David Rhoe
CRMI
Paseo de la Fuente
D-4 Calle Tivoli
San Juan, PR 00926

December 27, 2004

US NRC RII – Atlanta Federal Center
Suite 23T85, ATTN: DNMS
61 Forsyth Street
Atlanta, GA 30303

L 25430
03036804
02200
(52-25430-02)

Dear Mr. Sir or Madam:

Please find enclosed the ~~renewal~~ new license application ~~change of ownership for our NRC License Number 52-25058-01.~~

If you need any further information, please contact me at (787) 245-7248.

Sincerely,

David Rhoe

136251

REC'D IN LAT JAN - 3 2005

NRC FORM 313 (8-2000) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 08/31/2002

Estimated burden per response to comply with this mandatory collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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 APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS 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:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

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

L 25430
030 36804
02200
(52-25430-02)

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

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*
   David Rhoe
   Paseo de la Fuente
   D-4 Calle Tivoli
   San Juan, PR 00926
   CRMI
   MB

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   See Attached
   GPO Box 13798
   Aibonito, PR 00705-1375

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   David Rhoe
   TELEPHONE NUMBER
   787-245-7248

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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 EXPERIENCE.

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
   FEE CATEGORY | AMOUNT ENCLOSED $

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

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, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED 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.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
David Rhoe	David Rhoe	12-28-04

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	136251

Item 1 Address

a) Mailing address
David Rhoe
Paseo de la Fuente
D-4 Calle Tivoli
San Juan, PR 00926
(787) 245-7248
Fax (787) 292-7976

b) Main Office address

(Nuclear Gauges)	*(Nuclear Medicine)*	*(Nuclear Medicine)*
Office #1	Office #2	Office #3
David Rhoe	Mennonite General Hospital	Hospital Mennonite Cayey
Paseo de la Fuente	Nuclear Medicine Laboratory	Nuclear Medicine Laboratory
D-4 Calle Tivoli	Calle José Vazquez Esq. Dr. Troyer	Carr. #14 Km 72
San Juan, PR 00926	Aibonito, PR 00705-1379	Bo. Rincon, Sector Lomas
(787) 245-7248	(787) 735-8001 Ext. 1403	Cayey, PR
Fax (787) 292-7976	(787) 735-8082 Ext. 1558	N/A

c) Physical location (storage/location of the radiation sources & records)

(Nuclear Gauges)	*(Nuclear Medicine)*	*(Nuclear Medicine)*
Office #1	Office #2	Office #3
David Rhoe	Mennonite General Hospital	Hospital Mennonite Cayey
Paseo de la Fuente	Nuclear Medicine Laboratory	Nuclear Medicine Laboratory
D-4 Calle Tivoli	Calle José Vazquez Esq. Dr. Troyer	Carr. #14 Km 72
San Juan, PR 00926	Aibonito, PR 00705-1379	Bo. Rincon, Sector Lomas
(787) 245-7248	(787) 735-8001 Ext. 1403	Cayey, PR
Fax (787) 292-7976	(787) 735-8082 Ext. 1558	N/A

The following is based on Medical Use Licenses, NUREG 1556 Vol 9, October 2002, Appendix C

Item 5 and 6: Materials to be Possessed and Proposed Uses

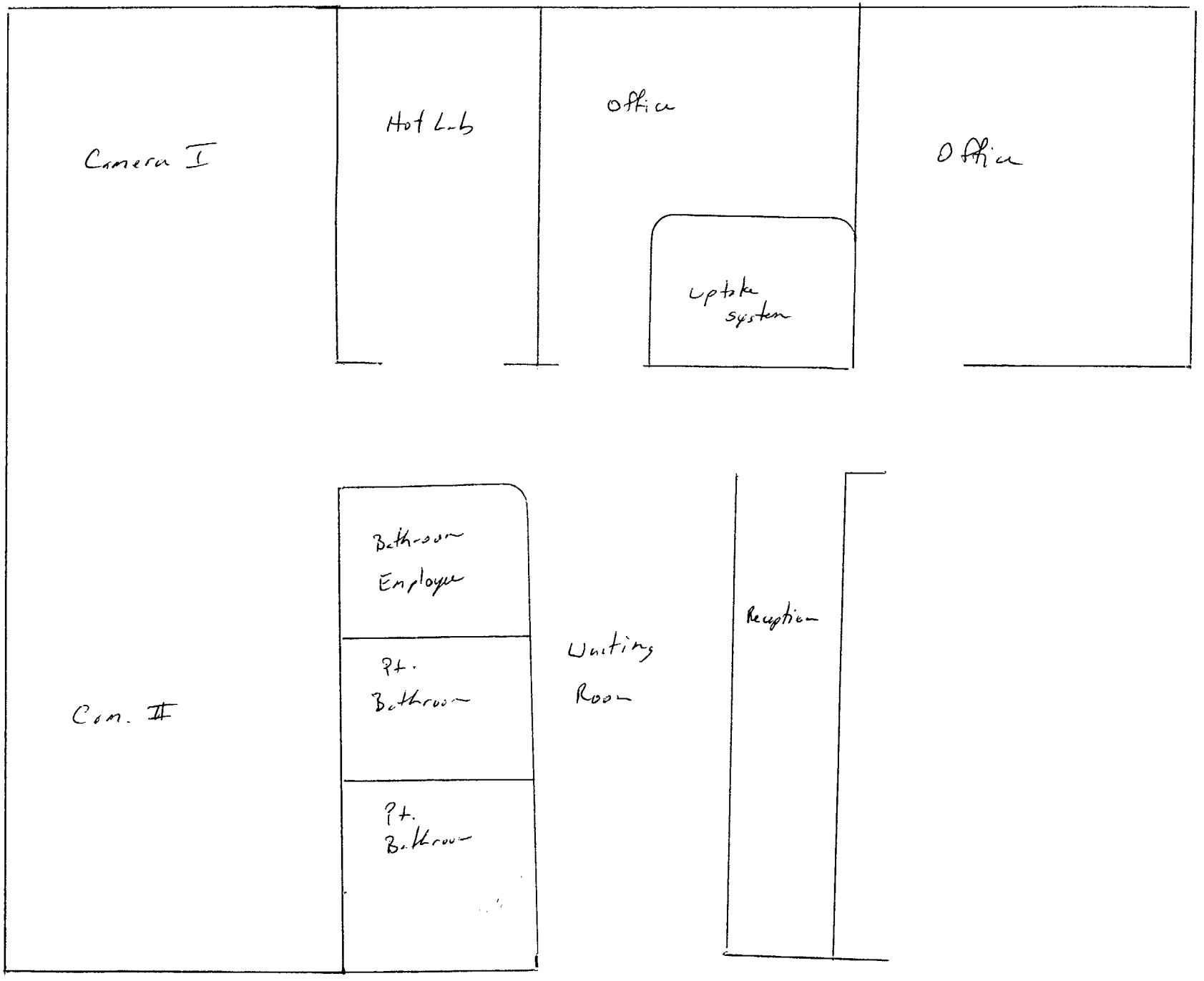
Nuclear Medicine

YES	Radionuclide	Form or Manufacturer	Maximum Quantity	Purpose of Use
X	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
X	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.200
X	Any byproduct material permitted by 10 CFR 35.300	Any	500 millicuries	Any uptake, dilution, and excretion study permitted by 10 CFR 35.300
	Any byproduct material permitted by 10 CFR 35.400	Sealed sources North American Model No. MED3631 (I-125)	500 millicuries	Any uptake, dilution, and excretion study permitted by 10 CFR 35.400
	Any byproduct material permitted by 10 CFR 35.500	Sealed sources _____ Model No. _____	___ Ci/source _____ Ci total	Diagnostic medical use of sealed source permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32 (g)
X	I-131	Any	500 millicuries	Administration of I-131 sodium iodide.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	50 millicuries	In vitro studies

Nuclear Medicine Laboratory

Item No. and Title	Response
7. Radiation Safety Officer. Name: David Rhoe.	☒ Previously on license number: NRC 52-25430-01. or ☐ Copy of the certification(s) for the board(s) recognized by the NRC and as applicable to the types of use for which he or she has RSO responsibilities. or ☐ Description of the training and experience specified in 10 CFR 35.900(b). or ☐ Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. and ☐ Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license has been achieved. and ☐ If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59 and ☐ RSO Signature: _____ Date: _____
7. Authorized Users Names and Requested Uses for Each Individual. Name: Sandra Gracia-Lopéz, MD	X Previously on license number: NRC 52-25058-01. or ☐ Copy of the certification(s) for the board(s) recognized by the NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested. or ☐ Description of the training and experience specified in 10 CFR 35.900(b). or ☐ Description of the training and experience specified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested. or ☐ A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested; and ☐ Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency to function independently as an AU for a medical uses authorized has been achieved. and ☐ If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59
9. Facility Diagram.	☒ A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included: ☒ Drawing should be to scale, and indicate the scale used. ☒ Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above the heading "Discussion"; ☒ Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is restricted or unrestricted area as defined in 10 CFR 20.1003; and

	❑ Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of the shielding calculations including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.) In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.
9. Radiation Monitoring Instrument. Geiger Mueller Range 1-100 mR/hr End window or pan probe	☒ A person qualified to perform survey meter calibrations will calibrate radiation monitoring instruments. and/or ❑ We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61. and ❑ A description of the instrument (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, LSC, proportional counter) that will be used to perform required surveys is indicated in the left column. and ☒ We reserve the right to upgrade our survey instrument as necessary as long as they are adequate to measure the type and level of radiation for which they are used.
9. Dose Calibrator and Other Dosage Measuring Equipment.	☒ Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.
10. Occupational Dose.	☒ Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide Dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9, "Consolidated Guidance About Materials License: Program-Specific Guidance About Medical Use Licensees," dated October 2002. or ❑ A description of an alternative method for demonstrating compliance with the referenced regulations.
10. Areas Surveys.	☒ We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.
10. Safe Use of Unsealed Licensed Material.	☒ We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 1301.
10. Spill Procedures and Minimization of Contamination.	☒ We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.
10. Minimization of Contamination	☒ A response is not required.
11. Waste Management.	☒ We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K tp 10 CFR Part 20 and 10 CFR Part 35.92.


Camera I
Hot Lab
Office
Office
uptake system
Bathroom Employee
Pt. Bathroom
Pt. Bathroom
Waiting Room
Reception
Cam. II

Office #2

This is to acknowledge the receipt of your letter/application dated
NRC314 / NRC 313 020
020 12/28/2004 / 12/28/2004 and to inform you that the initial processing which includes an administrative review has been performed.

TERM 52-25058-01 & NEW LICENSE APP. (03036804)

☑ 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** 136250 / 136251
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: 3
Fee Category: _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: CRMI
   Received Date: 20050103
   Docket No: 3036804
   Control No.: 136251
   License No.: 52-25430-02
   Action Type: New License

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

3. COMMENTS
   Ref. 136250.

Signed M. A. Berbian
Date 1/7/2005

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 _____