NRC FORM 313
(3-92)
10 CFR 30, 32 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO 3150-0120
EXPIRES 6-30-93
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3.25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATION WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATION AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
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:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

03020240
X

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 JURISDICTIONS.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [x] C. RENEWAL OF LICENSE NUMBER 45-23073-01

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

Woodburn Nuclear Medicine, Ltd.
Woodburn Medical Park, Suite 060
3289 Woodburn Road
Annandale, VA 22003
(703) 698-0666

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

Woodburn Nuclear Medicine, Ltd.
Woodburn Medical Park, Suite 050
3289 Woodburn Road
Annandale, VA 22003

Woodburn Nuclear Medicine, Ltd.
woodburn Nuclear Park, Suite 060
3289 Woodburn Road
Annandale, VA 22003

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: **Michael W. Lairmore, Medical Physics Consultation**

TELEPHONE NUMBER: **(201) 447-3303**

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 **N/A**

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 OFFICIAL	TYPED/PRINTED NAME	TITLE	DATE
Eric H. Norby MD	Eric H. Norby, M.D.,	President	3-16-05

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER

'05 MAR 24 P12:52

APPROVED BY | DATE

RECEIVED
REGION 1

NRC FORM 313 (3-92)

136820

NMSS/RGNI MATERIALS-002

	ITEM #5	ITEM #6
BYPRODUCT MATERIAL	**AMOUNT**	**PURPOSE**
Any byproduct materials identified in 10 CFR 35.100 for uptake, dilution and excretion procedures.	As needed	Medical Use
Any byproduct materials identified in 10 CFR 35.200 for imaging and localization procedures.	As needed	Medical Use
Any byproduct materials identified in 10 CFR 35.300 for diagnostic or therapy procedures.	As needed (not to exceed 55.5 gigabecquerels (1.5 curies of I-131)	Medical Use
Any byproduct materials identified in 10 CFR 35.311 for clinical in vitro studies.	As needed - pre-packaged kits	Medical Use

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM - THEIR TRAINING & EXPERIENCE

Item 7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER	
Julio Garcia, M.D.	35.100; 35.200; 35.300
Eric H. Norby, M.D.	35.100; 35.200; 35.300; 31.11
Patrick J. Peller, M.D.	35.100; 35.200; 35.300; 31.11
Aaron M. Kistler, M.D.	35.100; 35.200; 35.300
Aaron L. Stack, M.D.	35.100; 35.200; 35.300; 31.11

Please refer to our current license (License Number: 45-23073-01) for confirmation of authorized user status.

Item 7.2

RADIATION SAFETY OFFICER

Steven K. West, CNMT

Please refer to Attachment 7.2 for confirmation of training and experience

Item 8.1

TRAINING PROGRAM:

We will establish and implement the model training program outlined within the Final Report to Nuclear Regulatory Guide 1556, Volume #9, **Appendix J entitled; "Model Training Program".**

Item 9.1

FACILITIES AND EQUIPMENT DIAGRAM

Refer to Attachment 9.1

Item 9.2

INSTRUMENT CALIBRATIONS:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix K entitled; "Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program".**

Records of survey meter calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration. If needed, a loaner survey meter will be made available at the time of annual calibration.

Survey meter calibrations will be performed by W.H. Henken Industries or an equivalent service vendor. W.H. Henken operates under, Texas Radioactive Material License Number: LOO967.

Item 9.3

DOSE CALIBRATOR CALIBRATION

We will establish and implement the model procedure outlined in Revised Draft Report, Nuclear Regulatory Guide 1556, Volume #9, **Appendix J entitled; "Model Procedures For Dose Calibrator Calibration".**

In regards to instrument calibrations, will will follow all manufacturer's suggestions and guidance.

Item 9.4

PERSONNEL MONITORING PROGRAM:

We will establish and implement the model procedure outlined in the Final Report to Nuclear Regulatory Guide 1556, Volume #9, **Appendix M entitled; "Model Procedures For an Occupational Dose Program".**

Item 9.6

Attachment 9.6

NUCLEAR MEDICINE EQUIPMENT

1. **Survey Meters:**

a. Manufacturer's name: Ludlum 14C or comparable meter

Manufacturer's model number:14C with 44-9 pancake probe

Number of instruments available: 3

Instrument range:0.01 - 2000 mrem/hr

2. **Dose Calibrator:**

a. Manufacturer's name: Capintec

Manufacture's model number: CRC-15 or equivalent

Number of instruments available: 2

3. **Well/Uptake Probe Detector:**

a. Manufacturer's name: Atom Lab 950, Uptake Probe & Well Counter

Number of instruments available:1

4. **Gamma Camera:**

a. Manufacturer's name: Siemen's Dual Head or equivalent

Number of instruments available: 6

Item 10.1

RADIATION SAFETY OFFICER: DELEGATION OF AUTHORITY:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix I entitled; "Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority**".

Item 10.3

PROCEDURE FOR LEAK TESTING SEALED SOURCES:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix Q entitled; "Model Leak Test Program".**

Item 10.4

RULES FOR SAFE USE OF RADIOPHARMACEUTICAL:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix T entitled; "Model Procedure for Safe Use of Unsealed Licensed Material".**

Item 10.5

EMERGENCY PROCEDURES:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix N entitled; "Model Emergency Procedures".**

Item 10.6

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix O entitled; "Model Procedures for Ordering and Receiving Packages".**

Item 10.7

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix P entitled; "Model Procedures for Safely Opening Packages Containing Radioactive Material"**

Item 10.8

RECORDS OF UNIT DOSE USE:

We will establish and implement the model procedure outlined in Regulatory Guide 10.8, Revision 2, Appendix M. for Unit Dosage Record System.

Item 10.9

RECORDS OF MULTIDOSE VIAL USE:

We will establish and implement the model procedure outlined within Regulatory Guide 10.8, Revision 2, Appendix M for a Multi Dose Vial Record System

Item 10.12

PROCEDURE FOR AREA SURVEY:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix R entitled; "Model Procedures for Area Surveys"**

Action trigger limits for ambient exposure and removable contamination will be as follows:

Restricted Areas:	Unrestricted Areas:
Ambient exposure = 5.0 mR/hr	Ambient exposure = 0.05 mR/hr
Removable Contamination:	Removable Contamination:
2,000 dpm/100 cm2 (gamma emitters)	200 dpm/100 cm2

Item 11

PROCEDURE FOR WASTE DISPOSAL:

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix W entitled; "Model Procedures for Waste Disposal by Decay-In-Storage"**

Item 12

WRITTEN DIRECTIVE PROGRAM

We will establish and implement the model procedure outlined in the Final Report of Nuclear Regulatory Guide 1556, Volume #9, **Appendix S entitled; "Model Procedures for Developing, Maintaining, Implementing Written Directives"**

Attachment 7.2

Radiation Safety & Control Services, Inc.

Awards this certificate to

Steven K. West

in recognition of satisfactory completion of our 40-hour

Radiation Safety Officer Training Course

Las Vegas, Nevada

December 6 - 10, 2004

Frederick P. Straccia, CHP

This course has been approved for 40, Category A, CE credits (reference number NHZ0183001) by the ASRT Dept. of Education.

NOTE: This class satisfies the Department of Transportation requirements listed in 49 CFR 172.704 and expires three years from the date listed above.

WOODBURN NUCLEAR MEDICINE

March 14, 2005

Licensing Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Steven K. West, CNMT
Confirmation of RSO training
License Number: 45-23073-01
Woodburn Nuclear Medicine, Ltd.

Dear License Reviewer:

Please allow this correspondence to confirm, supervised radiation safety officer training for Steven K. West, CNMT. Over the past several years, Mr. West has worked under my supervision to acquire the necessary training to allow him to serve as a radiation safety officer.

In addition, Mr. West has completed a 40 hour radiation safety officer training course provided by "Radiation Safety & Control Services, Inc.". A copy of his academic training has been enclosed in Attachment 7.2 of the renewal application. Please refer to this document for details.

If you require additional information regarding Mr. West's RSO training, please contact me at (703) 698-0006.

Sincerely,

Eric H. Norby, M.D.
President/Radiation Safety Officer

3289 Woodburn Road ■ Suite 060 ■ Annandale, VA 22003-6800 ■ 703/698-0666

THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS

MINNEAPOLIS, MINNESOTA

Representative of

The American College of Radiology and

The American Society of Radiologic Technologists

HEREBY CERTIFIES THAT

Steven K. West

has pursued an approved educational program in Nuclear Medicine Technology, has met certain standards and qualifications and has passed the examinations conducted under authority of this Registry, and is thus qualified as a

Registered Technologist

Nuclear Medicine Technology

and by virtue of this certificate is authorized to use the title Registered Technologist and its abbreviation R.T. (N) (ARRT) as long as this certificate is in force as is indicated by the date appearing on the seal hereon attached.

Nuclear Medicine Technology Certification Board

SPONSORED BY

THE BOARD OF REGISTRY OF THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

THE SOCIETY OF NUCLEAR MEDICINE

AND

TECHNOLOGIST SECTION OF THE SOCIETY OF NUCLEAR MEDICINE

HEREBY CERTIFIES THAT

STEVEN K. WEST

HAS MET THE REQUIREMENTS THROUGH EXAMINATION BY THIS BOARD

AND IS HEREBY QUALIFIED TO PRACTICE THE SPECIALTY OF

NUCLEAR MEDICINE TECHNOLOGY

JUNE 24, 1989

NUCLEAR MEDICINE TECHNOLOGY

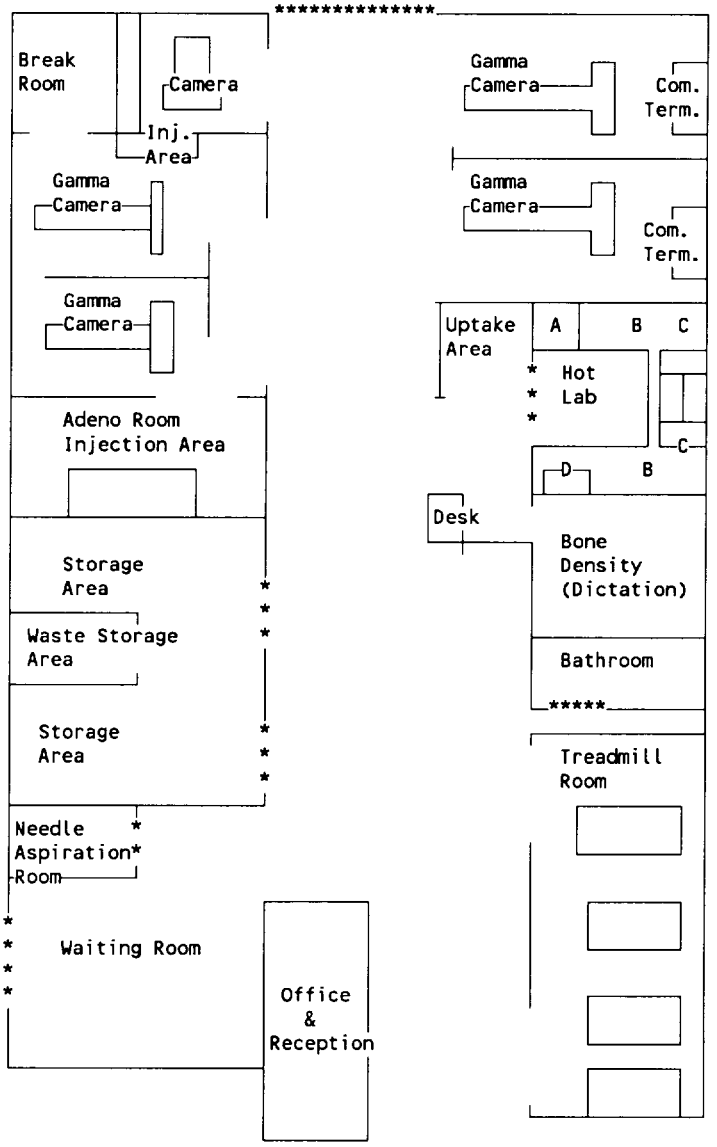
Helen M. Drew, C.N.M.T.

CHAIRMAN

Attachment 9.1

Woodburn Nuclear Medicine Ltd., Suite 60
Annandale, VA
Nuclear Medicine Department

North



Legend:

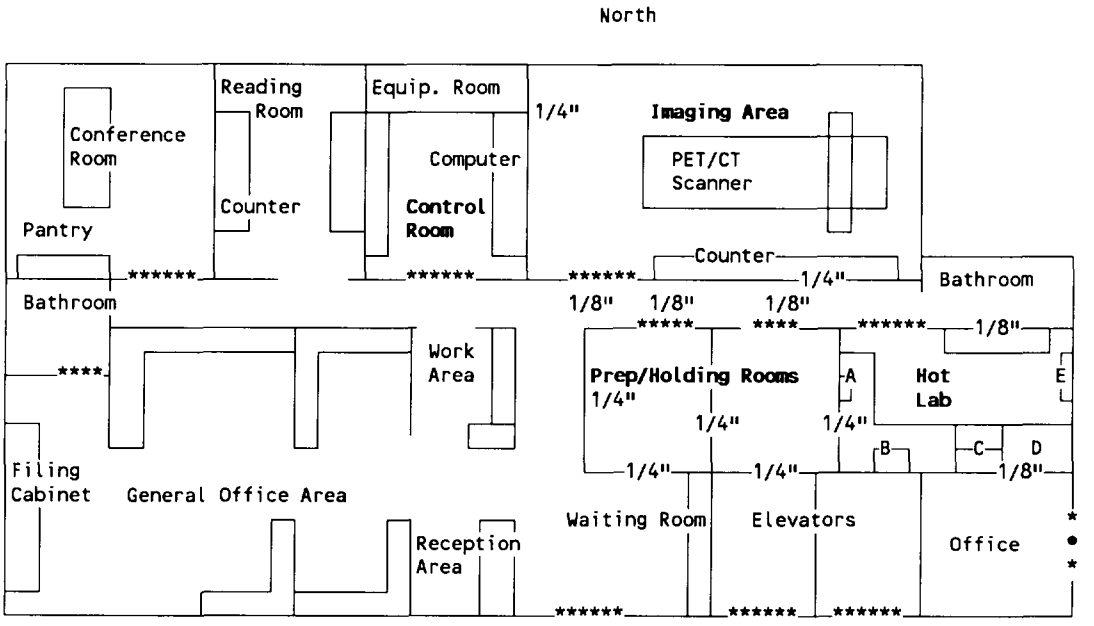
A. Waste/Sealed Source Storage Cabinet (1/4" lead-liner)
B. Package Receipt Area
C. Dose Calibrator
D. NMIS Computer

*** Locked Door

The nuclear medicine department is surrounded by professional office suites.

Woodburn Nuclear Medicine
PET/CT Imaging Center
3289 Woodburn Avenue, Suite 50
Annandale, VA 22003

PET Center Diagram



Legend:

A: Well Counter
B. Sink
C. L-Shield & Preparation Area (1/4" lead shielding)
D. Dose Calibrator & Package Receipt Area
E. Waste Disposal Area (1/4" lead-liner)

*** Locked Door
1/8" = 1'

This is to acknowledge the receipt of your letter/application dated

3/16/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Renew (45-23073-01)

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136820.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02200
Status Code: 2
Fee Category: 7C
Exp. Date: 20050531
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: WOODBURN NUCLEAR MEDICINE, LTD.
   Received Date: 20050324
   Docket No: 3020240
   Control No.: 136820
   License No.: 45-23073-01
   Action Type: Renewal

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Jurnod
Date 4/15/2005

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

1. Fee Category and Amount: _____

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

3. OTHER _____
   _____

Signed _____
Date _____