030-33308

ABANDONED
[redacted] SHEET

I

Dept 21
TC
118639

TO: License Fee Management Branch

FROM: Region I

SUBJECT: [redacted] APPLICATION
ABANDONED

Control Number: 118639

Applicant: Brahma N. Sharma, M.D.

Abandoned:
Date [redacted] 4/14/94

Abandonment:
Reason for [redacted] Failure to respond to Region I threat to abandon letter dated 2/7/94. New license application (Docket No. 030-33308). After review.

M. A. Perkins 4/14/94
Signature Date

Attachment:
Official Record Copy of
[redacted] Action
Abandoned

FOR LFMB USE ONLY

ABANDONMENT
Final Review of [redacted] Completed:

Refund Authorized and processed

No Refund Due

Fee Exempt or Fee Not Required

Comments:

Log completed

Processed by: Linda Mitchell
5-16-94

170140

9406010038 940414
PDR ADOCK 03033308
C PDR

OFFICIAL RECORD COPY

10

FEB - 7 1994

Docket No. 030-33308
Control No. 118639

Brahma N. Sharma, M.D.
1643 Pinoak Drive
Pittsburgh, Pennsylvania 15237

Dear Dr. Sharma:

This is to confirm the letter sent to you from this office dated November 23, 1993. This letter requested additional information that we need to continue our review of your NRC license application. A copy of our letter is enclosed.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
David G. Mann

David G. Mann
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosure
1. NRC letter dated November 23, 1993

DRSS:RI
Mann/dgm

2/4/94

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ML 10

NOV 23 1993

Docket No. 030-33308
Control No. 118639

Brahma N. Sharma, M.D.
1643 Pinoak Drive
Pittsburgh, Pennsylvania 15237

Dear Dr. Sharma:

This is in reference to your application dated August 10, 1993 for a byproduct material license. In order to continue our review, we need the following additional information:

1. Attachment A indicates that "All radioactive wastes from the radiopharmacy will be returned to the radiopharmacy for disposal. Records of this transfer will be maintained by the applicant."

   a. Clarify who will act as the D.O.T. shipper (licensee or radiopharmacy) for the material returned to the radiopharmacy. If the radiopharmacy agrees to act as the shipper, provide a copy of the letter explicitly stating this agreement for review.

   b. Confirm that the shipper will perform the appropriate exposure rate and contamination surveys in accordance with 49 CFR 173.421 and maintain documentation of these surveys in accordance with 10 CFR 30.51(a).

2. Attachment A states that the facility design will meet 10 CFR 20.105 restrictions for exposure limits in unrestricted areas or the equivalent state regulation." Revise this statement such that the exposure limits in unrestricted areas will, at a minimum, meet the 10 CFR 20.105 requirements.

3. Attachment B2 indicates that "sealed sources will not have activities less than those stated in 10 CFR 35.50(b)(1)(2) or equivalent State Requirement." Revise this statement such that sealed source activities will, at a minimum, meet the 10 CFR 35.50 requirements.

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ML 10

4. Attachment D describes your personnel training program. Confirm that the appropriate individuals (RSO and technologist at a minimum) will be instructed on the proper use of a radiation survey instrument, including the correct use of the radiation check source. Confirm that records will be maintained describing the training topics covered, the individuals in attendance, the date of the training, and the instructor.

5. Attachment E2 indicates that NC Systems developed facility plans for Dr. Sharma. Please clarify; does the facility exist as depicted in the facility diagram or is the facility under construction? In addition, the plans that was submitted (developed by NC Systems) list the address as 1643 Pinoak Drive, Pittsburgh, PA 15237; the application indicates that the location of possession and use is 125 Seventh Street, 4th Floor, Pittsburgh, PA 15222. What is the correct location where byproduct material will be used or stored?

6. Attachment E5 shows radiation safety equipment (eg. vail shields, syringe shields, etc.). Confirm that your radiation safety program includes the requirements to use the radiation safety equipment.

7. The "USE" column in Attachment F indicates that extremity dosimetry will be used for "monitoring the extremities of all personnel who handle sources, or of patients who have been recently injected." Confirm that you will monitor the extremities of all personnel who handle sources, or handle patient who have been recently injected.

8. 10 CFR 35.22 requires each medical institution licensee to establish a Radiation Safety Committee to oversee the use of byproduct material. 10 CFR 35.2 defines a medical institution as an organization in which several medical disciplines are practiced. Please describe the medical practice (i.e., multi-disciplinary; cardiology, endocrinology, nuclear medicine, etc.) for which you are requesting authorization to use byproduct materials.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 118639. If you have any technical questions regarding this deficiency letter please call me at (215) 337-5237.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
David G. Mann

David G. Mann
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Enclosures:
1. 10 CFR Parts 19, 20, 35 and 170
2. Regulatory Guide 10.8
3. Forms NRC-313 and 314

DRSS:RI
Mann/mlb

11/23/93

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION E
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

L&L 30079
030-33808
02200

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Brahma N. Sharma, M.D.
1643 Pinoak Drive
Pittsburgh, PA 15237

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4TH FLOOR, 125 SEVENTH STREET

Pittsburgh, PA 15222

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Brahma N. Sharma, M.D

TELEPHONE NUMBER: 412-578-7054

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY
AMOUNT ENCLOSED $ 760.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Brahma Sharma	Brahma N. Sharma, M.D.	Physician/Applicant/Owner	8-10-93

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–$500K
- [ ] $500K–$750K
- [V] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES (Those for entire facility including contractors) 10

c. NUMBER OF BEDS NA

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Senior and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence)
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Dept 21 I	7C	Remitter: Anthony P. Yates, M.D. Richard A. Rydze, M.D. John C. Phillips, M.D.	
AMOUNT RECEIVED	CHECK NUMBER			DATE
$760 + 7340	7166 7894			14/27/93

PRIVACY ACT STATEMENT ON THE REVERSE

118639

OFFICIAL RECORD COPY ML 10

(SEP 02 1993)

Documentation of Attachments to this Application

Section	Attachment Description
A.	Description of the Scope of the Operation
B.	Radioactive Materials Requested in This Application
C.	Training and Experience of Authorized User and Radiation Safety Officer
D.	Personnel Qualifications and Training
E.	Facilities and Related Equipment
F.	Radiation Detection Instrumentation
G.	Calibration of the Survey Instrument
H.	Calibration of the Dose Calibrator
I.	Quality Control of the Gamma Camera
J.	Personnel External Monitoring Program
	Radiation Safety Committee
	ALARA Program
K.	Leak Testing of Sealed Sources
L.	Rules for the Safe Use of Radiopharmaceuticals
M.	Procedure for Spills
N.	Procedure for Ordering Radioactive Materials
O.	Procedure for Opening Packages
P.	Radiopharmaceutical Records
Q.	Procedure for Area Surveys
R.	Radioisotope Waste Disposal Procedure

The documents in this application are ordered on the following pages as they are listed above.

Description of the Scope of Operation

This license application is only for nuclear cardiology procedures implemented in a private practice facility. The materials used will be obtained from a radiopharmacy. The applicant will not obtain a $^{99m}Tc/^{99}Mo$ generator. There is no intent to purchase any materials in "bulk" form, and all sources will be obtained in unidose from the radiopharmacy.

All radioactive wastes from the radiopharmacy (i.e., spoiled unidoses or used syringes that contain residual activity) will be returned to the radiopharmacy for disposal. Records of this transfer will be maintained by the applicant. Other wastes, such as wipes and contaminated materials, will be stored by the applicant for decay in storage (DIS). The facility design will meet 10 CFR 20.105 restrictions for exposure limits in unrestricted areas or the equivalent state regulation.

If the needs of the applicant-physician require the operational scope to change, the application will be amended before the applicant-physician makes those changes.

The South Side Hospital
2000 Mary Street
Pittsburgh, PA 15203
412 488-5550

July 2, 1993

Brahma Sharma, M.D.
125 Seventh Street
Sixth Floor
Pittsburgh, PA 15222

Dear Dr. Sharma:

This is to notify you that The South Side Hospital will accept patients that have had Diagnostic Nuclear Medical procedures performed on them on a routine basis. However, if a patient is dosed with a therapeutic radiopharmaceutical prior, notification to The South Side Hospital must be conducted prior to patient admission.

If you have any questions regarding this policy, please feel free to contact me.

Sincerely,

Marcie S. Caplan

Marcie S. Caplan
Vice President, Professional Services

md

cc: John Mikita, M.D.
Radiation Safety Officer

Radioactive Materials Requested in this Application

Radiopharmaceuticals

The applicant wishes to receive a license for all radiopharmaceuticals allowed under Group II, Schedule C Chapter 10D-91 FAC. These radiopharmaceuticals, to be used in an out-patient facility, will be limited to:

Radioisotope	Form	Amount (mCi) of each form	Item 6: Purpose of use
^{99m}Tc*	Pertechnetate	80.00	Human use
	HSA	40.00	Human use
	PYP	40.00	Human use
	Other FDA-approved forms	200.00	Human use
^{201}Tl*	Chloriue	60.00	Human use
^{99m}Tc*	Pertechnetate	5.00	Quality Control and Calibration
^{201}Tl*	Chloride	1.00	Quality Control and Calibration

Sealed Sources for Quality Control and Calibration as described on the next page.

*Note: The sources of radiopharmaceuticals will be obtained from the radiopharmaceutical supplier in unidose or multidose form. The applicant will not obtain a generator for ^{99m}Tc, or make "kits" using the radiopharmaceuticals listed in this application (the "supplier" includes the radiopharmacy).

All unused sources, contaminated syringes, etc., that are obtained from the radiopharmacy will be returned to the radiopharmacy for disposal. Only those materials originating in the facility (wipes, etc.) will be kept in the facility for decay in storage (DIS).

It is recognized that the ^{201}Tl and ^{57}Co are licensed by the "State," including Agreement States.

Sealed Sources

The sealed sources will be obtained from: **Biodex (Atomic Products)**
P.O. Box R
Shirley, New York 11967

The sources used for the dose calibrator are:

Element and Mass Number		Form	Max., mCi	Catalog Number
Ba	133	sealed	0.250	063-562
Cs	137	sealed	0.200-0.250	101-356
Co	57	sealed	5.000	063-261

The sources used for the gamma camera are:

Element and Mass Number		Form	Max., mCi	Catalog Number
Co	57	sealed	5.000	062-297

A description of the sources provided by the supplier is given below. These sealed sources will not have activities less than those stated in 10 CFR 35.50 (b) (1) (2) or equivalent State Requirement. If sources have activities less than required, they will be replaced.

Isotope Calibrator Reference Sources

For checking calibrator accuracy, performance and consistency.

Good practice dictates, and regulatory agencies recommend, that isotope calibrators used for measuring diagnostic and therapeutic doses of radiopharmaceuticals be checked regularly over the calibrator's range of measurements. Calibrator performance is easily monitored by using the following calibrated standards to verify the accuracy of its assays:

(a) A long-lived source, such as ^{137}Cs (T 1/2 = 30 years), to avoid the tedium of constant decay corrections.

(b) A ^{57}Co source (T 1/2 = 270 days) that simulates ^{99m}Tc, the most common radionuclide in nuclear medicine.

By keeping a daily log of the values obtained on selected ranges with both standards, the user develops a performance record that detects calibrator error or failure before a mistake is made in a patient's dose.

Both sources are supplied in a 20ml epoxy in a 27ml plastic vial, 85 mm H x 30 mm D. Calibrated to +/- 5%.

063-562 Calibrated ^{133}Barium Source, 250µCi
101-356 Calibrated ^{137}Cs Source, 200µCi
063-261 Calibrated Simulated ^{99m}Tc Source (^{57}Cobalt), 5mCi

^{57}Cobalt Flood Sources

Intended Uses:

- Daily intrinsic uniformity checks
- Extrinsic collimator checks
- Linearity and resolution checks with bar phantom
- As transmission sources
- Quality control for accreditation and regulatory requirements

The sources contain ^{57}Cobalt, uniformly dispersed and cured in a rigid/plastic leucite casting. Each source is supplied with an attractive cushioned, lead-lined, wooden storage case, reducing the exposure rate at surface to approximately 1.4mR/hr.

All sources are inspected for emission non-uniformity less than ±1% at 2 standard deviation and verified statistically. Each source is supplied with a Leak-Test certificate.

Flood Source: 062-297 18 3/4" diameter, 5mCi

Training and Experience of Authorized User and Radiation Safety Officer

The attached documents evidence the training and experience of the physician applicant. These documents indicate more than 200 total hours of Basics of Radioisotope Handling training. The applicant has completed the required preceptorial clinical and work experience. Additional clinical experience is not necessarily documented, and should not be required of the applicant.

A description of the training program provided by the Institute for Nuclear Medical Education is on file with your agency. This training program has been reviewed by all NRC Regions and by most Agreement States, and has also been reviewed by the State of Colorado's Radiological Health Section director, Charles Mattson. The program has been submitted by several agencies, including the State of Colorado, for inclusion in the NRC list of Service and Training Programs. If you require additional information concerning this program, please contact:

Institute for Nuclear Medical Education
Attention: Charles H. Rose, MA, MSPH, D (ABSNM)
Program Director
5171 Eldorado Springs Drive
Boulder, Colorado 80303

Telephone: 1-800-548-4024 or 303-499-4099
FAX: 303-499-3999

TRAINING AND EXPERIENCE OF AUTHORIZED USER AND RADIATION SAFETY OFFICER

This application is for a new site, under the control of one Authorized User and Radiation Safety Officer, Brahma N. Sharma, M.D.

Dr. Sharmas' experience and didactic training are described in the following Attachments.

This site will NOT be using a technetium generator, or iodine, and there will be NO radionuclide therapy procedures performed at this site.

Dial ext.: _____

WEST PENN
HOSPITAL

Friends for life.®

September 30, 1992

To Whom It May Concern:

This letter is to affirm that Brahma Sharma gained considerable clinical experience at the Western Pennsylvania Hospital in Nuclear Cardiology. This involved seven months of training which began in September, 1989 and also included the month of May 1990, March 1992, April 1992, May 1992, July 1992, and August 1992 (seven months total). During this time, Dr. Sharma actively participated in the following procedures:

10 first pass studies
10 Persantine thallium scans
14 Pyrophosphate scans
26 rest thallium scans
385 rest gated equilibrium studies (including wall motion analysis and calculation of ejection fraction)
100 planar stress thallium scans
546 SPECT thallium scans
22 stress gated blood equilibrium studies
323 Adenosine thallium scans (a pharmacologic stressor comparable to Persantine)

He gained considerable experience in examining patients and reviewing their histories, selecting suitable radio-pharmaceuticals, collaborating with his preceptors (both authorized users, including myself) in interpretation of test results and patient follow-up.

Additionally, Dr. Sharma rotated through the Syncor Radiopharmacy and was involved with radiopharmaceutical preparation and elution of the Technetium 99m-Molybdenum-99 generator. He was involved with quality control of the cameras in the department including daily floods, bar phantoms, SPECT uniformity correction, SPECT center of rotation, and Hot Lab Quality Control (dose calibrator, package receipts and returns, etc.)

In total, Dr. Sharma spent more than 1200 supervised hours in this facility during his clinical preceptorship and has developed a thorough understanding of Nuclear Cardiology.

Sincerely,

Stanley J. Grossman, MD

Stanley J. Grossman, M.D.
Director, Nuclear Medicine
and Chairman, Radiation Safety Committee
Western Pennsylvania Hospital
Pittsburgh, PA

NRC License # 37-02136-01

SUBSTITUTE NRC 313 M
SUPPLEMENT A

TRAINING OF 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
Brahma N. Sharma, M.D.	Penna/ALA/OK
ADDRESS 1643 Pinoak Drive Pittsburgh, PA 15237	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
ABIM	Internal Medicine	Sept 1989

4. Training Received in Basic Radioisotope Handling Techniques

Field of Training A	Location(s) and Date(s) of Training B	Type and Length of Training LECTURE LABORATORY COURSES (Hours) C				
		Principles of Radiation	Medical Radiation Instrumentation	Medical Radiation Protection	Radiopharmaceuticals and Chemistry	Total Hours per Subject
35.920(b)(1) and 35.32(b)(1)	The dates of the classes are given on the attached Certificates of Completion/Competency Institute for Nuclear Medical Education, Inc. Certified as Approved by the Colorado Department of Higher Education ACCET ACE AAHP NUSPEX					
a. RADIATION PHYSICS AND INSTRUMENTATION		39	31	8	22	100
b. RADIATION PROTECTION		2	4	20	4	30
c. MATHEMATICS PERTAINING TO THE USE AND MANAGEMENT OF RADIOACTIVITY		5	6	6	3	20
d. RADIATION BIOLOGY		2	3	12	3	20
e. RADIOPHARMACEUTICAL CHEMISTRY		2	6	4	18	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
	See the attached statement of experience			

6. TRAINING WAS COMPLETED UNDER THE DIRECT SUPERVISION OF:

NAME: Institute for Nuclear Medical Education, Inc.

ADDRESS: 5171 Eldorado Springs Drvive

CITY: Boulder STATE: CO ZIP: 80303

Clyde E. Pearce
Authorized Signature

TELEPHONE: 303-499-4099

1120 DOME 1/93

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

This document is to attest that

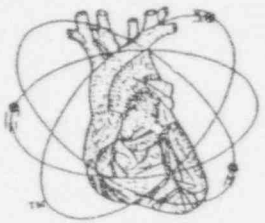
BRAHMA SHARMA, M.D.

has sucessfully completed the didactic program

RADIOPHARMACEUTICALS AND CHEMISTRY

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35)
5 Continuing Education Units (CEU)
50 Continuing Medical Education (CME)
50 Technical/Professional Credit as Specified by: APA & AAHP *
Additional Documentation will be provided to Regulatory Agencies upon participant request

10 April 1991
Date Class Commenced

Authorized Signature

07693-1
Affadavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

This document is to attest that

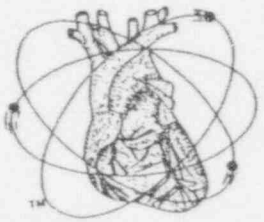
BRAHMA SHARMA, M.D.

has sucessfully completed the didactic program

MEDICAL RADIATION PROTECTION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35)
5 Continuing Education Units (CEU)
50 Continuing Medical Education (CME)
50 Technical/Professional Credit as Specified by: APA & AAHP *
Additional Documentation will be provided to Regulatory Agencies upon participant request

6 April 1991
Date Class Commenced

Authorized Signature

076906
Affadavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

This document is to attest that

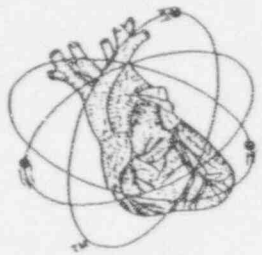
BRAHMA N. SHARMA, MD

has sucessfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35)
5 Continuing Education Units (CEU)
50 Continuing Medical Education (CME)
50 Technical/Professional Credit as Specified by: APA & AAHP *
Additional Documentation will be provided to Regulatory Agencies upon participant request

15 May 1991
Date Class Commenced

Authorized Signature

077029
Affadavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5785 Arapahoe, Suite D, Boulder, CO 80303 800-548-4024

Certified as an Approved Educational Institution by the Department of Higher Education, State of Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

This document is to attest that

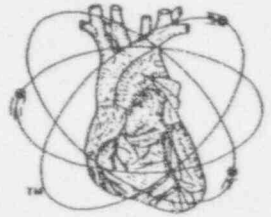
BRAHMA N. SHARMA, MD

has sucessfully completed the didactic program

PRINCIPLES OF RADIATION PHYSICS

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35)
5 Continuing Education Units (CEU)
50 Continuing Medical Education (CME)
50 Technical/Professional Credit as Specified by: APA & AAHP *

Additional Documentation will be provided to Regulatory Agencies upon participant request

11 May 1991
Date Class Commenced

077028
Affadavit of Competency

Authorized Signature

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Personnel Qualifications and Training

Technologist Qualifications

All nuclear medical technologists will be registered or certified in nuclear medicine by the ARRT, CNMT, or ASCP, *or* they will, if allowed by local or state laws, have the equivalent training in nuclear medicine. If local or state laws require registration/certification and a state license, then the applicant will comply with those laws.

In addition to the above, the physician applicant will interview the technologist, obtain a resume of his/her experience, and evaluate the technologist through close observation of her/his nuclear medical techniques in actual operation.

Personnel Training Program

Who will be instructed:
All personnel (professional/technical and ancillary) will be instructed. The professional/technical personnel will include, but not be limited to: technologists, authorized users, physicists, and physicians who are not authorized users, but may be present when by-product material is being used. The ancillary personnel include nursing, clerical, housekeeping, and other personnel who may frequent the area where material is being used.

Instruction Frequency:
Personnel will be instructed before assuming duties within the vicinity of radioactive materials, during an annual refresher training program, and whenever there is a significant change in the duties, regulations or terms of the license. There will also be instruction as deemed necessary by the RSO for all personnel after spills, misadministrations, and other incidents, including monitored high personnel exposure.

Topics of Instruction: Instruction will include, but not be limited to, the following subjects:

A. Applicable regulations, license conditions and workers' rights
B. Areas where radioactive materials are used or stored
C. Potential hazards associated with radioactive materials and bio-hazards, and procedures for each area where employees or physician staff work
D. Appropriate radiation safety procedures
E. Licensees' in-hours work rules
F. Each individual's obligation to report unsafe conditions to the RSO
G. Appropriate responses to emergencies or unsafe conditions

Personnel who work with the materials will also receive copies of procedures for the following: monitoring the performance of imaging equipment, ordering and receiving radioactive material, opening packages, recording by-product material use, surveying radiation areas, safely using radiopharmaceuticals, disposing of waste, and responding to emergencies.

Method of Instruction:
Instruction will be formal, didactic, and/or individual, as needed. It will include, but not be limited to: personnel monitoring programs, ALARA, rules for safe use of radiopharmaceuticals, emergency procedures, floor plans showing areas of use and storage, and a tour of the facility.

Method of Evaluation:
The RSO or her/his agent will evaluate and informally observe the individual's work activities.

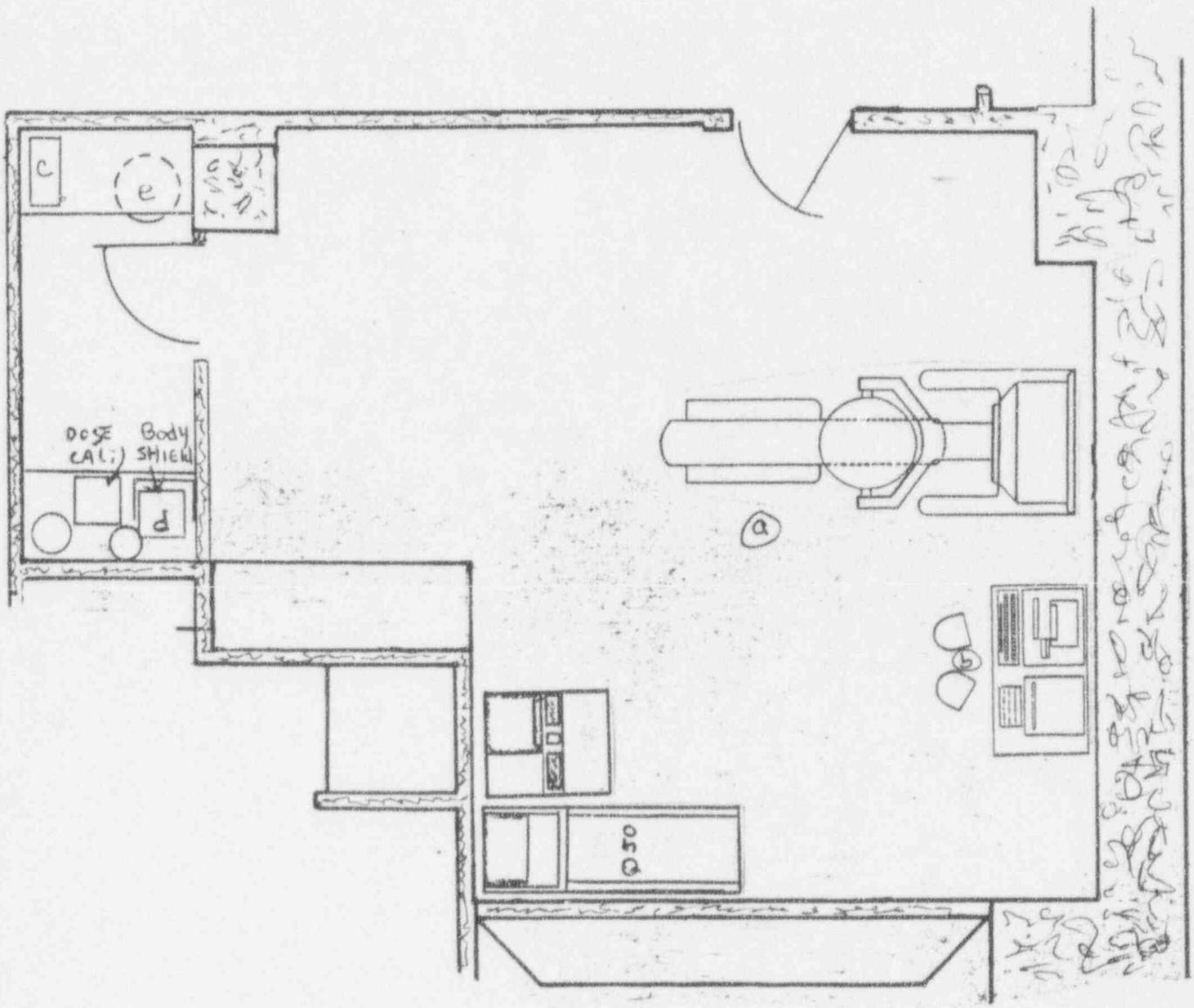
Facilities—Annotated Drawing of the Radioisotope Facility

B. Sharma, M.D.
Pittsburgh, PA

Scale: 1/4" = 1'0"
Direction: North

Shielding is indicated on the drawing
and on the following sheets of this application.

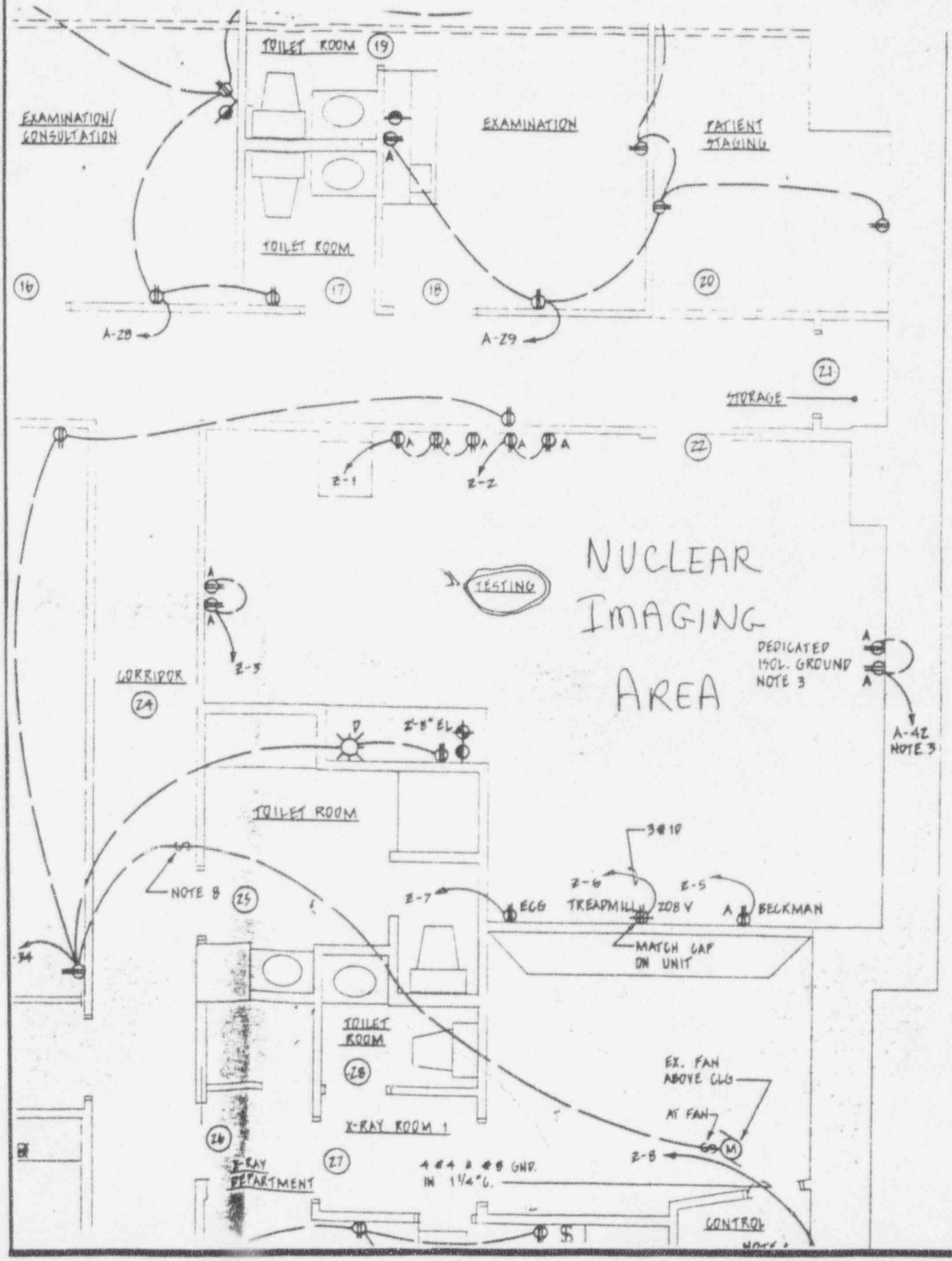
Identification of Areas:
a) Nuclear imaging area
b) Computer area
c) Radioisotope receipt
d) Radioisotope storage
e) Radioisotope waste



OVERALL VIEW - SHOWING RELATIONSHIPS TO OTHER ROOMS

Facilities—Annotated Drawing of the Radioisotope Facility

B. Sharma, M.D.
Pittsburgh, PA



APPLICATION FOR MATERIAL LICENSE

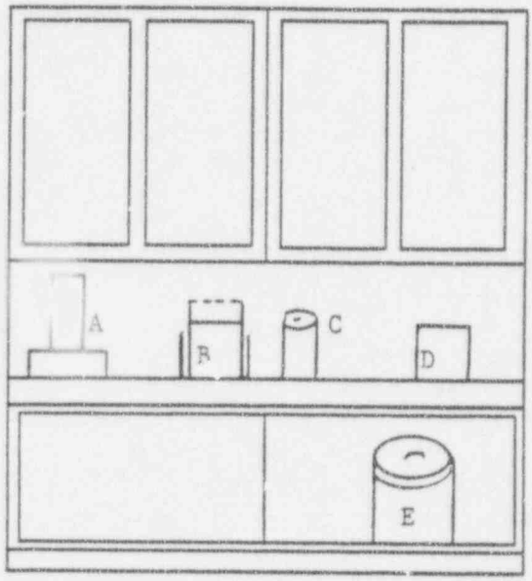
Attachment E 2

N C Systems
5171 Eldorado Springs Drive
Boulder, CO 80303
1-800-548-4024

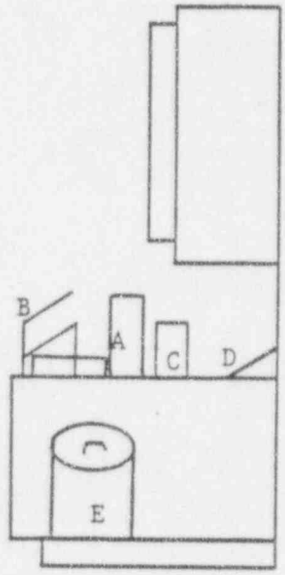
1643 Pinoak Drive
Pittsburgh, PA 15237

Plans developed for:
Brahma N. Sharma, M.D.

DATE	SCALE	SHEET	BY
8 Aug. 1993	¼" = 1'	2	CEP

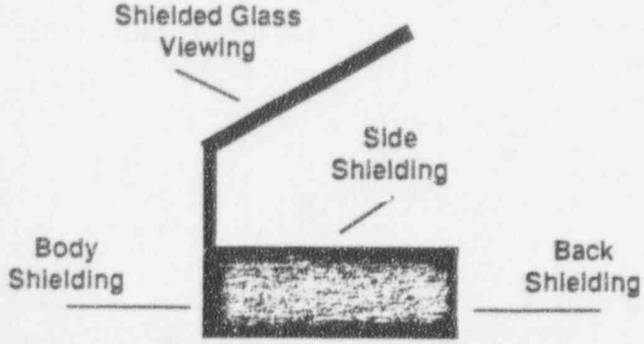


FRONT VIEW



SIDE VIEW

BODY SHIELD



LEGEND	
IDENTIFICATION	DESCRIPTION
A	Dose Calibrator
B	Body Shield
C	Radiopharmaceutical Storage
D	Radiopharmaceutical Receipt
E	Radioactive Waste

Facilities—Table Top Barrier Shield

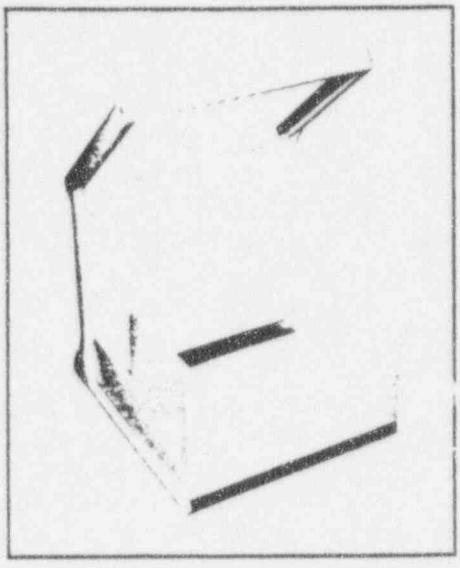


Table Top Lead Barrier Shield

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

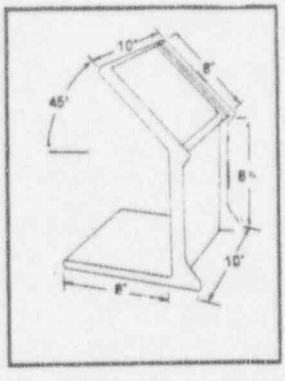
MINI TABLE TOP SHIELD—for small jobs in limited working areas.

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

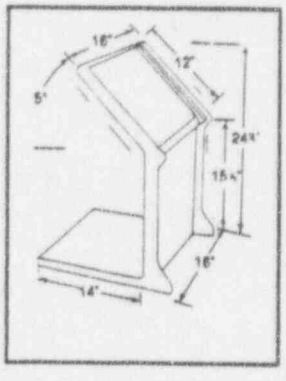
Select the shield most suited to your work load. Both units provide exceptional protection to the clinician when setting up technetium generators, filling syringes, performing radium loading procedures, etc.

1/2" thick lead wall protects the torso while the base provides ample working surface and balance against tipping. Face shielding is optically clear 1/4" thick lead glass (1 or 2 pieces may be specified when ordering), cantilevered for unimpaired viewing of 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



Standard Table Top Shield

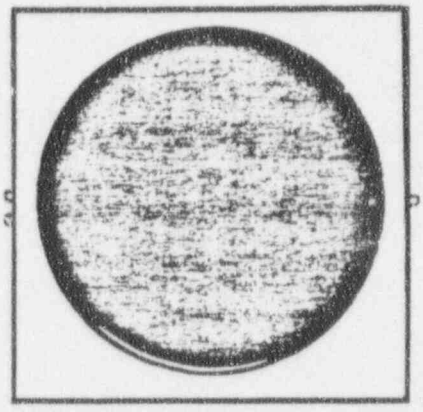
Equipment Quality Control Phantoms

See also "Notes on Sealed Sources" on page K 2 of this application.

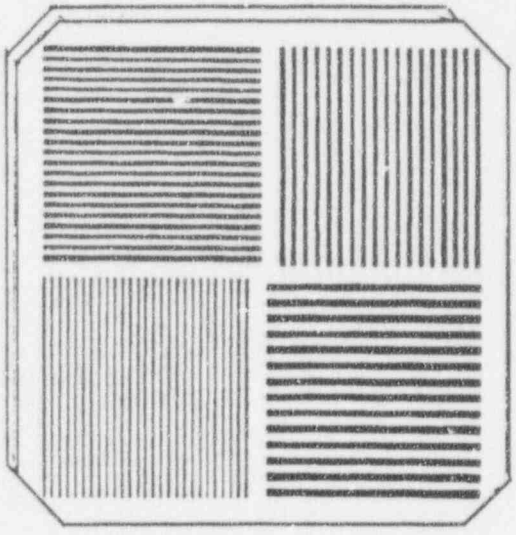
Extra Large Flood Phantom Source

- 15" diameter pool completely includes a patient's lungs, allowing accurate patient position when using a diverging collimator.
- 16 1/2" x 16 1/2" x 1" thick, with15" diameter x 1/2" cavity for suitable radionuclide
- Easy to fill—drain ports provided

Emission Phantom



Transmission Phantom



Standard High Resolution Bar Phantom

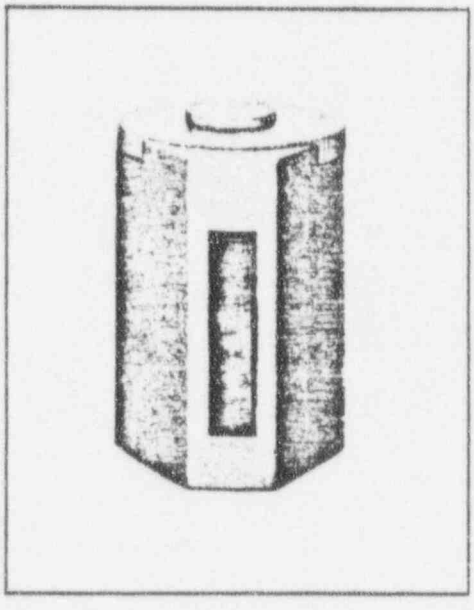
- Bar Widths: 1/4", 3/16", 5/32", 1/8" (6.4 mm, 4.8 mm, 4.0 mm, 3.2 mm)
- 15" field across bar configuration (38 cm)

Facilities—Radiation Safety Equipment

Vial Shields

This lead shield, available in either 1/2" or 1/4" thickness, was designed to permit safe, convenient handling of vials containing liquid radionuclides. It is particularly important when milking "cows." The vial provided with the generator may be placed in the shield, and the generator eluted in accordance with the manufacturer's instructions.

The shield has a high density lead-glass panel, with shielding thickness equivalent to that of the lead wall, so that the entire process may be viewed. The shield has a screw-type cover with an opening through which a syringe needle may be inserted for withdrawal of the radionuclide from the vial.



Lead Lined Storage Container

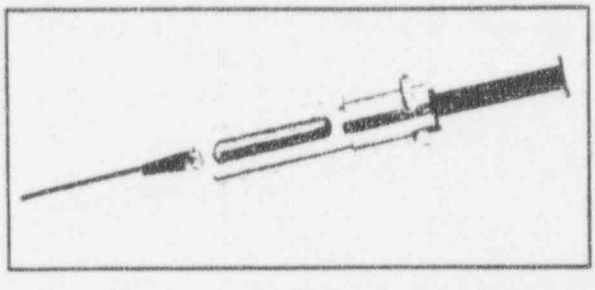
For Contaminated Syringes
- Safely holds used hot syringes
- Rapid, safe disposal

SPECIFICATIONS:

Lead Shielding:	1/8" Lead Shielding
Measures:	6 3/4" high
	5" diameter
Weight:	7 lbs.

Pro-Tec® Syringe Shield

Pro-Tec Syringe Shields are the first functional, safe, unobtrusive, easy to use, unbreakable, and lightweight syringe shields available. The slimline design is comfortable for both patient and clinician. The patented spring loaded twist lock of the stainless steel and brass screw lock keep disposable syringes snug inside the shield. Pro-Tec Syringe Shields are half the weight of other syringe shields, yet the Pro-Tec will normally reduce exposure from ^{99m}Tc by a factor of 20. The Pro-Tec Vu-Thru has a viewing port, so that drawing and injecting can be accomplished with the syringe in the shield. A special optical glass window with a density of 2.3 gm/cc covers the port.



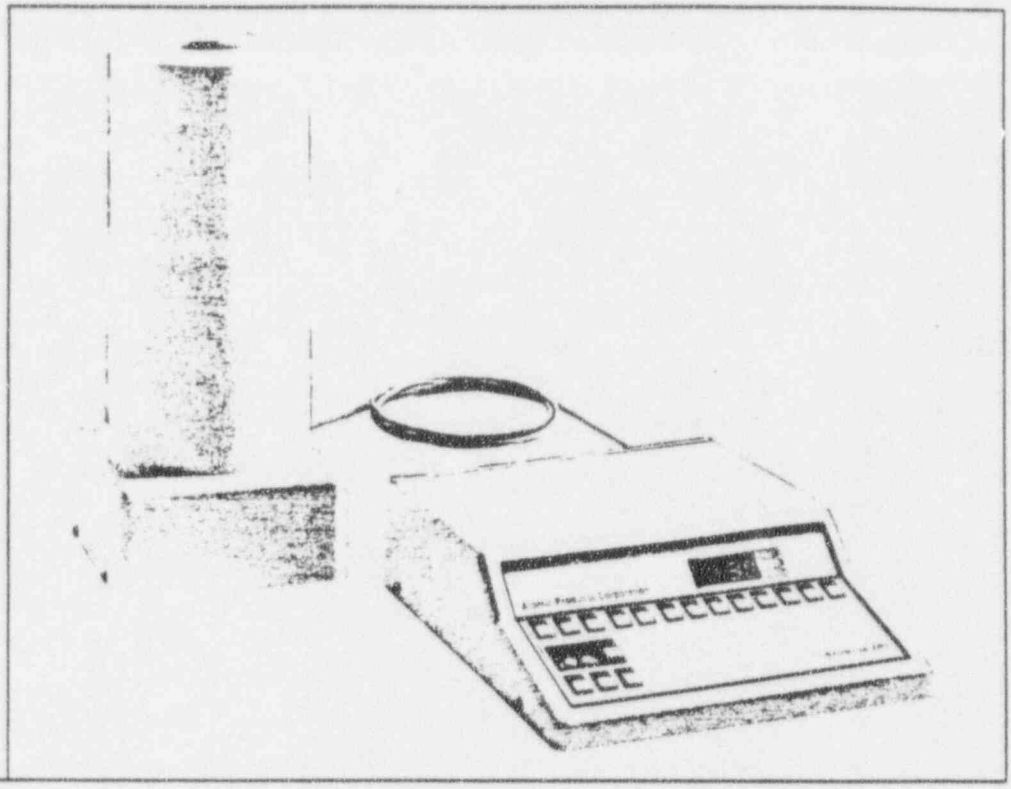
Radiation Detection Instrumentation

Instrument	Supplier/Model	Use
Gamma Camera System	CARDIO-CAM I, II, or SPECT System, furnished by: **CARDIO-CAM Corporation 5171 Eldorado Springs Drive Boulder, Colorado 80303**	Nuclear medical imaging for nuclear cardiology procedures
Nuclear Medical Computer	Supplied by **CARDIO-CAM Corporation** as described above	Nuclear medical data presentation and analysis
Dose Calibrator	Atomlab 100 Dose Calibrator Catalog #086-250, or equivalent, from: **Biodex (Atomic Products) P.O. Box 702 Shirley, New York 11967**	Radiopharmaceutical quality control of patient doses
Survey Meter	Bicron Surveyor 2000 Portable Survey Meter, supplied by: **Bicron Corporation 12345 Kinsman Road Newbury, Ohio 44065**	Daily surveys, ambient exposure surveys, package surveys, spill and contamination surveys, and other measurements
	External GM Probe Model: SWGM, furnished by **Bicron Corporation,** listed above	As described above
Sample Analysis	Cardio-Wipe II System, provided by **CARDIO-CAM Corporation,** described above	Counting of samples, wipes, or swipes for contamination surveys, spills, and other sample analysis
Film Badges—Body Personnel Dosimeters*	Furnished by: **R.S. Landauer, Tech/Ops Landauer, 2 Science Road Glenwood, IL 60425**	Whole body personnel monitoring of all individuals who frequent areas where radioactive materials are received, used, manipulated or stored
Extremity Dosimeters TLD Dosimeters	Furnished by: **R.S. Landauer, Tech/Ops Landauer,** described above	Monitoring the extremities of all personnel who handle sources, or of patients who have been recently injected

Note: See the attached pages for the description of the systems described in the above list.

*These dosimeters will be exchanged on a monthly basis, at the beginning of each month.

Atomlab 100



Activity Range:	0.01 uCi to 9999 mCi (or Bq equivalent)
Detector Linearity:	± 1% or 0.2 uCi, whichever is greater
Electrometer Linearity:	± 1% or 0.1 uCi, whichever is greater
Electrometer Accuracy:	± 1% or 0.1uCi, whichever is greater
Response Time:	Less than five seconds to reach 95% of final reading
Overall Accuracy:	± 3% or 0.3 uCi, whichever is greater

Overall accuracy is affected by such factors as the accuracy of the specific source calibration, geometric variations due to sample volume or configuration, detector linearity, electrometer accuracy, and readout accuracy.

Repeatability:	± 0.3% above 1 mCi short term (24 hr); 1% long term (1 yr)
Digital Readout:	4-Digit LED
Power Requirements:	100 to 120 VAC @ 1/2 A; 200 to 240 VAC @ 1/4 A
Frequency:	50/60 Hz
Display Unit:	*Dimensions:* 3.5" x 12" x 14.3" (8.9 cm x 30.5 cm x 36.3 cm)
	Weight: 6 lbs (2.7 kg)
Detector Unit:	*Dimensions:* 7.5" x 7.5" x 16"
	Overall Weight: 35 lbs (15.75 kg)
	Well Diameter: 2.5" x 10" (6.4 cm x 25.4 cm)
	Well Shielding: 1/4" Lead

The Atomlab 100 Features:

- Computerized, highly accurate dose calibration
- Activity display with bright, easy to read 4-digit LED
- 10 pre-programmed isotope selection push buttons
- Electronic thumbwheel with 4-digit LED display for isotope calibration settings
- Switch between activity display in curies or becquerels
- Remote ionization chamber with double the standard shielding and 10 foot cable
- Includes Vial Dipper, Well Insert and Moly Shield
- Software controlled, automatic background correction, display zeroing and range selection
- Optional computer interface: RS232 bi-directional serial communications port
- Coded error messages: almost instant display, update, memory protection
- All functions performed under push button control
- Industry exclusive 2-year warranty
- Lineator option available

Surveyor 2000™ Portable Survey Meter

Model 3SWGM

- Rugged Housing
- Sliding Beta Shield
- Solid Internal Connectors
- Energy Compensated
- Beta and Gamma Sensitivity

RADIATION DETECTED: Alpha, beta, gamma with external probe, gamma and x-ray with internal detector.
DETECTOR: GM tube, internal. Choice of GM probes, external.
RANGE: 0-2000 mR/h in 5 linear ranges. 0-240,000 cpm.
HIGH VOLTAGE: Electronically stabilized, factory set at 900 V.
HV TEST: Exclusive self test to verify detector HV power supply.
CONNECTOR: MHV
ACCURACY: Within 10% of reading for ^{137}Cs when calibrated according to NRC Reg. Guide 10.8.
ENERGY RESPONSE: ± 20% from 40 keV to 1.2 MeV (internal detector).
WARM-UP TIME: None.
SATURATION: Typically > 1000 R / hr for most GM probes (provided by exclusive anti-saturation circuit). More than 5R / h for pancake GM probes.
RESPONSE TIME: Switch-selectable optimized for each range. 0-90% of final reading as follows:

	Time	
Range	Fast	Slow
X0.1	6 sec	25 sec
X1	2 sec	6 sec
X10	1 sec	3 sec
X100	<1 sec	1 sec
X1000	<1 sec	1 sec

DEAD TIME COMPENSATION: Exclusive circuitry provides near linear response.
BATTERY COMPLEMENT: Single 9-volt (MN 1604 or equal). The additional battery holder may be used as storage of spare or parallel-wired.
BATTERY LIFE: More than 100 hours, or over 200 hours with parallel option.
TEMPERATURE: Operational from -40° to +60°C.
HUMIDITY: Less than 5% change in reading from 10-95% RH.
CONTROL: Eight-position rotary switch as indicated.
DISPLAY: Ruggedized, recessed, high-torque 1mA meter with 3.35" (8.51 cm) scale marked 0-2 mR/h, 0-2400 cpm, 'Bat. ok,' 'HV ok.' Meter protected by impact-resistant Lexan© polycarbonate window.
GEOTROPISM: Within ± 2% of full scale.
SHOCK: 100g per lightweight machine of MIL-STD 202C, method 202B.
VIBRATION: 5g in each of three mutually orthogonal axes at one or more frequencies, from 10-33Hz.
AUDIO: A built-in speaker, with panel mounted on/off switch, provides audible "click" for each detector pulse. With the speaker off, an audible alarm sounds (if desired) when meter is over full scale on any range.
CONSTRUCTION: Splash-proof, shock proof, two-piece all metal case. Scratch-resistant laminated control panel and Bicron Kleen-Krome© trim on case top, and durable black polyurethane paint on handle and case bottom.
SIZE: 4.25 x 8 x 6.8" including handle and probe clip (10.8 x 20.3 x 17.3 cm)
WEIGHT: 2.2 lbs (1 kg), excluding probe.

CARDIO-WIPE II

A scaler/timer system interfaced to a NaI crystal detector. The scaler/timer features a built-in power supply with full-range control from zero to 2000 volts. Separate light switches are provided for on-off, line frequency test, count, stop, and reset functions. A single MHV connector is provided on the back panel, along with a line fuse holder. The NaI (Tl) well scintillation probe is mounted in a base which provides 1.9 cm of virgin lead shielding to all externally exposed surfaces. The 4.5 x 5.1 cm crystal contains a well 3.8 cm deep and 1.7 cm in diameter. The well is lined with .25 mm aluminum. A single MHV cable connector is provided for interface.*

MODEL WP-2000 WELL SCINTILLATION PROBE (FOR TEST TUBE SAMPLES)

Scintillator:	1.75" (4.5 cm) x 2" (5.1 cm) NaI (Tl) well crystal; well: .7" (17 mm) diameter x 1.5" (3.8 cm) deep; well entrance window: 0.1 inch aluminum (.25 mm)
PM Tube:	2" (5.1 cm) diameter
Resolution:	9% or better full-width-half-maximum for ^{137}Cs (0.662 Mev)
Shielding:	.75" (1.9 cm) virgin lead surrounds crystal
Dimensions:	Height: 10.75" (27.3 cm) Base diameter: 6" (15.2 cm) Lead height: 5" (12.7 cm) Lead diameter: 4" (10.2 cm)
Connectors:	High voltage cable: MHV Signal cable: BNC

Note: with AA-2010 System, only one cable is required for both high voltage and signal; single MHV

TECHNICAL DATA MODEL 500 SCALER/TIMER

Readout:	999,999 counts, all electronic, no mechanical register
Resolving Time:	Better than one microsecond
Input Sensitivity:	0.25 volt negative
Voltage:	0 to 2000 volts, continuously variable; zener regulated; coarse and fine controls
Preset Timing:	0.5, 1, 2, 5, 10 minutes and manual; derived from power line frequency; accuracy to 0.03%
Power Requirement:	105-125 volts, 60 Hz (230 volts, 50 Hz optional)
Detector Input:	MHV connector
Shipping Weight:	14 pounds (6.4 kg)
Dimension:	4.5" (11.4 cm) high x 11" (27.9 cm) wide x 10.5" (26.7 cm) deep
In Line Fuse:	1 amp

*Manufacturer of origin is *The Nucleus*, 761 Emory Valley Road, Oak Ridge, TN 37830-2561.

CARDIO-WIPE II—Technical Specifications

The following empirical data was obtained in a controlled bench-top environment to determine the Minimum Detectable Acitivity (MDA) and Lower Limit of Detection (LLD) of the system, as required by 10 CFR 35.70. The instrument was operated without pulse height analysis. An NIST traceable ^{57}Co source was used to approximate the response of the system to ^{99m}Tc. Calculations were performed using the method described in the Appendix to Regulatory Guide 4.14 Revision 1, of the Nuclear Regulatory Commission. Because the system will be used to perform analysis of wipe and swipe samples, no correction factors were used for variations in sample volume or fractional radiochemical yield.

RAW DATA:

Average Background: 390 cpm, 6.5 cps
Standard Deviation of Background: 20 cpm, 2.5 cps

^{57}Co NIST Standard Source: Serial Number C-113-3
.69 uCi (1,528,572 dpm) on Date of Testing
Net Yield in Well: 1,050,610 cpm

CALCULATIONS:

System efficiency:

1050610 cpm/1528572 dpm = .68 cpm/dpm = 68% efficient

Lower Limit of Detection for ^{99m}Tc:

$$\frac{4.66 \times 2.5}{3.7 \times 10^4 \times .68 \times e^{-(.693/6h) \times 1h}} = .0005uCi\ (1144\ dpm)$$

This instrument meets the requirements of 10 CFR 35 to detect 2000 disintigrations per minute.

Procedure for Calibrating the Survey Instrument

The applicant will not calibrate the survey instrument, but will have a qualified contractor perform the calibration on an annual basis, or after any repair other than the replacement of batteries. The procedure for obtaining this calibration is outlined below:

1) The selected contractor will have an NRC or Agreement State license to perform calibrations, and the applicant will document this license before contracting the calibration. It is anticipated that the calibration will be performed either by the manufacturer of the instrument, or by *Romaes Laboratory/N C Systems, Inc.* (5171 Eldorado Springs Drive, Boulder, CO, 80303, 303-499-7730, License # COLO 715-01), by *Eberline Instrument Corporation* (312 Miami Street, West Columbia, SC, 1-800-234-4212 or 504 Airport Road, Santa Fe, NM, 87501, 1- 800-274-4212), or by *KNS Associates, Inc.* (1926 Elm Tree Drive, Nashville, TN, 37210, 615-883-9760, License # R-1975-C1).

2) If a contractor remote from the location of the facility is used, either a replacement survey meter will be obtained during the calibration, or the facility will not operate during the time the system is not present.

3) The Check Source will be read and documented at the time of calibration.

4) Upon receipt of the instrument from calibration, the applicant will check its apparent rate of exposure with a built-in or independent check source (license exempt), and note the level of exposure on the survey meter. Prior to each operation, the instrument will be checked to determine that the reading is still the same, indicating the instrument is still calibrated.

5) The report of survey meter calibration, obtained from the contractor after calibration, will include (but not be limited to) the following information:

- Identification of the contracted calibrator
- The calibrator's license number
- Identification of the instrument's owner
- Description of instrument, including:
  - Manufacturer
  - Model number
  - Serial number
  - Type of detector
- A description of the calibration source and its exposure rate on a specific date
- The calibration procedure
- For each calibration, note:
  - Calculated exposure rate
  - Indicated exposure rate
  - Deduced correction factor
  - Scale selected
- Reading indicated by the battery-check
- Angle between the flux field and detector
- Position of the detector and its shield
- Apparent exposure rate from the check source

6) The following information will be attached to the instrument on a calibration sticker or tag:
   a) The source used
   b) Proper deflection in the battery-check mode
   c) One of the following for each scale or decade:
      • Average correction factor
      • Graph(s) from which the calibration factor for each scale or decade may be deduced
      • Indication that the scale was checked for function, but not calibrated
      • Indication that the scale was inoperative
   d) Angle between the radiation flux and detector
   e) Apparent exposure rate from the check source

7) The form below will be used to document the calibration and service.

SURVEY INSTRUMENT CALIBRATION AND SERVICE RECORD

Survey Instrument Type:_____ Mfr: _____ Model:_____ Probe:_____ mg/cm² _____ Sr. Number:_____

Check Source Isotope: _____ Calibration:_____ Activity: _____ Exposure Rate: _____ mR/hr

Instrument Calibration* Date:_____ By: _____

Action		Check Source, mR/hr	Battery Check	Background mR/hr	Action Taken	By
Date	Time					

*Calibration must be performed at least annually, and after each servicing that involves more than replacing the batteries.

Calibration and Quality Control of the Dose Calibrator

The following procedures will be followed in performing calibration and quality control procedures on the dose calibrator. They may be performed more frequently at intervals determined by the RSO.

Geometry Dependence

Frequency: At time of installation and following repair or replacement of the chamber, or relocation of the device.
Acceptable Range: ± 5% with the types of containers used by the applicant.

a) Fill a syringe for routine procedures with 0.5 cc of ^{99m}Tc containing 1-10 mCi of ^{99m}Tc.
b) "Count" the syringe in the dose calibrator in the same way that patient doses are measured.
c) Draw an additional 0.5 cc of water into the syringe and count again as above.
d) Repeat the procedure until there is no less than 2.0 cc in the syringe.
e) Select the volume closest to that normally used for patients as the "standard," and divide the millicuries indicated by each of the other volumes into the standard to determine the volume correction factors.
f) If any of the correction factors are greater than 1.05 or less than 0.95, make a correction table for the calibrator, showing indicated activity at that volume vs. true activity at that volume.

Accuracy

Frequency: At time of installation, and not less than annually thereafter, as well as after repair, adjustment or relocation.

Acceptable Range: ± 5% of the expected activity.

a) Use the calibrated reference sources of ^{57}Co, ^{133}Ba, and ^{137}Cs as authorized under this license for this procedure (see "sealed sources").
b) "Count" each source at its correct setting on the calibrator, subtract the measure of background on that setting, and record the activity. Repeat this procedure three times for each of the sources.
c) Average the three readings of each source, and divide into certified activity of the source, after correcting for decay.
d) The results of the calculations (section c) must fall within the range of 1.05 and 0.95 (to fit within ± 5%). If calculations do not fall within this range, consider repair or recalibration. However, if they exceed 1.10 and .90 (±10% range), then repair, recalibration or replacement must be made.

Calibration and Quality Control of the Dose Calibrator
Geometry Dependence—Vials

To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the ^{99m}Tc solution into a syringe and inject it into the vial. Assay the vial, and record the volume and millicuries indicated.

Remove the vial from the calibrator, and using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water. Assay again, and record the volume and millicuries indicated.

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

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

If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% 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 and serial number of the calibrator. The Radiation Safety Officer (RSO) will sign this form (see attachment H5).

Linearity

Frequency: At time of installation, at least quarterly thereafter, and always after repair, adjustment, or relocation.

Acceptable Range: ±5% of the expected activity

a) Obtain a syringe of ^{99m}Tc from the pharmacy that contains no less than the highest dose ever administered to a patient .

b) "Count" the syringe in the dose calibrator in the early morning and record the indicated mCi, minus the background.

c) "Count" the syringe again at least six times during a 78 hour period of time (3.25 days). Record the readings, minus the background. Readings will be assayed over the range from the highest dose ever administered down to 10 microcuries.

d) Plot the obtained values on semi-log graph paper and draw the best-fit line through the values. Circle the point of greatest deviation from its value on the line (See attachment H4).

e) Calculate the maximum deviation of the circled point from its value on the line. If the deviation is more than ± 5%, the instrument must be adjusted or repaired. If it cannot be adjusted or repaired, a correction table or graph that will allow conversion from activity indicated to true activity will be made and placed on the calibrator.

On a quarterly basis, the applicant will determine that the measurement chamber is in place and that the instrument is zeroed according to the manufacturer's instructions.

Constancy

Frequency: Once prior to use on each day of operation, as well as after repair, adjustment or relocation.

Acceptable Range: ± 5% of the anticipated value.

If no radioisotopes are received or used during the day and no operations take place, then it is not necessary to check constancy on that day.

a) Measure the ^{57}Co sealed dose calibrator source on the ^{201}Tl, ^{57}Co, and ^{99m}Tc settings. Similarly measure the ^{137}Cs source, if deemed necessary by the RSO.
b) Record the background at the same settings.
c) Determine the activity indicated at the settings by subtracting the background of (b) from the readings of (a), and record this value.
d) Compare the measured ^{57}Co activity to the activity from a ^{57}Co decay table or graph.
e) Find reading action levels at each setting within ± 5% the anticipated readings. If the value is greater than ±5%, notify the RSO. If action levels are 10% or greater than the expected value, the instrument must be repaired or replaced.
f) Record the above constancy measurement.

Constancy Check with ^{57}Co NBS Source

This Decay Table can be used to correct the decay of the ^{57}Co source for the correction of the activity for Q.C. on the Dose Calibrator:

^{57} Cobalt Decay Table

Time (t), days	$e^{-0.693/T1/2\,t}$
1.0	0.9975
2.0	0.9949
3.0	0.9924
4.0	0.9898
5.0	0.9873
6.0	0.9848
7.0	0.9823
8.0	0.9798
9.0	0.9772
10.0	0.9748
11.0	0.9723
12.0	0.9698
13.0	0.9674
14.0	0.9649
28.0	0.9311
29.0	0.9287
30.0	0.9263
31.0	0.9240
365.0	0.3932
730.0	0.1546
1095.0	0.0608
1460.0	0.0241

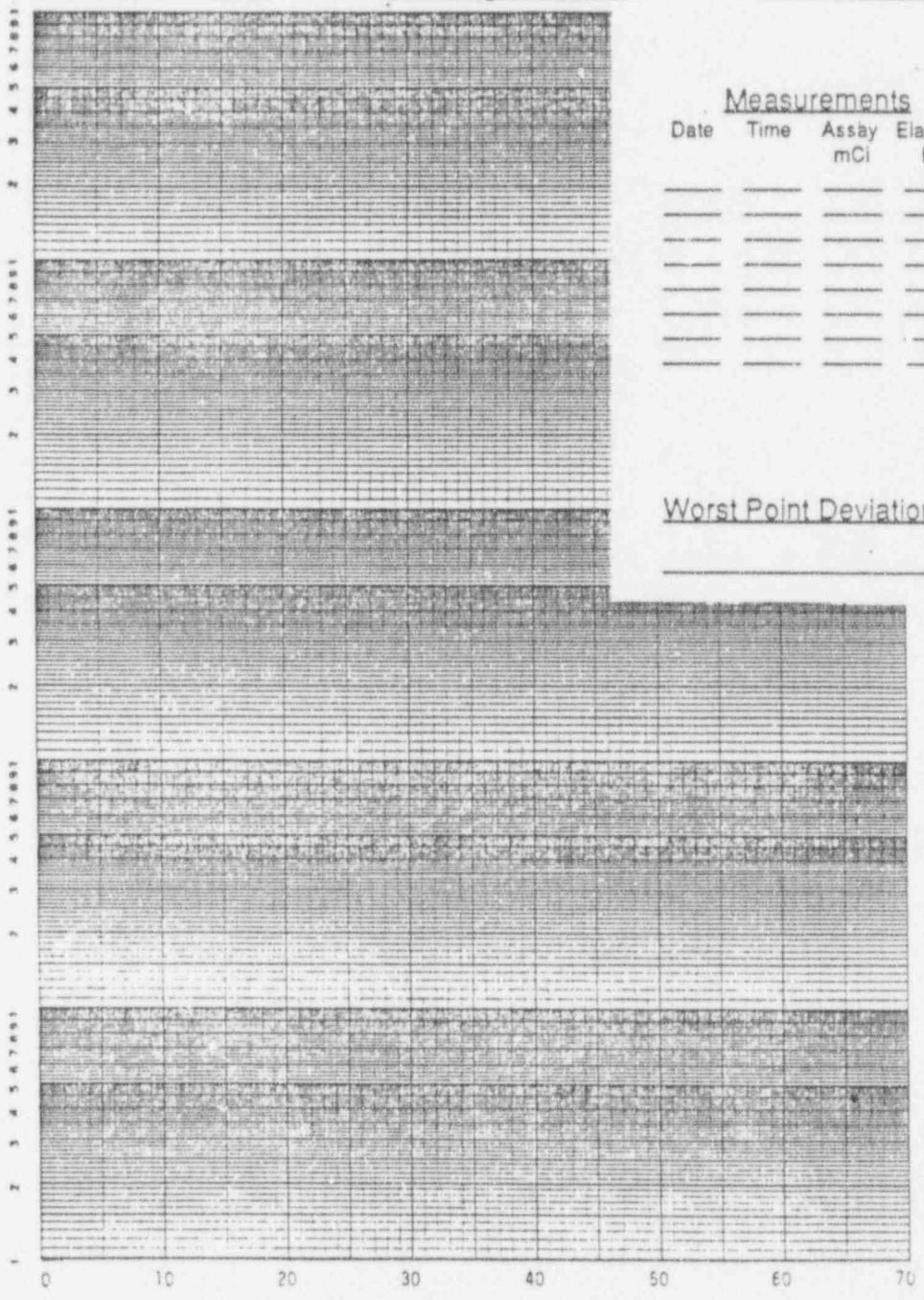
Dose Calibrator Linearity Test

Licensee: _____

License #: _____ Amendment: _____

Date: _____ Dose Calibrator Mfr: _____ Model: _____ Sr. #: _____

Radioisotope: _____ Activity: _____ Volume: _____



Measurements

Date	Time	Assay mCi	Elapsed hrs.

Worst Point Deviation

_____

Evaluation: Worst point deviation analysis / Point Indicated by: _____

_____

_____

Signed: _____ Date: _____

Radiation Safety Officer

Dose Calibrator Geometry Test

Licensee: _____

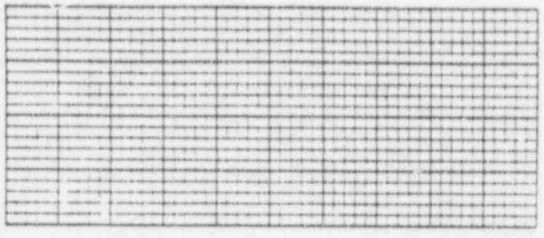
License Number: _____ Amendment: _____

Date: _____ Dose Calibrator Model: _____ Sr.#: _____

Radioisotope: _____ Form: _____

Syringe Geometry Dependence

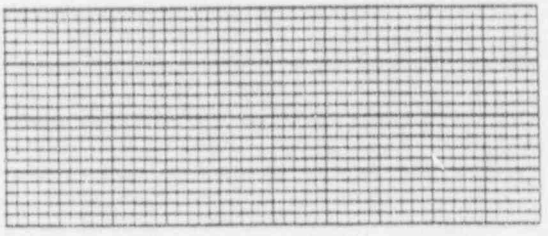
Syringe Geometry Dependence



0 0.5 1.0 1.5 2.0

CF ____ ____ ____ ____

Syringe Geometry Dependence

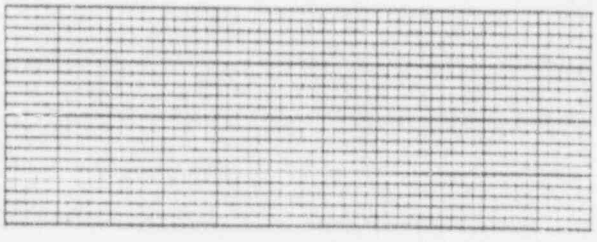


0 0.5 1.0 1.5 2.0

CF ____ ____ ____ ____

Syringe Geometry Dependence

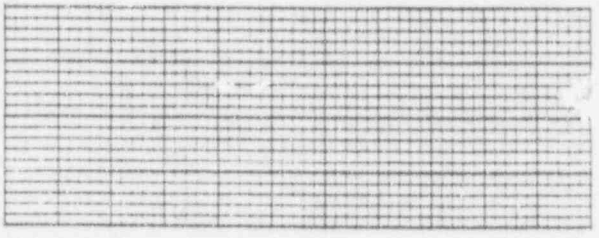
Vial Geometry Dependence



0 5 10 15 20 25

CF ____ ____ ____ ____ ____

Vial Geometry Dependence



0 5 10 15 20 25

CF ____ ____ ____ ____ ____

Analysis of Geometry Dependence Data From Above: _____

_____

Signed: _____ Date: _____

Radiation Safety Officer

Dose Calibrator Accuracy Test

Licensee: ______________________________

License Number: ______________ Amendment: ______________

Date: ______________ Dose Calibrator Model: ______________ Sr.#: ______________

____

<u>Source</u> Radioisotope: ______________ Activity: ______________ Model: ______________

Assay

A. ______________ Calibration Date: ______________

B. ______________ Decay Factor: ______________

C. ______________ Decay Corrected: ______________ Activity: ______________

Avg. ______________ Serial #: ______________

Calculated Deviation: ______________________________

<u>Source</u> Radioisotope: ______________ Activity: ______________ Model: ______________

Assay

A. ______________ Calibration Date: ______________

B. ______________ Decay Factor: ______________

C. ______________ Decay Corrected: ______________ Activity: ______________

Avg. ______________ Serial #: ______________

Calculated Deviation: ______________________________

<u>Source</u> Radioisotope: ______________ Activity: ______________ Model: ______________

Assay

A. ______________ Calibration Date: ______________

B. ______________ Decay Factor: ______________

C. ______________ Decay Corrected: ______________ Activity: ______________

Avg. ______________ Serial #: ______________

Calculated Deviation: ______________________________

Evaluation

____

____

Signed: ______________________________ Date: ______________

Radiation Safety Officer

Dose Calibrator Quality Control and Constancy Check

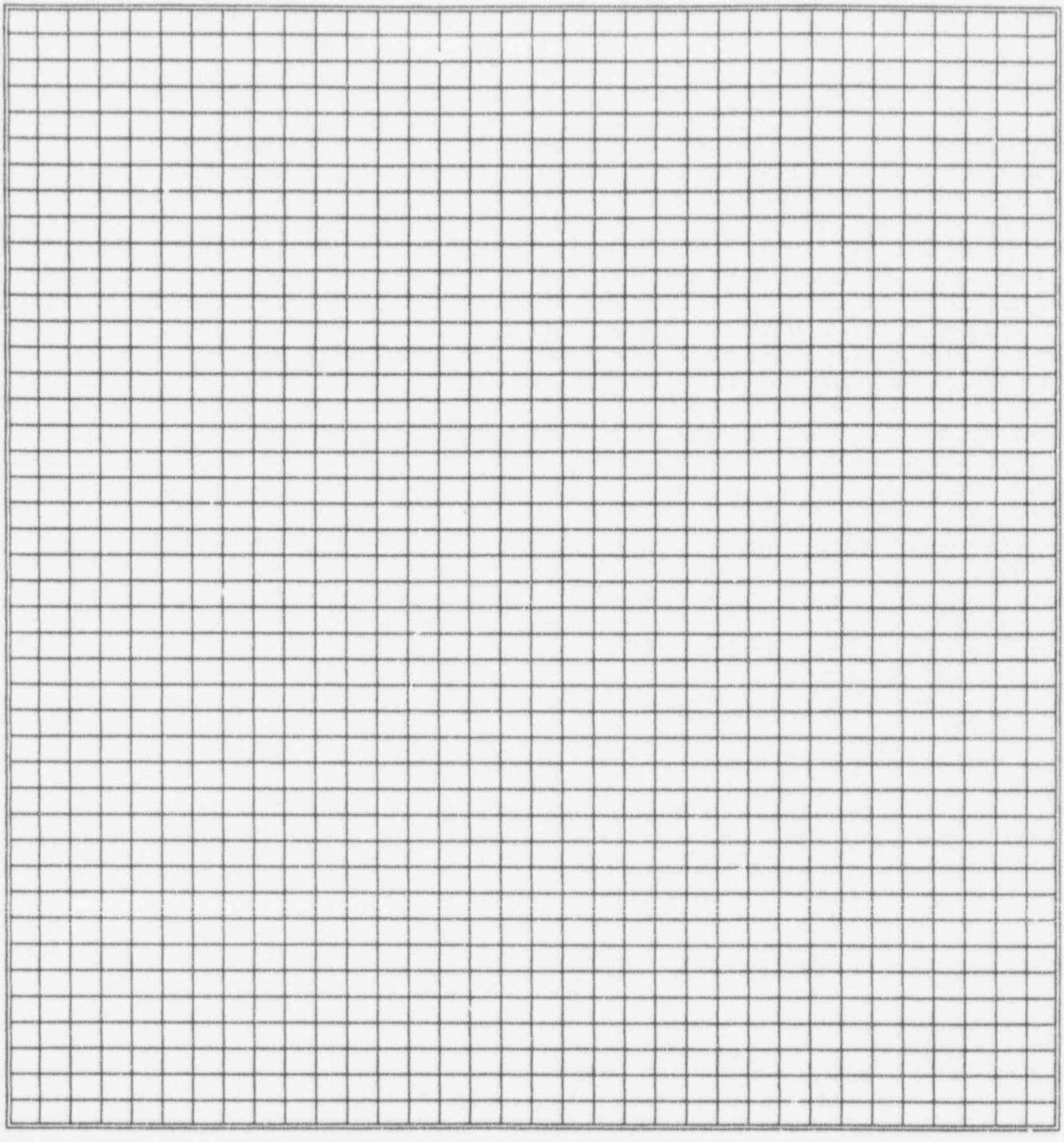
Dose Calibrator Identification: ______________________ Sealed Q.C. Sources Isotope Calculated Activity
Check Source Nuclide: __________ DC Model #: __________ DC Serial #: ______________

Action Level													
Date	Time											Notes	Init.
		Calc. Act.		bkg.	^{201}Tl	bkg.	^{99m}Tc	bkg.	Calc. Act.		bkg.		

GAMMA CAMERA LINEARITY QC TEST

Date:_____

Camera:_____



FACILITY NAME:_____CONTACT:_____

FACILITY ADDRESS:_____

Maximum Count Rate:_____ 20% Count Rate Loss:_____

System Efficiency: _____ Reference Source: _____ Activity:_____

Test Performed By: _____ Test Date: _____

-< * >-

Nuclear Cardiology Systems, Inc.
5171 Eldorado Springs Drive
Boulder, Colorado 80303

Quality Control Procedures for Gamma Cameras

I. It is crucial to practice routine quality control for the gamma camera. Your quality control program may vary from the one below due to individual equipment problems, but a basic routine program should include the following daily quality control activities. All records of your program must be retained for two years.

1. **Collimator:** The camera should be evaluated extrinsically with the collimator on the detector. The same collimator should always be used for proper reproducibility.

2. **Pulse Height Analyzer:** The Pulse Height Analyzer (PHA) should be adjusted according to the manufacturer's instructions. The PHA must be rechecked with the actual gamma spectrum emitted from the patient before you perform procedures. Any change in line voltage, ambient room temperature, or camera high voltage will change the PHA adjustment, so the PHA should be checked under these conditions.

3. **Resolution-Distortion:** A four-quadrant resolution bar phantom should be placed diagonally to the x- and y-axis directly on the collimator, and the flood field phantom (or flood field source) placed on the bar phantom. Obtain an image with a clinical PHA window of 20-30% and a total of 0.5 million-1 million counts (the acquisition should be for pre-set counts. Record the total number of counts and the acquisition time.)

Note: The resolution-distortion image will reveal changes in resolution-distortion or significant uniformity changes. This procedure is clinically important, because these factors will affect your study analysis. The uniformity flood image will only provide information on uniformity. Resolution imaging must be performed weekly, because uniformity will appear satisfactory in the presence of deteriorating resolution.

II. The following additional quality control activity should be performed at least once a week. Quality control records must be retained for two (2) years.

1. **Flood Field Uniformity:** Obtain a flood field uniformity image with the standard collimator on the detector. The flood field phantom or source should be placed on the collimator before obtaining an image (The acquisition should be for pre-set counts. Record the total number of counts and the acquisition time). Flood field uniformity should be performed daily.

Note: Evaluate the image for uniformity errors, and determine specific uniformity performance, if you note uniformity problems.

III. Other quality control procedures may be performed at monthly or quarterly intervals. These procedures include, but are not limited to:

1. **Background Flood:** a flood field done without a flood source, to determine noise, background electronic noise, and other factors affecting image quality. Obtain an image with the collimator on the detector for a preset time of at least 20 minutes. The PHA setting should be 30%. *Do not* increase the image intensity. Record the time, counts, and image evaluation.

2. **Check of Maximum Count Rate Capacity:** With the detector directed horizontally into the room and the collimator removed, set a 20-30% clinical window. Turn on the machine to display the received count rate. Place a syringe, containing a patient dose of 5-20 mCi of ^{99m}Tc, in a syringe shield. Bring the syringe shield toward the detector with the long axis of the shield directed at the detector. The count rate will increase to the maximum count rate, and then maintain ("saturate") or decrease ("paralyze").

IV. The following quality control procedures must be performed at least annually. You may need to perform some of them more frequently, as your results indicate.

1. **Crystal, Detector, Resolution:** Determine the detector resolution using a small point dry source of ^{99m}Tc or ^{57}Co. The activity should not exceed 50μCi. The procedure should be performed intrinsically with the collimator off the detector (intrinsic). The actual procedure will depend on the electronics available and the operator's techniques.

If the resolution (expressed in % full width half max) has changed by 50—80% from the anticipated value, you may need to examine the detector quality, PHA calibration, or measurement technique.

2. **Count Rate Linearity and 20% Count Rate Loss Determination:** This should be performed if changes appear in the detector efficiency, shifts in the detector resolution, changes in dynamic procedure accuracy, or increased count rates in clinical studies caused by changes in techniques or radiopharmaceutical agents. Follow each procedure's protocol to make these determinations.

V. From time to time, the system's operating conditions may warrant additional system performance studies. Studies may include point sensitivity, linearity, and an entire imaging chain analysis, including the computer, ECG gate, and other accessories.

VI. **Safety Checks:** All "safety checks" must be performed at least quarterly. They may be performed more often as indicated by manufacturer alerts.

Attachment I

APPLICATION FOR MATERIAL LICENSE

Gamma Camera Quality Control and Performance Record

Gamma Camera Identification: _____ Computer: _____

Quality Control		Source		PHA	Uniformity		Resolution		Background			
Date	Time	Isotope	Activity	ΔE	Cts.	Time	Cts.	Time	Cts./Minute	Other	Analysis	By

Note: Routine QC should include the following minimum procedures:

Daily: a) PHA adjustment, b) resolution

Weekly: a) uniformity, b) max CR capacity

Quarterly: a) background flood, b) CR at 20% loss, c) interlocks & switches

Service Repairs: a) review all weekly and quarterly routines, as necessary

Personnel External Exposure Monitoring Program

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

Our Personnel Exposure Monitoring Program will include, but not be limited to, the following activities:

1) The RSO will promptly review all exposure reports and look for workers whose exposure is unexpectedly high or low.
2) All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body film badge. A contract service will process these badges monthly.
3) All individuals who handle radioactive material that emits ionizing photons on a regular basis will be issued a TLD finger monitor. A contract service will process these badges monthly.
4) Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, secretarial staff, and nurses who care for patients containing diagnostic quantities of radiopharmaceuticals, will not normally be issued dosimeters. If the RSO deems that such personnel must be measured for exposure, a whole body dosimeter will be issued for three months.
5) All monthly personnel dosimeter reports will be posted for workers to read. Workers should sign the report when they have read it.

RADIATION SAFETY COMMITTEE

The applicant will not establish a Radiation Safety Committee, because no such committee is possible in a private office. The RSO will, however, carry out the activities as established in 35.21, 35.22, and 35.23 of the CFR, the Model Radiation Safety Committee Charter, and Radiation Safety Officer Delegation of Authority under the Appendix F of the Regulatory Guide 10.8, Rev. 2, NRC, or an equivalent Agreement State regulation.

ALARA PROGRAM

The applicant will establish an ALARA program as outlined in Appendix G to the Regulatory Guide 10.8, Rev. 2, NRC, or an equivalent Agreement State Regulation, excepting the formation of a Radiation Safety Committee. The ALARA concept will be applied on an informal basis by the RSO. The key elements of this program will be:

1) Commitment to keeping individual and collective doses as low as is reasonably achievable.
2) A ongoing review of the radiation safety program, with a more formal review performed at least annually.
3) Modifications of the radiation safety program, equipment and/or procedures, if such changes will reduce personnel exposure.
4) Establishment of "Investigational Levels" below the applicable limit, as stated in page two of this section.
5) Routine reviews by the RSO of the safety program (annually), occupational exposures (quarterly and monthly), and radiation surveys (monthly).
6) Cooperation with workers to reduce exposures.
7) An educational program for all workers on radiation safety (see the "Training Program").

Radiation Safety and Quality Control Schedule Table

Radiation Safety Officer and Nuclear Personnel Guide to Activities required of the Nuclear Medical Facility

	Daily	Weekly	Monthly	Quarterly	6 months	Annually	Other Frequencies
Survey Instruments							
Battery Check	x						
Reference Check	x						
Calibration						x	after service
Dose Calibrator							
Geometry							installation/service
Constancy	x						after service
Linearity				x			after service
Accuracy						x	installation/service
Gamma Camera							
PHA	x						after service
Resolution		x					after service
Uniformity	x						after service
Max CR				x			after service
Background Flood				x			after service
CR @ 20% loss				x			after service
Interlocks & Switches				x			after service
Area Surveys (Contamination)							
Exposure Survey							upon any incident
daily use areas	x						
storage		x					
Wipe Survey		x					upon any incident
Sealed Source Leak Testing							
Leak Test					x		upon damage
Worker Instruction							
Initial Instruction						x	prior to first entry
Training						x	prior to first entry
Personnel Monitoring							
Prior Dose							prior to first entry
Prenatal Exposure							prior to first entry
Exposure Reports			x				
Annual Exposure						x	
Accumulated Exposure							upon termination
ALARA			x	x			upon work changes

Note: this is a guide; check your license for specific requirements.
References: title 10, Parts 19,20 and 35 of the Federal Code of Regulations and State Requirements.

ALARA Program—Posting of Notices/Evaluation of Dosimeters

The following notices will be posted at the same location as the film badge (whole body) reports. The signs are shown smaller than actual size.

ALARA

(As Low As Reasonably Achievable)

Can you lower your exposure?

This facility is dedicated to maintaining all occupational exposures at the lowest possible level. Please tell the Radiation Safety Officer (RSO) your ideas for lowering exposures. Be aware of work activities that can reduce your exposure. Let's get everyone into Level I.

NOTICE TO ALL RADIATION WORKERS

This notice should be posted with the personnel dosimetry reports.

Please review the personnel dosimetry information on the dosimeter report. Note any exposure levels that are lower or higher than expected. As a facility committed to maintaining occupational radiation exposure as low as reasonably achievable (ALARA), we have established levels of exposure lower than those mandated by current regulations. Please compare your current levels to those given in the following table.

Acceptable levels of Radiation Exposure (mRems)

	Level I		Level II		Level III	
	month	13 weeks	month	13 weeks	month	13 weeks
Whole body, head and trunk, blood forming organs, lens of eyes or gonads	42	125	125	375	417	1,250
Hands and forearms, feet and ankles	625	1,875	1,875	5,625	6,250	18,750
Skin of whole body from beta exposure	250	750	750	2,250	2,500	7,750

*From Title 10, Part 20.101(c)

After reviewing the current report, please contact the Radiation Safety Officer (RSO) if you have any suggestions to reduce your exposure. Also contact the RSO if your exposure status has changed or may change. This includes changes in your activities, types of procedures or techniques. Please immediately contact the RSO if you are pregnant.

After reviewing the report, please initial the report next to your name to indicate your review.

NOTE: This report has been reviewed by the Radiation Safety Officer. If areas of concern have been noted, you will be contacted for a safety review.

See the next page for other notices related to ALARA and facility Radiation Safety.

ALARA Program—Emergency Notification/Posting of Notices

The following notices will be posted with complete information. The information required on these notices cannot be obtained until a license is issued and the facility is implemented. The notices should be posted 1) at room entrances where radioactive materials are used and 2) in the room's radioisotope storage and manipulation area. The "Notice to Workers" sign will be also posted on the employee notice board for employee viewing. The signs are shown smaller than actual size.

NOTICE TO WORKERS

This facility operates under a medical radioactive materials license. The license, its application, documents incorporated into the license by reference, license conditions, amendments, operational procedures, and all related materials and communication can be examined by contacting the individual listed below.

License Number: _____ **Issued:** _____
Contact: _____ **Telephone:** _____

Complete all information on this notice before posting.

NOTICE

Radioactive materials may be located within this room. If present, the location of radioactive materials is clearly identified by the radiation symbol and the words, "Caution: Radioactive Materials." In case of an emergency involving this room or the materials within the room, contact the Radiation Safety Officer (RSO) listed below.

Contact: _____ **Telephone:** _____

Complete all information on this notice before posting.

Specific Elements of the ALARA Program Management

We follow these procedures in addition to standard procedures for receiving, using, and disposing of radionuclides, for routine equipment surveys and procedures, and for radionuclide and incident handling.

1. We document all radiation workers' prior exposure history before issuing them dosimeters.

2. We issue a body dosimeter, or film badge, to all radiation workers. In addition, we issue a finger TLD dosimeter to workers who use radionuclides (receipt, administration, etc.), and change the dosimeters at monthly intervals.

3. Before use of radionuclides, we instruct each employee in the following areas:
   a. fundamental radiation effects and levels of exposure
   b. investigational levels established in the facility for ALARA management
   c. standard ALARA procedures
   d. prenatal exposure policy
   e. license authorization and conditions
   f. standard operational procedures
   g. location and control of all hazards in the facility

4. The authorized user/RSO or another experienced worker closely observes all new employees in person for the first few days of operation, to confirm proper techniques and answer any questions.

5. We evaluate personnel exposure on a monthly basis. All exposures should be at or below Level 1 (40 mrem for whole body or 625 mrem for the hands). We closely review any exposure above this level to decide whether the work activity justifies the higher exposure. If a worker receives more than Level II exposure (i.e., 125 mrem to the whole body, or 1,875 for the hands), our facility will open an immediate investigation. We explore the exposure's cause and possible techniques for exposure reduction with the affected individual. We implement all reasonable methods for exposure reduction. If exposure exceeds Level III (i.e., 417 mrem whole body, or 6,250 mrems to the hands), we will formally investigate and record the exposure to determine the cause. We may modify operational procedures to prevent further exposures at these levels. Additional dosimeters, measurements, etc., may be considered at this time.

Routine Responsibilities of the Radiation Safety Officer

The licensee has appointed a Radiation Safety Officer (RSO) to implement the radiation safety program. Through the RSO, the licensee will ensure that radiation safety activities are being performed according to ALARA and other approved procedures, conditions, and regulatory requirements. The RSO's activities include, but are not limited to, the following:

1. Investigating all incidents, including unexpected exposures, accidents, spills, losses, and theft; unauthorized receipts, uses, transfers, and disposals; and misadministration, adverse reactions and other deviations, including biohazard incidents.

2. Holding all of the materials required for the radiation safety program in a single binder or file, including notices, regulations, and related documents and procedures for the following:

   a. Authorizing the purchase of radioactive material
   b. Receiving and opening packages of radioactive material
   c. Inventorying radioactive materials
   d. Storing and using radioactive material
   e. Taking emergency action if material is lost, stolen, spilled or subjected to other operational deviations
   f. Checking survey meters, safety, quality control, and performance
   g. Disposing of radioactive material
   h. Training personnel who frequent areas where radioactive material is received, used or stored
   i. Recordkeeping required by the regulatory agencies, including OSHA

3. Briefing management (the licensee) once each year on the radioactive material program.

4. Establishing personnel investigational levels, investigating the causes, and developing preventative actions when these levels are exceeded.

5. Approving or disapproving minor changes in the radiation safety procedures that do not interfere with safety, with the advice and consent of management (the licensee).

6. Removing the workers from an exposed area, documenting the investigation, retraining workers, and modifying procedures and/or the physical facility when reportable exposures occur (of more than 1,250 mrem per 13 weeks to the whole body or 18,750 mrem to the hands). If and when the RSO finds that it is reasonable to resume activities, the workers will be allowed to return to their duties.

7. Providing female radiation workers who are anticipating pregnancy with a second, abdominal film badge. The worker will be instructed to tell the RSO when pregnancy is confirmed. When pregnancy occurs, female workers will wear an abdominal film badge to monitor the potential prenatal exposure. The workers' abdominal exposure will be limited to 0.5 rem for the remainder of the gestation period.

8. Immediately investigating and documenting spills, contraindications, and other abnormal occurrences. Corrective actions will be guided by the individual event.

9. Bioassay will not be necessary, as no ^{131}I unsealed sources will be used. If the RSO suspects that radioactive material was absorbed or ingested, he/she will bioassay the worker's urine, saliva, and/or blood with the gamma camera. As with all other monitoring, the RSO will hold these records in the facility.

10. Establishing a "Quarterly ALARA Audit." This audit will review personnel exposure, surveys, incidents, biohazards, and all events related to the safety of personnel. This audit will be used by management to review the program, evaluate risks, and establish changes that may be required to keep all exposures ALARA.

11. Establishing an "Annual Facility Review," evaluating all incidents and the overall safety of personnel. The yearly review will be presented to management, all radiation personnel, and others involved in facility operation. This review will be included in an annual educational program for all radiation workers.

Notes on Absolute Counting for Contamination, Spills, and Sealed Sources

Reference Sources

The reference sources used for absolute counting analysis (to convert cpm to dpm or cpm to uCi) and to test detector sensitivity are license exempt. These sources, therefore, are not part of this application. These sources will consist of ^{133}Ba or ^{137}Cs and will be obtained from *NEN/DuPont* of North Billerica, MA, 01862. These sources are registered with the USNRC or BRH/FDA, according to NEN, and are NBS traceable with the error analysis calculated according to the recommended format of the International Commission on Radiation Units and Measurements, Report 12. Each source has a certificate of radioactivity calibration from NEN.

Each source will be 0.1 uCi, calibrated to ±3-5% accuracy. With the NaI (Tl) well/scaler, these sources can be expected to produce more than 2,220 cpm per 0.1 uCi, or 111 cpm/0.005 uCi, even if the efficiency of the system is only 1%. This efficiency would produce 0.01 dpm per cpm for counting contamination swipes from routine surveys and from radioactive spills.

Documentation of Wipe Testing

Each sealed source wipe tested will be identified with a label or tag indicating the following information:

Wipe Testing Completed

Date_____ Operator_____
This source was wipe tested on the above date. Analysis of the sample indicated _____uCi of removable contamination, which meets the requirements as established under this license.

If the sealed source does not meet the requirements as established under the license, because more than 0.005 uCi of activity can be removed, the source will be removed from service and labeled with the following information:

Leaking Source-Do Not Use

Date_____Operator_____
This source was wipe tested on the above date. Analysis of the sample indicated _____uCi of removable contamination, which does not meet the requirements as established under this license. This source MUST NOT BE USED UNDER ANY CONDITIONS UNTIL CERTIFIED AS REPAIRED OR RENDERED SAFE BY THE RADIATION SAFETY OFFICER. If you have questions, call:
_____

Note: The reference source will be of the same type or spectrum / energy-gamma flux as the sample to be assayed.

Leak Testing

Licensee: _____ License # _____
Address: _____
City: _____ State: _____ Zip: _____
LEAK TEST Date: _____ Time: _____ By: _____
ASSAY Date: _____ Time: _____ By: _____
INSTRUMENT _____ PHA E _____ Kev to _____ kev
STANDARD Radionuclide: _____ Assay Activity: _____ Date: _____
Source Serial #: _____ Model #: _____

I. LEAK TESTING

Swipe/Sample #	Isotope	Activity mCi	Serial #	Assay Date	Form	Use	Swipe/Sample Method

II. SAMPLE ANALYSIS

Swipe/Sample	Gross cpm	—	Bkg cpm	=	Net cpm	x	dpm* cpm	x	1 u Cl $22x10^5$dpm	=	uCi	Action Taken**

*from Line D
*See item IV, below

III. STANDARD ANALYSIS

A. Gross cpm_____ — Bkg cpm_____ = Net cpm
B. Assay uCi _____ x Decay Factor _____ = uCi
C. uCi _____ x 2.22 x 10^5 dpm/uCi = dpm _____
D. Calibration Factor C / A = dpm / Net cpm = _____ = dpm/cpm

IV. LEAK TEST ACTION LEVELS

If the above test reveals 0.005 uCi (1.11×10^4 dpm) of removable activity, the source must be removed for repair or replacement. Any required repair or disposal will be performed according to license conditions and current regulations. In addition, a contamination survey for removable contamination will be performed to ensure that no contamination exists in the facility, and the source will be labeled "Leaking Source—Do Not Use."

By: _____ Date: _____

Radiation Safety Officer (Required)

ALTERNATIVE LEAK TEST REPORT

Attachment K4

License #_____ Licensee_____

Date Samples Taken: _____ Date of sample Analysis _____ Date Next Test Due _____

Sample data:

Nuclide Source	Serial #	Source Use	Source Form	Swipe method	Sample cpm	Bkg cpm	Net cpm	Std dis t	1μCi/2.2 •E6 dpm	Sample μCi	Action *

* Action to be taken if sample analysis exceeds 0.005 μCi: Label the source "Leaking source-DO NOT USE". Remove the source from service and repair or replace. In addition, perform a contamination survey for removable contamination. (NOTE: •E6 dpm is equivalent to $x10^6$ dpm or $x10^6$ d min^{-1})

CALIBRATION INFORMATION:

Date of data analysis: _____

Detector NaI(Tl) 3" shielded
PHA 0-1000 keV (127 channels)

Sources:

Calibration:

	Ser. No.	Assay	Date
^{137}Cesium	_____	_____	_____
^{57}Cobalt	_____	_____	_____
^{133}Barium	_____	_____	_____

Activity on _____

^{137}Cs	____ μCi	(___ years decayed-D.F.=.___)
^{57}Co	____ Ci	(___ days decayed -D.F.=.___)
^{133}Ba	____ μCi	(___ years decayed-D.F.=.___)

Data:

Background	_____/_____/_____ =	_____ acpm/2	n/a
^{137}Cs	_____/_____/_____ =	_____ acpm/2	___ disintegrations ct^{-1}
^{57}Co	_____/_____/_____ =	_____ acpm/2	___ disintegrations ct^{-1}
^{133}Ba	_____/_____/_____ =	_____ acpm/2	___ disintegrations ct^{-1}

Efficiency:

By: _____ Date:_____

-- □ --

5171 Eldorado Springs Drive, Boulder, CO 80303 (303) 499-4099

Rules for the Safe Use of Radiopharmaceuticals

The "Notice" shown below outlines this facility's procedures for safe use of radiopharmaceuticals. This notice, shown in a reduced size below, will be posted at full size in any room where radiopharmaceuticals are used.

NOTICE
RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

1. Read and understand the material in the license, the license application, and all other documents related to the license and its conditions of operation.
2. Only authorized personnel may use radiopharmaceuticals. Radiopharmaceuticals may only be used in ways authorized by the license.
3. Personnel dosimeters (body film badges) must be worn in areas where radiopharmaceuticals are stored, prepared or used. Personnel dosimeters must be worn when radiation workers attend patients containing radiopharmaceuticals.
4. Finger dosimeters (TLDs) must be worn while preparing, assaying and administering radiopharmaceuticals. TLDs must also be worn while holding patients during nuclear procedures.
5. Laboratory coats or other protective clothing must be worn at all times in areas where radioactive materials are stored or used.
6. Disposable gloves must be worn while administering radioactive materials to patients. Wear gloves whenever you are handling radioactive materials.
7. Use shielded containers or tongs while handling sources. Never touch sources with your hands.
8. Never pipette any materials, radioactive or otherwise, by mouth.
9. Do not store food, drink, or personal effects in areas where radioactive materials are stored or used.
10. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
11. All radioactive materials must be kept in shielded containers, including sealed sources, syringes and active waste. All containers will be clearly labeled with the name of the radionuclide, its form, date and activity.
12. Use syringe shields for preparing and administering patient doses.
13. Assay each patient dosage in the dose calibrator before administering it, to ensure that it is within 10% of prescribed activity. If dosage is not within 10%, do not administer the radiopharmaceutical.
14. Place radioactive waste only in designated, labeled and properly shielded receptacles. Do not dispose of radioactive materials in any other manner.
15. Use a cart, wheelchair or tray to move all radioactive materials. Never leave radioactive materials unattended.
16. Before administering the patient's dosage, complete all radiopharmaceutical quality control procedures and records. Check the patient's name and identification, requested procedure and radiopharmaceutical. Check for any technical or medical contraconsiderations.
17. Use great care to avoid contamination during the preparation, administration or disposal of radioactive material. Avoid any contact with patient's blood or body fluids.
18. After each procedure, and before leaving the radioactive materials area, monitor your hands and clothing for contamination.
19. Monitor the preparation and administration areas for contamination at the end of each working day. Use the low range of the GM survey meter to monitor. If contamination is found, notify the Radiation Safety Officer and decontaminate or secure the area for decay.
20. Survey all radioactive material storage, preparation and administration areas for contamination at the end of each week in which radioactive materials were received, manipulated or used. Use wipe test (wipe, smear or swipe) to survey. If contamination is found, notify the Radiation Safety Officer and decontaminate or secure the area for decay.

Radiopharmaceutical Control Notices

The following notices will be used in the radiopharmaceutical control program.

RADIOPHARMACEUTICAL RECEIPT AREA

Place All Packages Here

Receipt of Packages

RADIOPHARMACEUTICALS TO BE RETURNED TO THE RADIOPHARMACY

Disposal by Transfer

DO NOT EMPTY

RADIOACTIVE WASTE MATERIALS

Disposal by Decay In Storage (DIS)

RESTRICTED RADIOSOTOPE STORAGE AREA

Admittance only by Authorized Personnel with Dosimeters and in Compliance with Operational Procedures.

Radioisotope Storage Area

Procedure for Spills

The following procedures for major* and minor* spills will be followed in our facility. These procedures will be posted, in larger form, and used in the employee training program, as indicated in that section.

NOTICE
SPILL PROCEDURE

MINOR SPILLS

1. Notify all persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill area with absorbent paper. Secure the area.
3. Survey all personnel in the area to ensure that they are not contaminated. If contamination is present, decontaminate.
4. With the RSO or another person (not involved in the spill), monitor with a GM survey meter. Determine the margins of the contaminated area.
5. Clean up the spill using disposable gloves, foot coverings if needed, and absorbent paper. Remove the paper covering the area, clean side out to avoid contamination, and place in a plastic bag for transfer to the radioactive waste container. Clean the area, decontaminate, and place all wipes, papers and gloves in the bag for transfer to the waste container.
6. After decontamination, survey the area with the GM survey meter. Include the area around the spill area in the survey. Check your hands, clothing and shoes for contamination.
7. Complete the "Radioactive Spill Report" and the "Radioactive Spill Contamination Survey."
8. With the RSO, evaluate measures to be taken to prevent such spills in the future.

MAJOR SPILLS

1. Clear the area by notifying all persons in the room that a spill has occurred. Use caution that no contaminated individuals leave the area.
2. Prevent the spread of contamination by covering the spill area with absorbent paper. Secure the area.
3. Confine potentially contaminated personnel to an area in the same room where they can be monitored and decontaminated. Take care that personnel do not spread the contamination. Survey personnel and have them leave the area if no contamination is found.
4. If practical (without spreading contamination), shield the spill. Don't allow contamination to spread or your exposure to increase.
5. Close the room and secure the area to prevent entry. Post a notice on the door to indicate that entry is prohibited.
6. Notify the Radiation Safety Officer (RSO).
7. Follow the direction of the RSO to decontaminate the area, complete required documentation, and evaluate the incident.

Personnel Decontamination Suggestions (First Steps):

a) Remove contaminated clothing and store for evaluation and decay.
b) Flush the skin with tepid water, wash with mild soap and dry with absorbent paper. Repeat this step as required as long as at least 15% of the counts are removed with each washing. Avoid contamination from the wash water. Use as little water as practical.
c) Radioactive material in the eyes should be flushed with water or eye wash and an eye cup.

*The applicant considers a "major" spill to be a release of more than 50 mCi of ^{99m}Tc, or more than 25 mCi of ^{201}Tl. A major spill may also be defined as one in which a potential exposure rate of more than 10 millirems per hour could occur. Sealed sources, being solid material, cannot spill. If sealed sources could spill, values for a spill considered "major" would be adjusted upward.

Radioactive Spill Documentation

The following document, "Radioactive Spill Report," will be completed for all radioactive spills, including major and minor spills. This report will be used as an operational document for each evaluation and documentation of spill incidents. In addition, each incident will also require a completed "Radioactive Spill Contamination Survey" report.

RADIOACTIVE SPILL REPORT
(Complete for all Radioactive Spills)

I. INCIDENTS

Spill: Date_____ Time_____ Location_____

Radionuclude: Isotope_____ Form_____ Est. Activity_____

Person controlling incident:_____

II. SPILL AREA (diagram)

Note: show the spill area and extent of spill on this drawing.

III. EVENT

A. Personnel Present* Personnel Contamination Results**

_____ _____

_____ _____

_____ _____

_____ _____

*Include patients and other "non-personnel"

**Use the back of this sheet to indicate decontamination, monitoring, bioassay or other actions.

B. Describe the incident _____

_____

_____

_____

C. Evaluate the magnitude of hazard associated with the incident _____

_____

_____

D. Describe all reporting and related actions taken _____

_____

_____

E. Describe follow-up actions taken to prevent recurrence _____

_____

_____

Report completed by _____ Date _____

Signature

Radioactive Spill Documentation—Continued

The following document, "Radioactive Spill Contamination Survey," will be used to determine the location, extent and decontamination of radioactive spills. The survey will be done with the GM survey detector system. This document will be used in addition to the "Radioactive Spill Report," printed on page M 2 of this application. Please also see Attachment K 2.

RADIOACTIVE SPILL CONTAMINATION SURVEY
(See "Radioactive Spill Report")

I. INCIDENTS

Spill: Date_____ Time_____ Location_____

Radionuclude: Isotope_____ Form_____ Est. Activity_____

Person controlling incident:_____

II. SPILL AREA (diagram)

Note: show the spill area and extent of spill on this drawing.

III. SURVEY

A. Exposure Instrument _____ Probe _____

B. Swipe Instrument _____ PHASE _____ Kev to _____Kev

Location #	Initial mR/hr	Decontamination mR/hr	dpm/100cm²	Comments

IV. ADDITIONAL CONTAMINATION NOTES
(Personnel, Clothes, Equipment, etc.)

Description	Contamination	Disposition

EMERGENCY MATERIALS

PERSONNEL DECONTAMINATION SYSTEM

Do Not Obstruct Access to these Materials

RADIOISOTOPE CONTAMINATION AREA

Do Not Enter this Area without Permission of the Radiation Safety Officer

Decontamination Procedures

I. General Rules

A. Contain the contamination—never allow uncontaminated areas to be contaminated in the clean-up process.

B. Avoid any activity release from the restricted area by immediately isolating the suspected area. It is acceptable to "overreact" to the spill by initially isolating an area significantly larger than the initial spill site.

C. Address personnel contamination before decontaminating the facility.

D. Obtain others' help to monitor and carry out decontamination procedures and other activities.

E. Always follow the license conditions and established protocols for spills, surveys, and documentation.

II. Personnel Decontamination

A. If physical injury requires medical attention, administer care immediately. Keep in mind that contamination may be present.

B. Decontaminate eyes by washing them with the eye wash solution from the "decontamination kit." Wash eyes over a sink, and allow the water to flush down the drain.

C. Remove all contaminated garments, i.e., laboratory coat, gloves, etc., and step onto an uncontaminated surface to monitor residual activity.

D. Use the following decontamination techniques for skin decontamination. Take great care not to spread the contamination to clean surfaces during these procedures. Decontaminate in a sink, and allow the water to flush down the drain.

1. Flush the surface with *tepid* water, and remonitor for removal/residual activity.
2. Wash with NUC-WASH A and rinse with tepid water. Remonitor for removal/residual activity.
3. Wash with NUC-WASH B, NUC-WASH C, and NUC-WASH D, if necessary. With each wash, and rinse with tepid water and remonitor for removal/residual activity.
4. If NUC-WASH D is used, and residual activity exists, use a soft brush on the skin. AVOID BREAKING OR IRRITATING THE SKIN.
5. If residual activity persists after all decontamination steps are completed, and if the RSO agrees that additional decontaminations are not warranted or practical, then ensure that the contaminated area is not further spread and contaminated materials are not ingested. Adding moisture to the skin may allow contaminated skin to release more activity after a few hours. At that time, washing the skin again may be helpful. If hands are contaminated, cotton gloves may absorb moisture containing activity and prevent contamination from spreading.
6. Determine the value of performing Bio-Assays on the individual for any ingested or inhaled activity. These Bio-Assay techniques include, but are not limited to: nose wipes, saliva samples, and/or after a few hours, blood and/or urine samples. If any Bio-Assay samples are obtained, the personnel exposure records must show the nature of the samples, and the numerical results of their analysis.
7. Complete all required records, including the appropriate spill, personnel exposure, ingestion, or incident reports.

III. Surface Decontamination

A. Avoid all unnecessary exposure of personnel during decontamination, and never allow uncontaminated areas to become contaminated during these procedures.
B. Consider using radioactive decay as a decontamination technique if the activity can be isolated and secured.
C. Wear booties, gloves, a laboratory coat and, if possible, an apron, or other materials that will allow easy removal of contaminated articles.
D Cover all "wet" areas with absorbent papers.
E. Monitor the area suspected of contamination, and identify its outer limits with a marker or barrier.
F. Place absorbent pads adjacent to the area to prevent exposure to decontamination personnel.
G. Decontaminate the outer margins of the area with the appropriate NUC CONTAM Solution (I, II, and/or III,) working inward toward the major area of the spill.
    1. Use a minimum amount of solution and water.
    2. Clean successively smaller areas
    3. Use tongs; don't touch the wipes or decontamination materials.
    4. Place all contaminated materials in plastic bags for Decay in Storage (DIS).
    5. After decontamination, place absorbent paper over the "clean" area to avoid contact with residual activity.
    6. When all areas are decontaminated and released, they must be swipe tested for residual activity.
    7. Complete all required spill reports and records and document the decontamination.

•Notes: If the surface is waxed, a wax remover may help remove the contamination. When using a brush or abrasive instrument, use care not to damage the surface, puncture the protective gloves or spread the contamination through moisture drops or mists. Be careful not to contaminate the survey meter.

Procedure for Ordering Radioactive Materials

We will follow the procedures below when ordering radioactive materials.

1. The RSO or a designee must authorize each order for radioactive materials. Each ordered material must be authorized under the license. The amount ordered must not exceed the possession limits under that license.
2. A record of all orders will be maintained. The record should show the isotope, activity, form and supplier of the radioactive material (see the "Radioactive Material Package Order and Receipt Record").
3. Radioactive materials will only be received during normal working hours. The materials will be delivered directly to the nuclear medical area and placed on the table by the nuclear medical technologist or RSO, as indicated in the floor plan. If the technologist or RSO are not present when the material is delivered, the reception staff will follow the procedures listed below. The procedures will also be posted in both the reception office and the nuclear medical room.
4. The technologist or RSO will check to ensure that the package contains the ordered material.
5. The technologist or RSO will then follow the "Procedures for Safely Opening Packages Containing Radioactive Material."

NOTICE

Receipt of Packages Containing Radioactive Materials

When packages containing radioactive material are delivered, have the carrier agent (delivery person) wait in the reception area. Call the nuclear technologist or the Radiation Safety Officer.

If the nuclear technologist or the Radiation Safety Officer are not available, then follow the instructions below.

1. Have the carrier's agent place the package on a cart or wheelchair.

2. If the package is damaged, or shows signs of being wet or having been wet, immediately contact one of the individuals listed below.
   - Demand that the carrier's agent remain at the facility to be monitored.
   - Determine whether the person or the vehicle is contaminated.
   - Do not touch the package or allow others to touch the package. Remove the package, on the cart or wheelchair, to a secure area, such as the nuclear medicine room. The RSO or other authorized personnel will examine the package in that room.

3. If the package is not damaged, and shows no signs of being wet,
   - Sign the receipt and retain a copy.
   - Transport the package to the nuclear medicine area on the cart or wheelchair
   - Place the package at the location marked, "Radiopharmaceutical Receipt Area," and lock the room.

Note to cleaning, security, and other personnel—if packages are delivered before or after regular working hours, you are not authorized to receive the package and must refuse it. The carrier's agent may not leave the package at the facility during non-working hours. If you have any questions, contact one of the individuals listed below.

Radiation Safety Officer: _____

Nuclear Medical Technologist: _____

Procedure for Safely Opening Packages that Contain Radioactive Material

Procedure for safely opening packages:

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage, such as wetness, stains, etc. If any damage is noted, immediately notify the RSO.

3. Measure the exposure rate from the package at one meter, and then at the surface. If exposure rate is higher than expected, stop and notify the RSO for specific instructions.

   Note: Maximum surface exposure rate of labeled packages:
   White—10.5 mR/hr, Yellow I—50 mR/hr, and Yellow III—200 mR/hr.
   None of these rates should be exceeded.

4. Open the package according to the following steps:
   a. Remove the packing slip.
   b. Open the outer package according to the supplier's instructions, if instructions are provided.
   c. Open the inner package and verify that the contents agree with the packing slip.
   d. Check the integrity of the final source container. Look for broken seals and loss of volume, moisture, or stains on the packing material. If anything is found in an unexpected condition, immediately notify the RSO.
   e. Remove the source container and place it on an absorbent pad.
   f. Remove the emptied shipping box to an area with low background exposure, and survey with a sensitive GM survey meter. If contaminated:
      (1) Treat as radioactive waste and remove for DIS.
      (2) Wipe the external surface of the final source container. Assay the wipe in a low background area for any removable radioactivity. Use the procedure for wipe assay as established in the "Contamination Survey Record" (section III) to determine the sample counts to dpm.
      (3) Notify the RSO.
   g. If the shipping box is not contaminated, remove and obliterate the radiation labels before discarding in the in-house trash.

5. Recheck the contents of the package to be sure it is the ordered material.

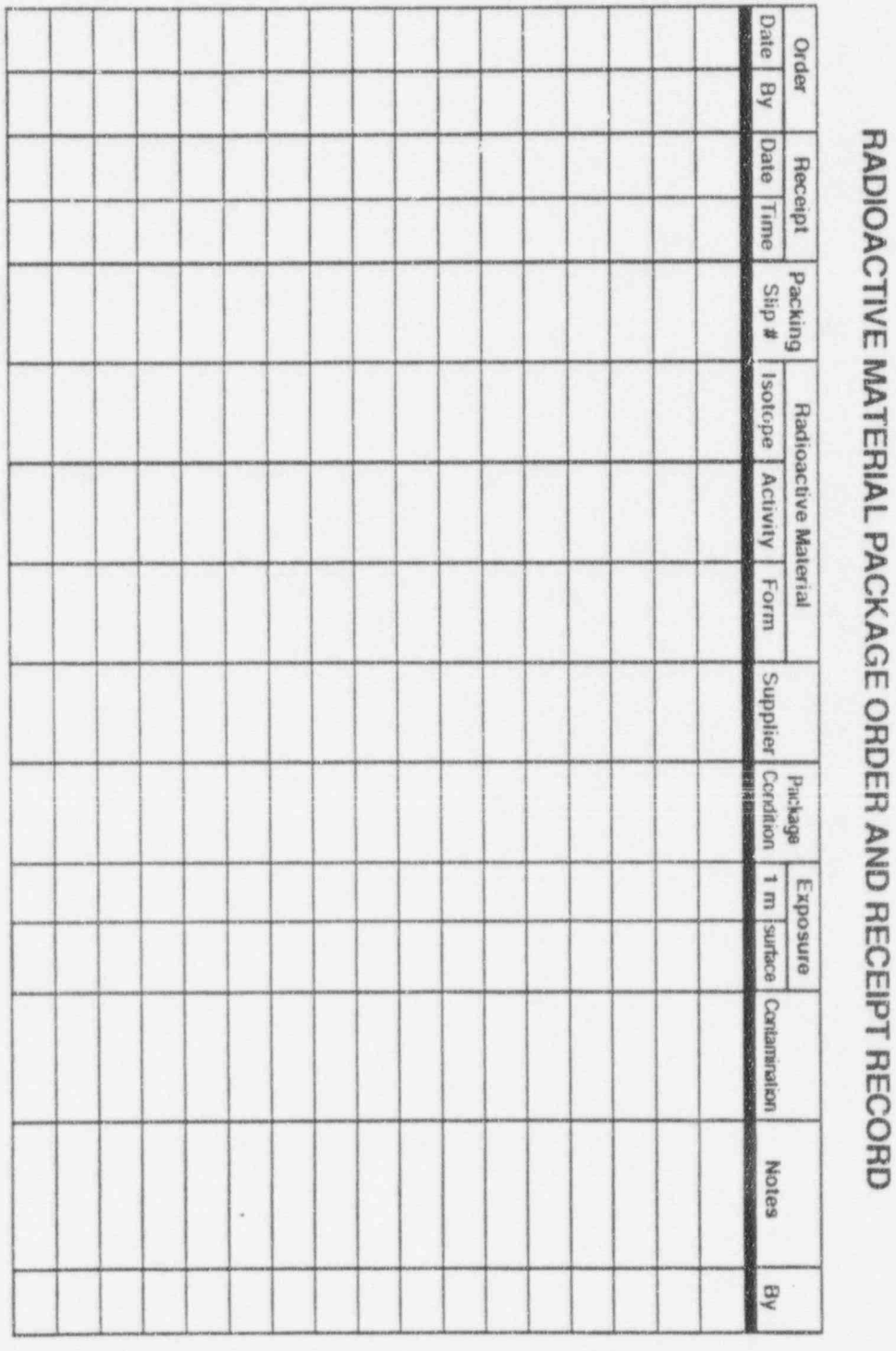
6. Check the source's activity in the Dose Calibrator.

7. Log the material on the correct Radioisotope Distribution Record.

8. Finish the "Radioactive Material Package Order and Receipt Record," on the next page of this section.

Procedure for Safely Opening Packages Containing Radioactive Materials—Radioactive Material Package Order and Receipt Form

These records will be maintained on the following record form, shown below in a reduced size.



Radiopharmaceutical Records

Records of the radiopharmaceutical, supplier, date, time, activity, patient, pre-administration calibrator assay and person administering the material will be maintained by the facility. These records will be completed on the forms shown below, or on a form supplied by the radiopharmacy containing all of the same information.

UNIDOSE RECORD: RADIOPHARMACY RADIOPHARMACEUTICAL UNIDOSE RECORD

PACKAGE RECEIPT AND MONITOR RECORD

RECEIPT Date: ____________ Time: ____________ am / pm By: ____________ Confirmation with Order: ________

Package Condition: ____________ Surface Exposure Rate: ____________ mR/hr Contamination: ________

Notes: ____

Prescription Record Activity ________ Isotope ________ Form ________ Patient ________ Time ________ By ________	Dose Calibrator Pre-Administration Activity Check ______	Disposal Record Exp. Date _____ Disposal Route ________ Date ________ Returned to Radiopharmacy ________
Prescription Record Activity ________ Isotope ________ Form ________ Patient ________ Time ________ By ________	Dose Calibrator Pre-Administration Activity Check ______	Disposal Record Exp. Date _____ Disposal Route ________ Date ________ Returned to Radiopharmacy ________
Prescription Record Activity ________ Isotope ________ Form ________ Patient ________ Time ________ By ________	Dose Calibrator Pre-Administration Activity Check ______	Disposal Record Exp. Date _____ Disposal Route ________ Date ________ Returned to Radiopharmacy ________
Prescription Record Activity ________ Isotope ________ Form ________ Patient ________ Time ________ By ________	Dose Calibrator Pre-Administration Activity Check ______	Disposal Record Exp. Date _____ Disposal Route ________ Date ________ Returned to Radiopharmacy ________
Prescription Record Activity ________ Isotope ________ Form ________ Patient ________ Time ________ By ________	Dose Calibrator Pre-Administration Activity Check ______	Disposal Record Exp. Date _____ Disposal Route ________ Date ________ Returned to Radiopharmacy ________

UNIDOSE RECORD: ISOTOPE ____________ FORM ____________

Note: complete the Order and Receipt Record before entering any information on this form.

Date Received	Supplier	Lot #	Calibration			Administration		Dose Calibrator Activity Check	Expir. Date	Patient		By	Disposal	
			Activity	Date	Time	Date	Time			Name	Number		Date	Route

Radioactive Material Package Order and Receipt Record

Order		Receipt		Packing	Radioactive Material				Package	Surface			
Date	By	Date	Time	Slip #	Isotope	Activity	Form	Supplier	Condition	Exposure	Contamination	Notes	By

Procedure for Area Surveys

Ambient Exposure Surveys

1) All areas where radiopharmaceuticals are used, stored, prepared, or administered will be surveyed with the GM survey detector at the end of each day.
2) Areas that are used for only radiopharmaceutical waste storage, where there are no daily activities, will be surveyed with the GM survey detector at the end of each week.
3) The above survey information will be recorded on the "Ambient Exposure Survey" report form (see next page), and the RSO will be notified if unexpectedly high or low levels are found. Prompt notification is particularly important where radionuclides should not be present, or levels exceed established values.
4) Surveys will be completed as part of the "spill" procedure.

Removable Contamination Surveys

1) All areas where radiopharmaceuticals are used, stored, prepared, or administrated will be surveyed for removable contamination by wipe testing at the end of each week that the materials are used.
2) The above survey information will be recorded on the "Contamination Survey Record" report form (see page three). The RSO will be notified if removable contamination of 1000 dpm/100cm^2 of ^{57}Co, ^{99m}Tc, or ^{201}Tl is found. Also notify the RSO if 100dpm/100cm^2 of any other radioisotope is found, or if any removable contamination is found in an unrestricted area. The assay must be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of ^{57}Co, ^{99m}Tc, or ^{201}T1. The assay must also be able to detect 200 dpm/100cm^2 of any other radioisotope. This assay will use the absolute counting technique outlined in the "Contamination Survey Record." The survey will use "swipes," as indicated on the third page of this section.
3) Surveys will be completed as part of the "spill" procedure.

Contamination Action Levels: (dpm/100cm^2 of surface contamination)

Area	Contaminant Radionuclide ^{57}Co, ^{99m}Tc, ^{201}T1	All Others
Unrestricted Areas and Personnel Clothing, Skin.....	2,000	200
Restricted Areas, Protective Clothing.....	20,000	2,000

Contamination Survey Record Form

The form used for this survey is found below at a reduced size. The facility's floor plan will be reproduced on the form. Numbers on the floor plan will indicate the location of "swipes." The type of "swipe" that will be used is listed below on this page.

CONTAMINATION SURVEY RECORD

(Survey for Removable Contamination)

Survey: Date _____ Time _____ By _____ Assay: Date _____ Time _____ By _____
Instrument: _____ PHA ΔE _____ Kev to _____
Kev
Standard: Radionuclide _____ Assay: Activity _____ Date _____

I. SURVEY AREA

II. SAMPLE ANALYSIS

Swipe #	Gross cpm		Bkg. cpm	=	Net cpm	x	dpm*	=	dpm	Action Taken**

*from "Standard Analysis" below
**see "Contamination Action Levels" below

III. STANDARD ANALYSIS

A. Gross cpm _____ — Bkg. cpm _____ = Net cpm _____
B. Assay uci _____ x Decay Factor _____ = uCi _____
C. uCi _____ x 2.22 x 10^6 dpm / uCi = dpm _____
D. Calibration Factor $A/_E$ = Net dpm/cpm = _____ / _____ = dpm/cpm _____

IV CONTAMINATION ACTION LEVELS (dpm/100 cm² of surface contamination)

Area	Contaminant Radionuclide		
	^{57}Co, ^{99m}Tc, ^{201}Tl		All Others
Unrestricted areas and personnel clothing	2,000		200
Restricted areas and protective clothing	20,000		2,000

"SWIPE"

Direction:
1. Complete the lower panel.
2. Place this panel on the dry surface to be surveyed
3. Using the index finger, lightly press the swipe on the surface (1 cm²)
4. Wipe a distance of 100 cm for a sample area of 100 cm²
5. Fold the swipe with the sample area on the inside

Note:
—Avoid touching the surface or swipe with your finger
—Do not spread known contamination
—Do not cross-contaminate the swipe

Radioactive Contamination Wipe
Sample # _____
Location: _____
_____
Date: _____ Time: _____
Analysis (dpm) _____ _____
Suspect Radionuclide(s): _____

Ambient Exposure Survey Record Form

The form used for this survey is shown below at a reduced size. The facility floor plan is reproduced below. Measurements are marked at their locations.

AMBIENT EXPOSURE SURVEY
(Survey for Source Exposure and Contamination)

Instrument: _____ Probe: _____
Date of Calibration: _____ Reference Check: _____ mR/hr

I. SURVEY AREA

II. SURVEY

		Identification of Location and Exposure in mR/hr												
Surveyed by:	Date:	1	2	3	4	5	6	7	8	9	10	11	12	Operator Action*

*See "Exposure Action Levels" below.

II. EXPOSURE SURVEY ACTION LEVELS (mR/hr of ambient exposure)

1. All areas	Any unexpectely high or low levels
2. All areas	Any exposure where radionuclides should not be present
3. Unrestricted areas	2.0 mR/hr or higher
4. Restricted areas	5.0 mR/hr or higher

Radioisotope Waste Disposal Procedure

Disposal By Transfer

1) Return spent syringes and unused sources from the radiopharmacy to the supplier. Return materials from the radiopharmacy *only* to the supplier. Retain records of all materials returned to the radiopharmacy with the "Radiopharmacy Radiopharmaceutical Unidose Record" form, located in the Radiopharmaceutical Record section of this application.

Disposal By Decay-In-Storage (DIS)

1) Short-lived material, i.e., materials with a physical half-life of less than 65 days, will be disposed of by DIS.
2) Radioisotopes that are currently active (activities not used or returned to the radiopharmacy) will be kept in the lead storage container for not less than two half-lives. These will then be transferred to the DIS storage container, as described below, after the radiation label has been violated and shielding removed.
3) Syringes and capped needles will be placed in a separate container for eventual disposal (after DIS) in compliance with state and local public health regulations .
4) Injection paraphernalia (swabs, gauze, tubes, and other contaminated materials) will be placed directly in the DIS containers.
5) All materials placed in the DIS container will have the radiation labels violated and the shielding removed. These materials will be placed in 2-ply plastic bags inside the container . When the bag is full, or every few weeks, the bag will be sealed with string or tape and identified with the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The bag will then be contained for additional DIS, if required. No material will be disposed in less than ten half-lives of the longest half-life in the container.
6) Prior to disposal, as in-house waste, the bag will be monitored with the following technique:
   a) Check the GM survey detector for proper operation
   b) Remove the bag to a low-level background area (less than 0.05 mR/hr)
   c) Monitor all surfaces of the bag
   d) If there is no exposure above background, discard the bag. If the bag still shows exposure, return the bag to DIS
   e) Complete records of DIS will be maintained on the "Disposal By Decay In Storage Record" form, located on the next page.

Note: Sealed sources (^{57}Co, ^{133}Ba, and ^{137}Cs) that must be disposed of by the applicant will be transferred to a supplier who is licensed to receive such material. This transfer will be completely documented by the applicant prior to disposal.

DISPOSAL BY DECAY-IN-STORAGE RECORD

Storage containinner	Input			Survey Before Disposal				Disposal				
	Date	Isotope	Activity	Date	Instrument	Bkgrd*	Container**	By	Date	Route	By	Notes

*Must be less than 0.05 mR/hr

**Must be the same as background at surface of container, with all shielding removed

Note:
- All radionuclides must have half-lives of less than 65 days
- Place the material in the Decay-In-Storage cntainer only after substantial decay in the shielded container (at least 5-10 half lives).
- Remove or violate all radiation symbols and radioactive material signs before placing the radioisotope in the bag and marked container.
- Separate needles and other BioHazards from the radioactive materials for proper dispoal, as stipulated by State and OSHA regulations.

DO NOT EMPTY— RADIOACTIVE WASTE MATERIALS

RADIOPHARMACEUTICALS—

TO BE RETURNED TO THE RADIOPHARMACY

October 6, 1993

Brahma N. Sharma, M.D.
1643 Pinoak Drive
Pittsburgh, Pennsylvania 15237

Gentlemen:

This refers to your application dated August 10, 1993, for a Materials License.

We received your check for $760.00. Your request is subject to an application fee of $1,100.00 as specified in fee Category 7C of 10 CFR 170.31 of the enclosed July 20, 1993, Federal Register notice. Payment of the additional $340.00 fee should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

U.S. Nuclear Regulatory Commission
ATTN: Brenda Brown
License Fee and Debt Collection Branch, OC/DAF
Mail Stop MNBB 4503
Washington, D.C. 20555

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, PA 19406. The fee, however, is required prior to issuance of the license. When submitting the additional fee, please refer to CONTROL NUMBER 118639.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application and will void this action.

Sincerely,

Signed by Brenda E. Brown

Brenda Brown
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
July 20, 1993, Federal Register notice

cc: Region I

DISTRIBUTION
Pending Fee File
OC/DAF R/F
LFDCB R/F (2)

OFFICE:	OC/LFDCB	OC/LFDCB
NAME:	BBrown	SKimberley
DATE:	9/30/93	10/6/93

RCJ3/A:\BSHARMA.ARC

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02200
STATUS CODE: 3
FEE CATEGORY: ----------
EXP. DATE: 0
FEE COMMENTS: ----------
DECOM FIN ASSUR REQD: _

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SHARMA, BRAHMA N. M.D.
RECEIVED DATE: 930902
DOCKET NO: 3033308
CONTROL NO.: 118639
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $760.00
CHECK NO.: 7766

3. COMMENTS

SIGNED Brown, Rebecca J.
DATE 9-3-93

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /)

1. FEE CATEGORY AND AMOUNT: 7C ----------

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ----------
RENEWAL ----------/----------
LICENSE ----------

3. OTHER ----------

SIGNED ----------
DATE 9/9/93

1993 SEP 10 PM 5:41