of containment period

(b) assay date + at least 60 days