NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

302333

Licensee	
1. Ali N. Shaikh, M.D.	3. License Number 34-26783-01
2. 21851 Center Ridge Road Rocky River, OH 44116	4. Expiration Date March 31, 2007
	5. Docket or Reference No. 030-34400

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.200	A. Any radiopharmaceutical identified in 10 CFR 35.200 (limited to cardiac) excluding generators and xenon-133	A. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.200 for cardiovascular clinical procedures.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Rocky River Professional Building, Suite 109, 21851 Center Ridge Road, Rocky River, Ohio.

11. Radiation Safety Officer: Basel Moussa, M.D.

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. Basel Moussa, M.D.	10 CFR 35.200 limited to diagnostic cardiac imaging.

280097

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-26783-01
Docket or Reference Number: 030-34400

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:

    A. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and

    B. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.

14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated February 7, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date March 17, 1997

By Evelyn R. Weston
Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code:
Status Code: 3
Fee Category:
Exp. Date: 0
Fee Comments:
Decom Fin Assur Reqd:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: ROCKY RIVER PROFESSIONAL BUILDING
   Received Date: 970218
   Docket No: 3034400
   Control No.: 302333
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount:
   Check No.: ~~0~~

3. COMMENTS

Signed D. Hersey
Date 2-26-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: 7C $1400

2. Correct Fee Paid. Application may be processed for:
   Amendment
   Renewal
   License ✓

3. OTHER

Signed SC
Date 3/5/97

RECEIVED FEB 21 PM 1:34

MAR 10 1997

Log Feb 10 III
Remitter Ali & Shaikh, MD
Check No. 7110
Amount $1400
Fee Category 7C
Type of Fee App
Date Check Rec'd 3/5/97
Date Completed 3/5/97
By: SC

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ROCKY RIVER PROFESSIONAL BUILDING
ATTN: DR. BASEL MOUSSA
21851 CENTER RIDGE ROAD
SUITE 109
ROCKY RIVER, OH 44116

TYPE OF ACTION

- [X] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 2-7-97

LICENSE NUMBER:

CONTROL NUMBER: 302333

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$	$ 1,400.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,400.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 1,400.00

- [X] Your request was received without the prescribed application fee.
- [ ] We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [ ] License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB
SHIRLEY CRUTCHFIELD	SC 2/25/97	

Distribution: OC/DAF/RF
Pending Fee File OC/DAF/SF(LF-3 2.7)
LFARB R/F (2) Region 3

DATE: Feb 25 1997

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

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

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

APPLICATION FOR MATERIAL LICENSE

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 B
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

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)

Basel Moussa, M.D.
Rocky River Professional Building Suite 109
21851 Center Ridge Road
Rocky River, OH 44116

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

same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Basel Moussa, M.D.

TELEPHONE NUMBER

216-895-1555

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 7C

AMOUNT ENCLOSED $ 1400.00

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
[signature]	Basel Moussa, M.D.	applicant	2/7/97

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES (Total for entire facility including outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (labor 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

RECEIVED
FEB 18 1997
REGION III

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER		FEB 18 1997	DATE
				302333

PRIVACY ACT STATEMENT ON THE REVERSE

Documentation of Attachments to this Application

Section	Attachment Description
A.	Description of the Scope of Operation
B.	Radioactive Materials Requested in This Application
C.	Training and Experience of Authorized User and RSO
D.	Personnel Qualifications and Training
E.	Facilities and Related Equipment
F.	Radiation Detection Instrumentation
G.	Calibration of 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 Radioactive Spills
N.	Procedure for Ordering Radioactive Materials
O.	Procedure for Opening Packages
P.	Radiopharmaceutical Records
Q.	Procedure for Area Surveys
R.	Radionuclide Waste Disposal Procedure

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

APP' ICATION FOR MATERIAL LICENSE Attachment A

DESCRIPTION OF THE SCOPE OF OPERATION

This license is for diagnostic nuclear medicine procedures only as described by 10 CFR 35.200 for the quantities as needed, implemented in a private office facility. The materials used at this facility will be obtained from a radiopharmacy or licensed radiopharmaceutical supplier. The applicant will not obtain a 99Mo/99mTc generator. The facility will not perform any studies using radio sodium iodide or radioactive gasses. No radiotherapy will be performed.

This facility is exempt from Quality Management requirements; thus, no quality management program will be developed.

All unused radioactive doses and spent syringes containing residual radioactive contamination will be returned to the radiopharmacy for disposal as allowed. Records of the return will be maintained by the applicant. Other contaminated wastes, such as wipes, tubings with residual activity, contaminated gloves, etc. will be stored for disposal via the Decay in Storage procedure.

The facility design will meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301 for exposure limits to the radiation workers and to the members of the general public. Specifics of this program are given in Attachment J.

Forms attached to this license application are intended as examples. We will use these forms or others which supply equivalent information. We commit to maintain all facility records as required by statute and as outlined in Regulatory Guide 10.8 Revision 2 of the Office of the Nuclear Regulatory Commission.

If the needs of the applicant/physician require the operational scope to change other than as described, an amendment request will be filed prior to implementation of the requested changes.

APPLICATION FOR MATERIAL LICENSE Attachment B

Radioactive Materials Requested in this Application

Radiopharmaceuticals:

This application is for the possession and use of all radiopharmaceuticals allowed under 10 CFR 35.200 or state equivalent limited to diagnostic cardiology imaging. The materials, to be used in an out patient facility will be limited to:

Radioisotopes:
^{99m}Tc and ^{201}Tl

In the form of
all FDA approved materials for diagnostic nuclear cardiology use

In the quantities
as needed for the studies scheduled.

NOTE: Radiopharmaceuticals will be obtained from a licensed supplier in unit dose form. No ^{99}Mo/^{99m}Tc generator will be obtained by this facility.

Also, requested are sealed sources, and calibration and reference sources as allowed by 10 CFR 35.57 or equivalent state regulation. Requested pharmaceuticals for calibration and reference are:

^{99m}Tc	pertechnetate	50.0 mCi	for Quality Control and Calibration
^{201}Tl	chloride	1.00 mCi	for Quality Control and Calibration

Sealed sources for calibration and Quality Control are listed on the next page.

Sealed Sources

The sealed sources will be obtained from: E. I. DuPont de Nemours & Co.,
331 Treble Cove Road
Billerica, MA 01862

The sources used for the dose calibrator are:

Element and Mass Number		Form	Max., mCi	Catalog Number
Ba	133	sealed	0.250	NES-358
Cs	137	sealed	0.200	NES-356
Co	57	sealed	5.000	NES-206

The sources used for the gamma camera are:

Element and Mass Number		Form	Max., mCi	Catalog Number
Co	57	sealed	5.000	NES-391

A description of the sources provided by the supplier is given below. These sealed sources will not have activities greater than those stated in 41.26(b)(4). If the sources decay to levels below those stated in 10 CFR 35.50(b)(1)(2) 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.

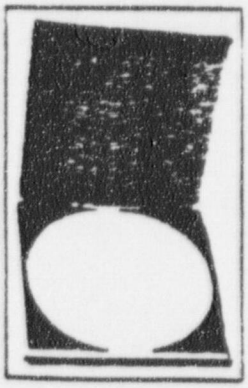
By keeping a daily log of the values obtained on selected ranges with both standards, the user develops a performance record that detects calibrator error or failure before a mistake is made in a patient's dose.

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

APPLICATION FOR MATERIAL LICENSE Attachment C

TRAINING AND EXPERIENCE OF AUTHORIZED USER AND RADIATION SAFETY OFFICER

The Authorized User physician and the Radiation Safety Officer for this facility will be Basel Moussa, M.D. Copies documentation of Dr. Moussa's training and experience qualifications are attached.

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
1540 Spring Valley Drive
Huntington WV 25704

January 8, 1997

In Reply Refer To:

To Whom It May Concern:

This letter is to affirm that Dr. Basel Mousea gained clinical experience at our institution in Nuclear Cardiology. The preceptorship began 7/1/93 and continued through 6/30/96. During this period, the doctor actively participated in the following number of procedures:

1. Thallium stress imaging/function procedures: 250
2. Thallium rest imaging/function procedures: 50
3. PYP/RBC multi-gated acquisition stress procedures: 25
4. PYP/RBC multi-gated acquisition rest procedures: 150
5. Ejection fraction calculation procedures: 90
6. Wall motion evaluation studies: 110
7. Shunt evaluation calculations: 10
8. Tc99m Sestamibi imaging procedures: 100

During this time, the doctor also acquired experience in health physics, radiopharmaceutical preparations, technical and administrative procedures of our facility, as well as general operations as stipulated by our license conditions.

The doctor gained experience in the preparation of radiopharmaceutical kits during this period, and eluted the Tc99m/Mo99 generator.

The hours of nuclear cardiology clinical and work experience accrued during this period total 1000 hours.

Sincerely,

HARESH P. SOLANKI, M.D.
NUCLEAR MEDICINE SECTION
RADIATION SAFETY OFFICER

NRC LICENSE #
47-03630-02

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

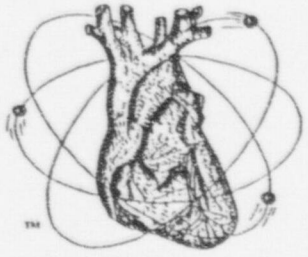
This document is to attest that

BASEL MOUSSA, M.D.

has successfully 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 specified by the American Pharmaceutical Association and the American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

9 March 1996
Date Class Commenced

Authorized Signature

191168
Affidavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80303 — 800-548-4024

1132 INME 8/94

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in 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

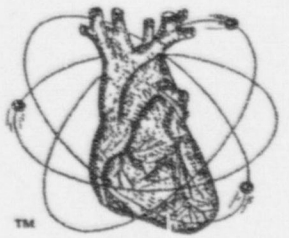
This document is to attest that

BASEL MOUSSA, M.D.

has successfully 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 and Agreement States)

5 Continuing Education Units (CEU)

50 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

June 15, 1996
Date Class Commenced

Authorized Signature

Affidavit of Competency

Institute for Nuclear Medical Education

5560 Airport Blvd., Suite 101, Boulder, Colorado 80301 — 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in 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

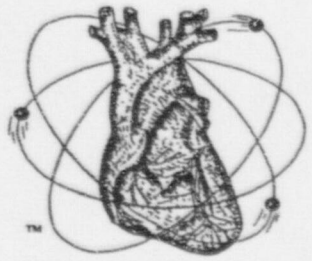
This document is to attest that

BASEL MOUSSA, M.D.

has successfully 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 specified by the American Pharmaceutical Association and the American Association of Health Physicists*

**additional documentation will be provided to Regulatory Agencies upon participant request*

June 15, 1996
Date Class Commenced

Charles H. Rose
Authorized Signature

0-19144
Affidavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80303 — 800-548-4024

1132 INME

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in 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

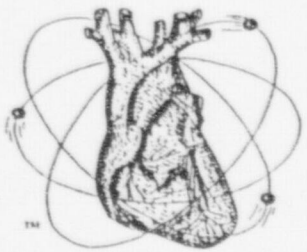
This document is to attest that

BASEL MOUSSA, M.D.

has successfully 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 specified by the American Pharmaceutical Association and the American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

13 March 1996
Date Class Commenced

Authorized Signature

191151
Affidavit of Competency

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80303 — 800-548-4024

1132 INME 8/94

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in 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.

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.

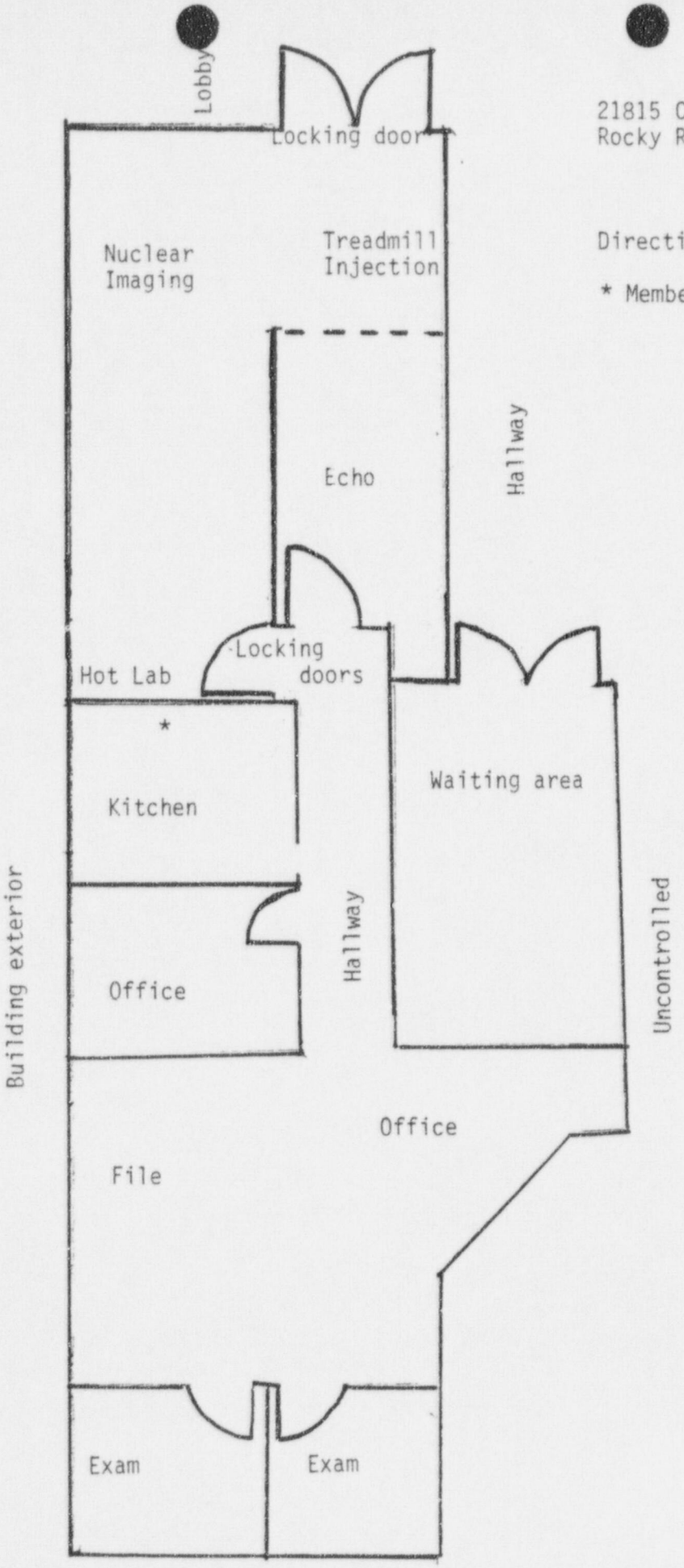
Method of Evaluation:
The RSO or her/his agent will evaluate and informally observe the individual's work activities.

Attachment E-1

21815 Centre Ridge Road
Rocky River, OH 44130

Direction of North ↑

* Members of public monitoring.



Facilities—Annotated Drawing of the Radioisotope Facility

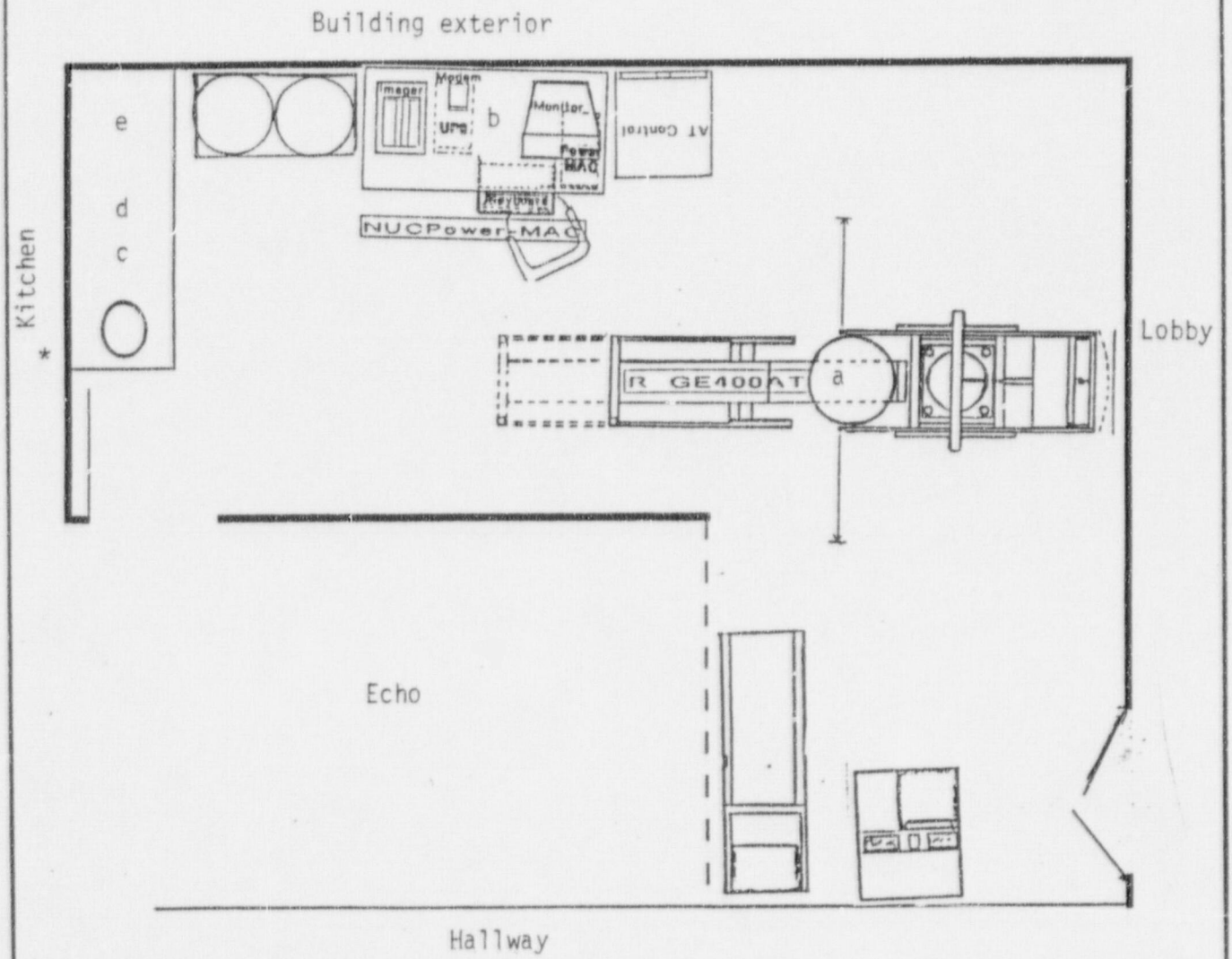
Scale: 1/4" = 1'0"
Direction: North →

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

21815 Centre Ridge Road
Rocky River, OH 44130

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

* monitor for Member of Public



APPLICATION FOR MATERIAL LICENSE

Attachment E 2

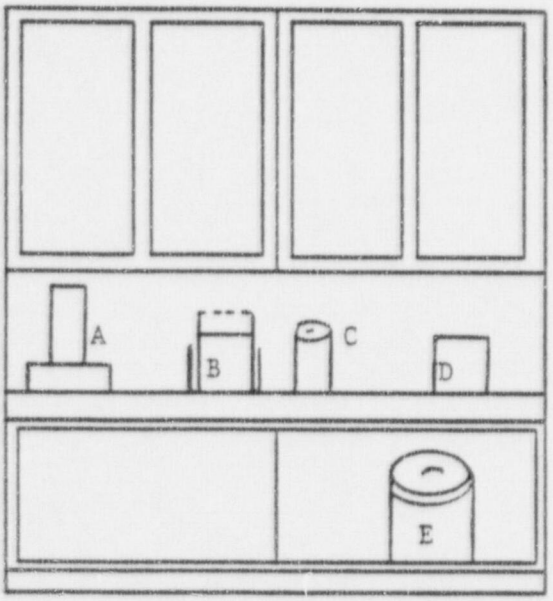
N C Systems

Boulder, CO 80303
1-800-548-4024

21815 Centre Ridge Road
Rocky River, OH 44130

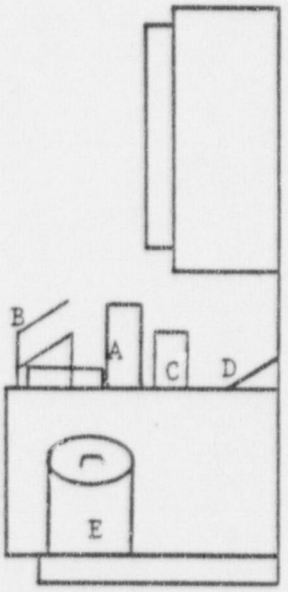
Plans developed for: Dr. Moussa

DATE	SCALE	SHEET	BY
2-97	¼" = 1'	2	GSW



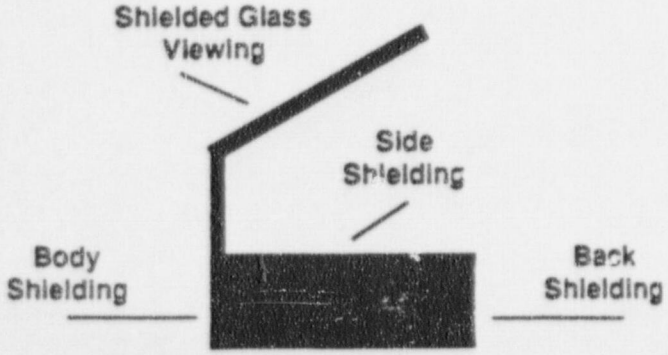
not necessarily to scale.

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

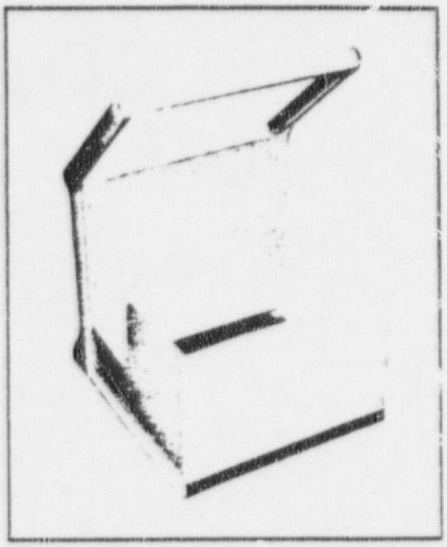


Table Top Lead Barrier Shield

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

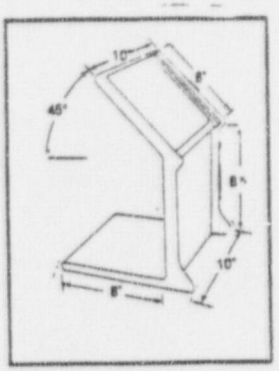
MINI TABLE TOP SHIELD—for small jobs in limited working areas.

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

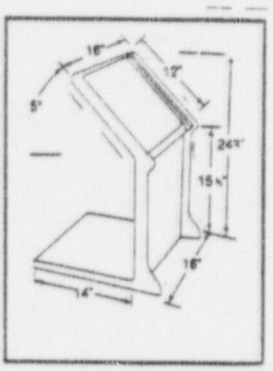
Select the shield most suited to your work load. Both units provide exceptional protection to the clinician when setting up technetium generators, filling syringes, performing radium loading procedures, etc.

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

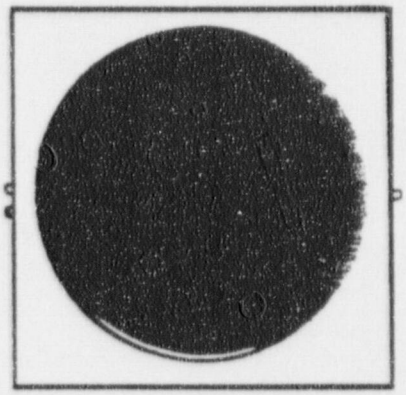
Equipment Quality Control Phantoms

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

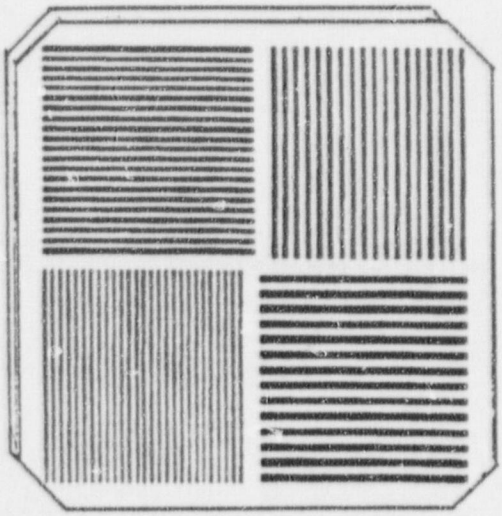
Extra Large Flood Phantom Source

- 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, with 15" diameter x 1/2" cavity for suitable radionuclide
- Easy to fill—drain ports provided

Emission Phantom



Transmission Phantom



Standard High Resolution Bar Phantom

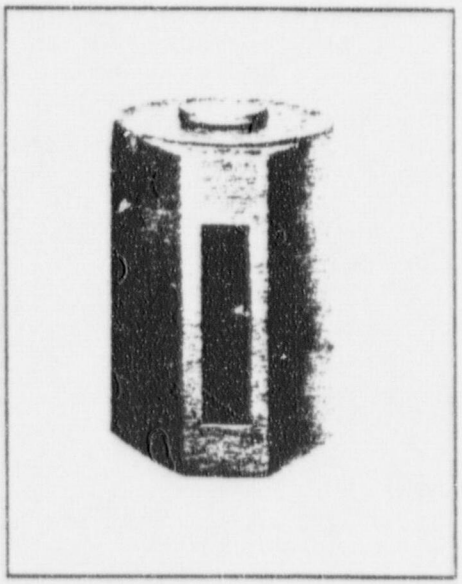
- Bar Widths: 1/4", 3/16", 5/32", 1/8" (6.4 mm, 4.8 mm, 4.0 mm, 3.2 mm)
- 15" field across bar configuration (38 cm)

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

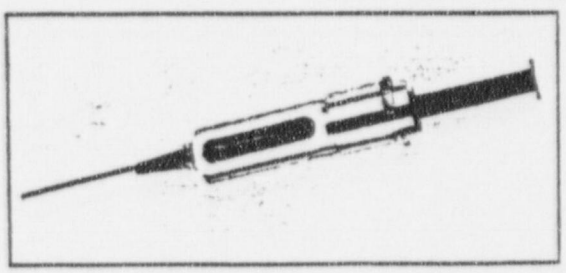
For Contaminated Syringes
- Safely holds used hot syringes
- Rapid, safe disposal

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.



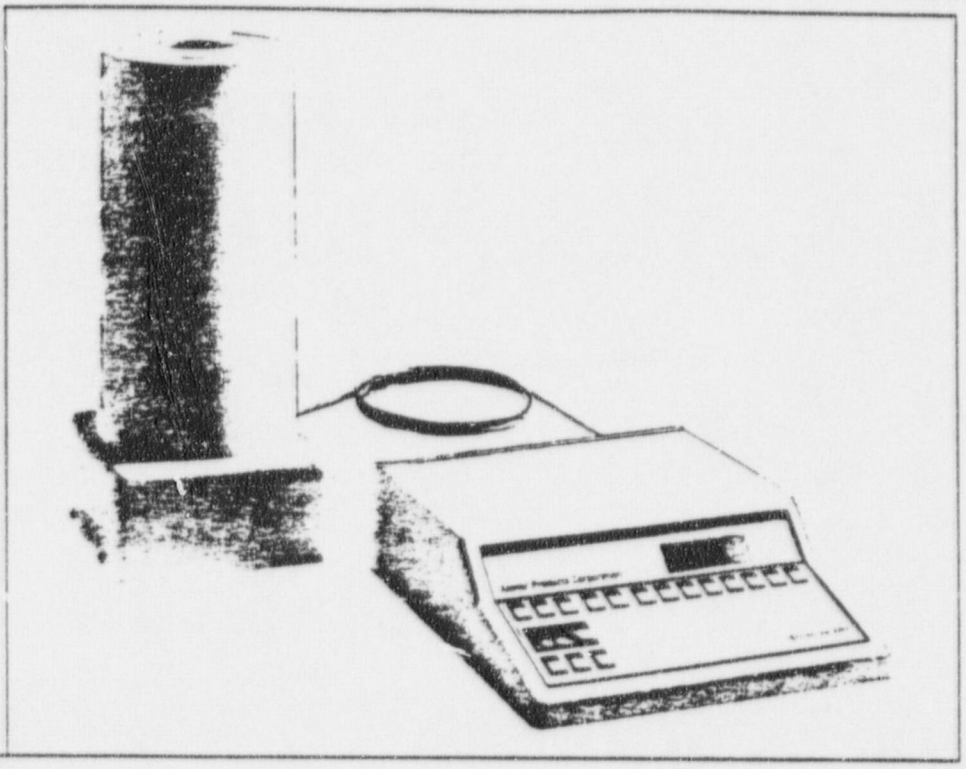
Radiation Detection Instrumentation

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 0.1 uCi, 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: SWGM

- 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 qualifed 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 calibrations will be performed either by the manufacturer of the instrument, or by *Romaes Laboratory/INME/NC Systems* (5171 Eldorado Springs Drive, Boulder, CO 80303, 303-499-4099, License #COLO 751-01), by *Eberline Instrument Corporation*, 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. The replacement meter will match the performance of the original meter.

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.

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 99mTc 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 millicuries (mCi), minus any background reading.

c) "Count" the syringe again at least *seven* times during a 72 hour period of time (3.25 days). Record each of the readings, minus the background. Readings will be assayed over the range from the highest dose ever administered down to ten (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 the true activity will be made and placed on the dose calibrator.

Alternatively, the applicant may obtain a Calchek or Lineator device to perform this test, using the manufacturers procedures and conducting an annual calibration of the device.

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 expected activity

If no radiopharmaceuticals 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 57Cobalt sealed dose calibrator source on the 201Tl, 57Co, and 99mTc settings. Similarly measure the 137Cs 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 57Co activity to the activity from a 57Co decay table, graph or calculated value.
e) Find reading action levels at each setting within ±5% the anticipated readings. If the value is greater that ±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

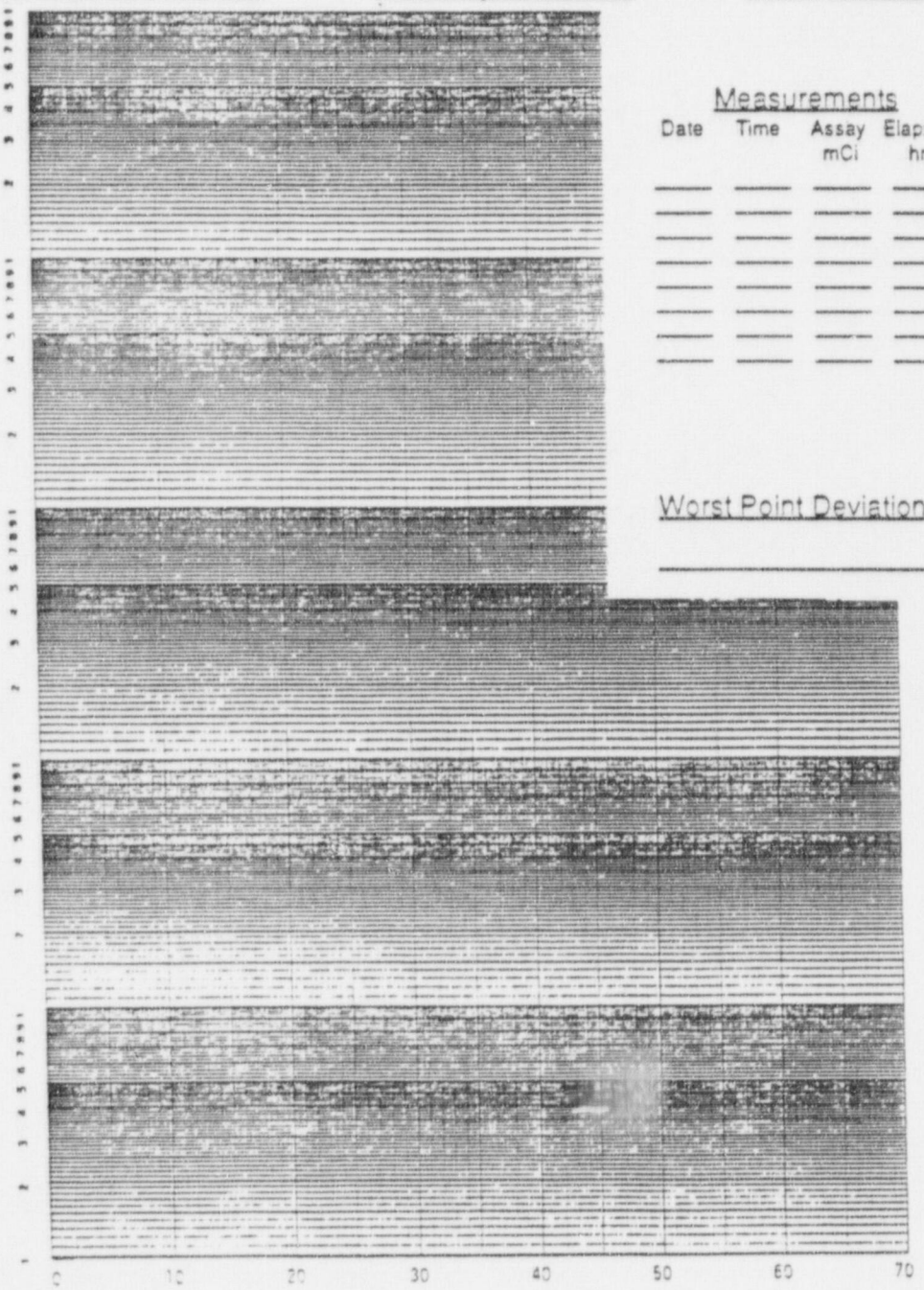
Dose Calibrator Linearity Test

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

DOSE CALIBRATOR GEOMETRY TEST -

Unit Dose Systems

Licensee: _____

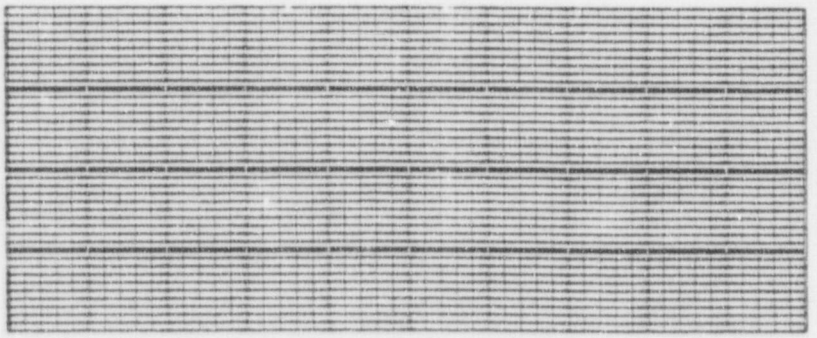
License Number: _____ Amendment: _____

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

Dose Calibrator Setting: _____ Background: _____

Radionuclide: _____ Activity: _____ Form: _____

Syringe Geometry Dependence



0.5 _____
1.0 _____
1.5 _____
2.0 _____
2.5 _____
3.0 _____
3.5 _____
4.0 _____

Analysis of Geometry Dependence Data From Above: _____

_____

Tested By: _____ RSO: _____ Date: _____

Dose Calibrator Accuracy Test

Licensee: ____________________

License Number: ____________ Amendment: ____________

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

____

Source Radioisotope: ____________ Activity: ____________ Model: ____________

Assay

A. ____________ Calibration Date: ____________

B. ____________ Decay Factor: ____________

C. ____________ Decay Corrected: ____________ Activity: ____________

Avg. ____________ Serial #: ____________

Calculated Deviation: ____________

Source Radioisotope: ____________ Activity: ____________ Model: ____________

Assay

A. ____________ Calibration Date: ____________

B. ____________ Decay Factor: ____________

C. ____________ Decay Corrected: ____________ Activity: ____________

Avg. ____________ Serial #: ____________

Calculated Deviation: ____________

Source 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	Calc. Act.		bkg.	^{201}Tl	bkg.	^{99m}Tc	bkg.	Calc. Act.		bkg.	Notes	Init.

APPLICATION FOR MATERIAL LICENSE

Attachment 1

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) uniformity

Weekly: a) resolution 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

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. **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.

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. **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.

FREQUENCY OF TESTS:

Uniformity	Daily
Resolution-Distortion	Weekly
Pulse Height Analysis	As used

III. Other quality control procedures may be performed at monthly and 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.

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 Personnel Guide to Activities recommended for 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
Uniformity		X						after service
Resolution			X					after service
COR (SPECT)				X				after service
30,000,000 Cts				X				after service
Max CR								acceptance testing
Background Flood								acceptance testing
CR @ 20% loss								acceptance testing
Interlocks							X	after service
Switches							X	after service
Area Surveys (Contamination)								
Exposure Survey								
daily use areas		X						upon any incident
storage			X					
Wipe Survey			X					upon any incident
Sealed Sources								
Leak Test						X		upon damage
Sealed Source Inventory					X			upon suspected loss
Worker Instruction								
Initial Instruction							X	prior to first entry
Annual Training							X	prior to first entry
Personnel Monitoring								
Prior Dose								prior to first entry
Prenatal Exposure								prior to first entry
Exposure Reports				X			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

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.

	Investigational Levels (mRems per calender month) Level I (Caution)	Level II (Investigate)	Level III ANNUAL MPD
1. Whole body; head and trunk; active blood-forming organs; or gonads (a)	40 (0.4 mSv)	210 (21 mSv)	5,000 (0.05 Sv)
2. Lens of eye (b)	125 (12.5 mSv)	625 (62.5 mSv)	15,000 (0.15 Sv)
3. Hands and forearms; feet and ankles	415 (41.5 mSv)	2,100 (210 mSv)	50,000 (0.5 Sv)
4. Skin of whole body (c)	415 (41.5 mSv)	2,100 (210 mSv)	50,000 (0.5 Sv)

Action levels are evaluated monthly. Level I action levels are set at anproximately one-tenth of one-twelfth the Annual Limits. Level II action levels are set at one-half of one twelfth the Annual Limits.
(a) Total Effective Dose Equivalent (TEDE)
(b) Lens Dose Equivalent (LDE)
(c) Skin Dose Equivalent (SDE)
Data derived from 10 CFR 20.1201 and 10D-91.439 (FAC)

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 using, receiving, 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 dosimeters to them.

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 exchange the dosimeters at monthly intervals.

3. Prior to using radionuclides, each employee is instructed in at least the following:
   a. fundamental radiation effects and levels of exposure
   b. investigational levels established in the facility 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
   h. proper operation and use of radiation detectors

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

5. We evaluate personnel exposure on a monthly basis. All exposures should be below Level I (0.1 times one-twelfth the Annual MPD, or 40 mrem for the whole body or 415 mrem for hands & feet). We closely review any exposure below this level to decide whether the work activity justifies any higher exposure. If the worker received more than Level I exposure, but less than Level II (0.5 times one-twelfth the Annual MPD - 210 mrem to the whole body, 2,100 mrem to the hands and feet) we will review the exposure records with the individual to determine possible techniques for exposure reduction. If the individual received an exposure equal to or greater than Level II (0.5 times one-twelfth the Annual MPD) the causes of the exposure will be investigated and the employee counseled as necessary to reduce the the likelihood of additional exposures above ALARA. The results of the investigation will be recorded and operational procedures may be modified to prevent further exposures at these levels. These additional procedures may include the use of additional dosimeters, measurements, or administrative remedies.

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 12,500 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 no more than 0.5 rem for the total duration of the gestation period. If after declaring pregnancy it is determined that the exposure already received is within 0.05 rem of the 0.5 rem limit, the exposure will be limited to 0.05 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.

Attachment J7

UNITED STATES NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20); NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19); EMPLOYEE PROTECTION

WHAT IS THE NUCLEAR REGULATORY COMMISSION?

The Nuclear Regulatory Commission is an independent Federal regulatory agency responsible for licensing and inspecting nuclear power plants and other commercial uses of radioactive materials.

WHAT DOES THE NRC DO?

The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation and that nuclear facilities including power plants are constructed to high quality standards and operated in a safe manner. The NRC does this by establishing requirements in Title 10 of the Code of Federal Regulations (10 CFR) and in licenses issued to nuclear users.

WHAT RESPONSIBILITY DOES MY EMPLOYER HAVE?

Any company that conducts activities licensed by the NRC must comply with the NRC's requirements. If a company violates NRC requirements, it can be fined or have its license modified, suspended or revoked.

Your employer must tell you which NRC radiation requirements apply to your work and must post NRC Notices of Violation involving radiological working conditions.

WHAT IS MY RESPONSIBILITY?

For your own protection and the protection of your co-workers, you should know how NRC requirements relate to your work and should obey them. If you observe violations of the requirements, you should report them.

HOW DO I REPORT VIOLATIONS?

If you believe that violations of NRC rules or of the terms of the license have occurred, you should report them immediately to your supervisor. If you believe that adequate corrective action is not being taken, you may report this to an NRC inspector or the nearest NRC Regional Office.

WHAT IF I WORK IN A RADIATION AREA?

If you work with radioactive materials or in a radiation (controlled) area, the amount of radiation exposure that you may legally receive is limited by NRC Regulations. The limits on your exposure are contained in sections 20.101, 20.103, and 20.104 of Title 10 of the Code of Federal Regulations (10 CFR 20). While those are the maximum allowable limits, your employer should also keep your radiation exposure as far below those limits as is "reasonably achievable."

MAY I GET A RECORD OF MY RADIATION EXPOSURE?

Yes. Your employer is required to tell you, in writing, if you receive any radiation exposure above the limits set in the NRC regulations or your employer's license. In addition, if your job involves radiation, you may request from your employer a record of your annual radiation exposures and a written report of your total exposure when you leave your job.

HOW ARE VIOLATIONS OF NRC REQUIREMENTS IDENTIFIED?

NRC conducts regular inspections at licensed facilities to assure compliance with NRC requirements. In addition, your employer and site contractors conduct their own inspections to assure compliance. All inspectors are protected by Federal law. Interference with them may result in criminal prosecution for a Federal offense.

MAY I TALK WITH AN NRC INSPECTOR?

Yes. Your employer may not prevent you from talking with an NRC inspector and you may talk privately with an inspector and request that your identity remain confidential.

MAY I REQUEST AN INSPECTION?

If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the nearest NRC Regional Office and must describe the alleged violation in detail. It must be signed by you or your representative.

HOW DO I CONTACT THE NRC?

Notify an NRC inspector on-site or call the nearest NRC Regional office collect. NRC inspectors want to talk to you if you are worried about radiation safety or other aspects of licensed activities, such as the quality of construction or operations at your plant.

CAN I BE FIRED FOR TALKING TO THE NRC?

No. Federal law prohibits an employer from firing or otherwise discriminating against a worker for bringing safety concerns to the attention of the NRC. You may not be fired or discriminated against because you:

- ask the NRC to enforce its rules against your employer;
- testify in an NRC proceeding;
- provide information or are about to provide information to the NRC about violations of requirements;
- are about to ask for or testify, help, or take part in an NRC proceeding.

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

No employer may fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the NRC.

HOW AM I PROTECTED FROM DISCRIMINATION?

If you believe that you have been discriminated against for bringing safety concerns to the NRC, you may file a complaint with the U.S. Department of Labor. Your complaint must describe the firing or discrimination and must be filed within 30 days of the occurrence.

Send complaints to:

Office of the Administrator
Wage and Hour Division
Employment Standards Administration
Room S3502
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

or any local office of the Department of Labor, Wage and Hour Division. Check your telephone directory under U.S. Government listings.

WHAT CAN THE LABOR DEPARTMENT DO?

The Department of Labor will notify the employer that a complaint has been filed and will investigate the case.

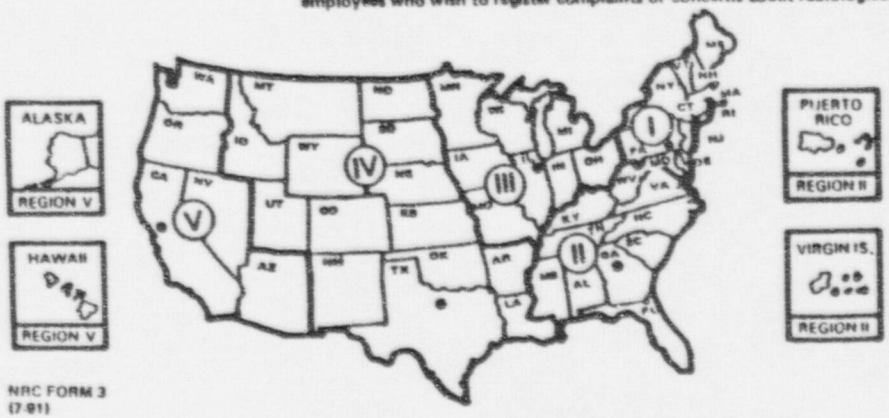
If the Department of Labor finds that your employer has unlawfully discriminated against you, it may order you to be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination.

WHAT WILL THE NRC DO?

The NRC may assist the Department of Labor in its investigation. NRC may conduct its own investigation where necessary to determine whether unlawful discrimination has prevented the free flow of information to the Commission. Also, if the NRC or Department of Labor finds that unlawful discrimination has occurred, the NRC may issue a Notice of Violation to your employer, impose a fine, or suspend, modify, or revoke your employer's NRC licenses.

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICE LOCATIONS

A representative of the Nuclear Regulatory Commission can be contacted at the following addresses and telephone numbers. The Regional Office will accept collect telephone calls from employees who wish to register complaints or concerns about radiological working conditions or other matters regarding compliance with Commission rules and regulations.



Regional Offices

REGION	ADDRESS	TELEPHONE
I	U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415	(215) 337-5000
II	U.S. Nuclear Regulatory Commission Region II 101 Marietta St., N.W., Suite 2900 Atlanta, GA 30323	(404) 331-4503
III	U.S. Nuclear Regulatory Commission Region III 799 Roosevelt Road Glen Ellyn, IL 60137	(708) 790-5500
IV	U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-8064	(817) 860-8100
V	U.S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596-5368	(510) 975-0200

To report incidents involving fraud, waste or abuse by an NRC employee or NRC contractor,

telephone:

OFFICE OF THE INSPECTOR GENERAL

HOTLINE

1-800-233-3497

NRC FORM 3
(7-91)

Environmental Monitoring

To assure compliance with 10 CFR 20.1301 -1501 of the Code of Federal Regulations *Dose limits for individual members of the public,* the licensee will establish a program of environmental monitoring. Elements of the monitoring program will consist of (1) 24 hour environmental using thermoluminescent dosimeters, and (2) radiation exposure surveys conducted in the unrestricted area.

The area to be monitored will be chosen as that area most accessible to members of the public and considering the probable occupancy time in that area by any one member of the public. The licensee will assume a member of the public occupying the monitored area to be accompanying a patient for a test and waiting a period of 4 hours in this area. The area to be monitored is marked with the symbol "*" on the facility floor plan.

Should significant operational changes occur, the Radiation Safety Officer will determine the appropriateness of revising this environmental monitoring program.

Procedure for twenty-four hour environmental monitoring:

The licensee will use thermoluminescent dosimeters (TLD's) as environmental monitors and will evaluate the exposure received by the dosimeters on a per three month basis.

The licensee will set a trigger level using a 10x safety factor to initiate action by the RSO.

Factors:

$$\text{Three month limit} = \frac{100\text{mRem/yr}}{4\ \text{quarters/yr}} = 25\text{mRem}$$

$$\text{Occupancy factor} = \frac{1\text{person x 4 hours occupancy}}{2184\ \text{hours monitored}} = .002$$

Safety factor for trigger level = 10

Calculations:

$$\text{Trigger level} = \frac{25\text{mRem}}{.002 \times 10} = 1250\ \text{mRem}$$

The Radiation Safety Officer will evaluate the environmental readings each monitored period and take appropriate action should the three month TLD reading trigger level be reached.

Procedure of radiation exposure surveys:

The licensee will perform radiation exposure surveys using the survey instrument in the unrestricted area indicated not less than each week of use after a daily supply of radiopharmaceuticals has been received. A trigger level of 2 millirems per hour net of background will be set to initiate notification of the Radiation Safety Officer.

Leak Testing of Sealed Sources

The procedure for leak testing of sealed sources, referenced elsewhere in this application, is given below. Leak testing of sealed sources will be performed every six months.

1. Our facility will list all sources to be leak tested. The list will include the following information: (a) radioisotope, (b) activity at a specific date, (c) the physical form of the source.
2. Each source will be wiped ("swiped") with a cotton swab, using caution to not touch the source with anything other than the swab. The source will be shielded as much as possible. Each swab will be identified according to the tested source. The operator will use caution not to become contaminated with the swab or source or to allow swabs to be cross contaminated.
3. After counting a gamma reference source of ^{133}Ba or ^{137}Cs, count the "swipe swabs" with the NaI well/scaler under the same conditions to determine if any counts (activity indication) are present. Testing will determine the operation and detection sensitivity of the system.
4. If no above background swipe-swab counts are present, record all information as cpm and note that the leak testing was completed on the container of each source. If swipe-swab counts are present, calculate the uCi using the cpm/uCi determined from the reference source (these are the same calculations performed in the Removable Contamination Survey).
5. If the swipe-swab activity is 0.005 uCi or more, the RSO will be notified and the source withdrawn from use. The source will either be repaired or discarded according to the Waste Disposal Procedures.

Sample Record Form for Wipe Testing of Sealed Sources

Date_____ Time_____ By_____ ASSAY—Date_____ Time_____ By_____

SAMPLE ANALYSIS

Radioactive Material			Swipe	Gross	—	Bkg.	=	Net	x	uCi	=	µCi	notes
Isotope	Activity	Form	#	cpm		cpm		cpm		cpm			

STANDARD ANALYSIS

A. Assay uCi _____ x Decay Factor _____ = uCi _____

B. Gross cpm _____ — Bkg. cpm _____ = Net cpm _____

C. Calibration Factor = _____ $\frac{uCi}{cpm}$

Instrument: _____

STANDARD—Radionuclide: _____ ASSAY—Activity: _____ Date: _____

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 TEST REPORT

License #_____ Licensee_____

Licensee Address:_____

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

Sample data:

Nuclide Source	Serial Number	Source Use	Source Form	Swipe method	Sample cpm	Bkg cpm	Net cpm	Std dis/ct	dpm/2.22 ·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

Sources:

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

Activity on _____

^{137}Cs _____ µCi (_____ years decayed-D.F.=._____)

^{57}Co _____ µCi (_____ days decayed -D.F.=._____)

^{133}Ba _____ µCi (_____ years decayed-D.F.=._____)

Data: (Averages from 3 counts each)		Calculated Dpm	Efficiency:
Background	_____ ncpm		n/a
^{137}Cs	_____ ncpm	_____ dpm	___ disintegrations ct^{-1}
^{57}Co	_____ ncpm	_____ dpm	___ disintegrations ct^{-1}
^{133}Ba	_____ ncpm	_____ dpm	___ disintegrations ct^{-1}

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 I and rinse with tepid water. Remonitor for removal/residual activity.
3. Wash with NUC-WASH II and NUC-WASH III, if necessary. With each wash, and rinse with tepid water and remonitor for removal/residual activity.
4. If NUC-WASH III 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 (A, B, and/or C,) 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

1. Wear rubber or latex 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 Radiation Safety Officer (RSO).

3. Measure the exposure rate from the package with a GM type survey meter (side window) at one meter, and then at the surface. If the exposure rate is higher than expected stop and notify the RSO for specific instructions before proceeding. (Exceptions: See 20.1906)

> **NOTE:** Maximum surface exposure rate of labeled packages: White I-0.5 mR/hr, Yellow II-50 mR/hr, Yellow III-200 mR/hr. None of these rates should be exceeded. (DOT 49 CFR 172)

4. Wipe an area of 100 square cm to evaluate the possible presence of removeable contamination. Measure wipes using a sodium iodide true detector to insure dpm do not exceed regulatory limit. (See 5f2)

5. If the initial surveys are satisfactory, open the package according to the following procedure:
   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 box is 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.

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

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

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

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

DIS - Decay In Storage dpm - disintegrations per minute

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

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

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

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

Prescription Record	Dose Calibrator	Disposal Record
Activity ______ Isotope ______ Form ______ Patient ______ Time ______ By ______	Pre-Administration Activity Check ______	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	Expr. Date	Patient		By	Disposal	
			Activity	Date	Time	Date	Time			Name	Number		Date	Route

Radioactive Material Package Order and Receipt Record

Order		Receipt		Package	Radioactive Material			Package	Exposure		Contamination						By
Date	By	Date	Time	ID #	Isotope	Total Activity (mCi)	Form	Condition	1 M mR/hr	Surface mR/hr	BG (cpm)	Net Ext (cpm)	Net Int (cpm)	d/c	Net Ext (dpm)	Net Int (dpm)	

Package Condition: Acceptable (A)
Damaged (D)
Wet/Discolored (W)
Uneven Exposure Rate (U)

Trigger Levels: Exposure Rate
Radioactive I Surface < 0.5mrem/hr — 1m = NA
Radioactive II Surface > 0.5 to ≤50 mrem/hr — 1m = > 0 to < 1.0 mrem/hr
Radioactive III Surface > 50 to ≤200 mrem/hr — 1m = > 1.0 to < 10 mrem/hr
2x BG (BG determined individually for each site) surface for empty packages
Contamination
Package Wipes 22,000 dpm

APPLICATION FOR MATERIAL LICENSE

Attachment P 3

UNIDOSE DISTRIBUTION RECORD

Nuclear Record System

Nuclide: _____

Form: _____

Date Received	Supplier	Lot Number	Supplier Assay			Patient Name	#	Patient ID	Referral	Prescription	Clinical Proc.	Pres. Activity	Dose Cal.	Administration			Disposal	
			Activity	Date	Time									Date	Time	By	Date	Route

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 only for 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" 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 administered will be surveyed for removable contamination at the end of each week that radioactive materials are used, by means of a sodium iodide detector system, or one of comparable sensitivity.
2) Areas that are used only for radiopharmaceutical waste storage, where no daily activities take place, will be surveyed at the end of each week by wipe or swipe testing using a sodium iodide detector.
3) 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 greater than 1000 dpm per 100 square cm of 57-Co, 99m-Tc, or 201-Tl is found. Also notify RSO if 100 dpm per 100 square cm of any other radionuclide is found. This assay will use "swipes" or "wipes", as indicated on the third page of this section.
4) Removable contamination surveys will be completed as part of the "spill" procedure.

Contamination **Action Levels: (dpm/100 square cm of surface contamination)**

	Contaminant Radionuclide	
Area	57Co, 99mTc, 201Tl	All Others
Unrestricted or Uncontrolled Areas	2000	200
Controlled or Restricted Areas	20,000	2,000

APPLICATION FOR MATERIAL LICENSE

Attachment Q 2

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/E _____ Kev to _____ Kev

Standard: Radionuclide _____ Assay: Activity _____ Date _____

I. SURVEY AREA

II. SAMPLE ANALYSIS

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

*from "Standard Analysis" below

**see "Contamination Action Levels" below

III. STANDARD ANALYSIS

A. Gross cpm _____ — Bkg. cpm _____ = Net cpm _____

B. Assay ucl _____ x Decay Factor _____ = uCl _____

C. uCl _____ x 2.22 x 10^6 dpm / uCl = dpm _____

D. Calibration Factor $^A/_c$ = Net cpm / dpm = _____ / _____ = cpm,/dpm _____

IV. CONTAMINATION ACTION LEVELS (dpm/100 cm^2 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 surveysd
3. Usi.g the index finger, lightly press the swipe on the surfc:s (1 cm^2)
4. Wipe a distance of 100 cm for a sample area of 100 cm^2
5. Fold the swipe wiht he 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 containiner	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

MAR 2 1 1997

Ali N. Shaikh, M.D.
Rock River Professional Building
Suite 109
21851 Center Ridge Road
Rocky River, OH 44116

Dear Dr. Shaikh:

Enclosed is your NRC Material License Number 34-26783-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. You have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. You have notified the U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Licensing Branch, in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

302333

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

5. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issue pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the

General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 34-26783-01
Docket No.: 030-34400

Enclosure: License No. 34-26783-01

DOCUMENT NAME: M:\03034400.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	N						
NAME	EMATSON:jaw							
DATE	03/ /97							

OFFICIAL RECORD COPY

Attn:

Mrss. EVELYN MATSON

from BASEL MOUSSA

Reg: NRC license

enclosures:

(1) OH ~~to~~ Medical license

(2) pls Have Dr. Ali Shaikh's name as owner of license.

Thank you for your time and thoroughness.

Basel

Please notify the board in writing, of any change in your address.

Please refer to your license number on all correspondence with the board.

Ohio law requires that every physician's wall certificate be displayed in the physician's office where a major portion of such physician's practice is conducted.

STATE MEDICAL BOARD OF OHIO
77 S. High St., Columbus, Ohio 43266-0315

EXPIRES: 09/30/98 *LICENSE NUMBER* 35-87-1067

1 9 9 6 **Celebrating 100 Years 1896-1996** 1 9 9 8

BASEL ZAHEER MOUSSA,MD
is duly registered and entitled to practice in The State of Ohio until the expiration date.

AUDIT # : 633490

BASEL ZAHEER MOUSSA,MD

1313 HUNTINGTON AVE
HUNGTINGTON WV 25701

Mary F. Boledovic

MARY F. BOLEDOVIC
Notary Public, State of Ohio
County of Columbus
Commission 6-21-98

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

February 20, 1997

Basel Moussa, M.D.
Radiation Safety Officer
Rocky River Professional Building
21851 Center Ridge Road, Suite 109
Rocky River, OH 44116

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Application Dated 02/18/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

X New License ___ Amendment ___ Renewal

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

It appears that your request is routine (see 1-3 below as, applicable).

Incomplete information is as follows: In order for us to complete your request for a NRC License the required fee is necessary. Please contact our License Fee & Debt Collection Branch, as referenced below, to obtain the correct fee amount.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however under timely filing (before expiration) you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302333
License No. 34-26783-01