12-24337-01
030-18492

NRC Form 313 I (12-81) 10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

# APPLICATION FOR BYPRODUCT MATERIAL LICENSE
## INDUSTRIAL

*See attached instructions for details.*

*Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.*

1. APPLICATION FOR: *(Check and/or complete as appropriate)*

| | |
|---|---|
| X | a. NEW LICENSE |
| | b. AMENDMENT TO: LICENSE NUMBER |
| | c. RENEWAL OF: LICENSE NUMBER |

2. APPLICANT'S NAME *(Institution, firm, person, etc.)*

Biotec Biomedical Tech., Inc.

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION

312-837-6484

3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION

James M. Raue

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION

312-837-6484

4. APPLICANT'S MAILING ADDRESS *(Include Zip Code)*
*(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)*

320 South Main
Bartlett, IL 60103

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED *(Include Zip Code)*

Various--to be used for demonstration purposes

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
*(See Items 16 and 17 for required training and experience of each individual named below)*

| | FULL NAME | TITLE |
|---|---|---|
| a. | James M. Raue | |
| b. | | |
| c. | | |

RECEIVED BY LMB
Applicant James Raue for
Check No. 5351
Amount/Fee Category 3L $150
Type of Fee APP
Date Check Rec'd 5/7/84
Received By
Date 5/7/84
Log
By
Orig To
Action Compl

7. RADIATION PROTECTION OFFICER

James M. Raue

*Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.*

8. LICENSED MATERIAL

| LINE NO. | A ELEMENT AND MASS NUMBER | B CHEMICAL AND/OR PHYSICAL FORM | C NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)* | D MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME |
|---|---|---|---|---|
| (1) | Iodine 125 | absorbed on solid sealed | Lixi, Inc. Lixiscope Model | 500mCi per |
| (2) | | source AECL-C-324 | LSM82-209 | source |
| (3) | | | | |
| (4) | | | | |

| | E DESCRIBE USE OF LICENSED MATERIAL |
|---|---|
| (1) | Demonstration purposes |
| (2) | |

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REG3 LIC30
PDR

Control No. 76700

## 9. STORAGE OF SEALED SOURCES

| LINE NO. | CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A. | NAME OF MANUFACTURER B. | MODEL NUMBER C. |
|---|---|---|---|
| (1) | Lixiscope | Lixi, Inc. | LSM82-209 |
| (2) | | | |
| (3) | | | |
| (4) | | | |

## 10. RADIATION DETECTION INSTRUMENTS

| LINE NO. | TYPE OF INSTRUMENT A | MANUFACTURER'S NAME B | MODEL NUMBER C | NUMBER AVAILABLE D | RADIATION DETECTED (alpha, beta, gamma, neutron) E | SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F |
|---|---|---|---|---|---|---|
| (1) | N/A SEE CERTIFICATE OF SAFETY IN YOUR FILES | | | | | |
| (2) | | | | | | |
| (3) | | | | | | |
| (4) | | | | | | |

## 11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

N/A

☐ b. CALIBRATED BY APPLICANT

*Attach a separate sheet describing method, frequency and standards used for calibrating instruments.*

## 12. PERSONNEL MONITORING DEVICES

| TYPE (Check and/or complete as appropriate.) A | SUPPLIER (Service Company) B | EXCHANGE FREQUENCY C |
|---|---|---|
| ☐ (1) FILM BADGE N/A<br>☐ (2) THERMOLUMINESCENCE DOSIMETER (TLD) N/A<br>☐ (3) OTHER (Specify): _____ | | ☐ MONTHLY<br>☐ QUARTERLY<br>☐ OTHER (Specify) |

## 13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☐ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
☒ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

## 14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

Spent isotope will be returned to Lixi, Inc. for disposal

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

SEE ATTACHED SUPPLEMENT



Control No. 76700

## INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

## 18. CERTIFICATE

*(This item must be completed by applicant)*

*The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our 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.**

| | |
|---|---|
| a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)* | b. CERTIFYING OFFICIAL *(Signature)* James M Raue Jr |
| | c. NAME *(Type or print)* James M. Raue, Jr. |
| (1) LICENSE FEE CATEGORY: | d. TITLE Control No. 76700 |
| (2) LICENSE FEE ENCLOSED: $ 110.00 | e. DATE April 30, 1984 |

SUPPLEMENTAL INFORMATION

11. Sketch of facility attached.

12. Qualified personnel will be trained by licensee using the S.A. Huber training course and Lixiscope instruction manual. Outline of course attached (Supplement A, 4b). Such persons may only use the device under the direct supervision and presence of licensee.

13. Orders for material will be placed using Lixi, Inc., catalog
14. numbers and specifications. When received, packages will be inspected for damage. Contents will be inspected and operational checks performed. Receiving records will be maintained and material will be logged into accountability system. Device will be placed in secured storage until utilized.

15. Licensee will observe the following general rules:
    1. Device will be kept in secure storage when not in use. Locks will be kept in place.
    2. Licensee will not permit anyone to place fingers, hands or feet into beam to test device for operation.
    3. The device will not be used to experiment on patients. Use will be limited to diagnostic examination of patients with specific applicable medical problems.
    4. Source holder will be left attached to device except for leak testing and source exchange.
    5. Device will be returned to secure storage after use.

16. Lost of stolen material will be reported immediately to the NRC.

18. Disposal of material will be by return of source holders to Lixi, Inc.

23. All precautions and procedures as described in item 15 plus the following:
    1. Licensee will not remove the sealed source from the source holder.
    2. Leak test will be performed at six month intervals.
    3. Transport of materials will be in accordance with D.O.T. regulations.
    4. Source exchange will be through the manufacturer.
    5. All procedures covered by the Lixiscope instruction manual will be followed.
    6. During transport and at temporary job sites, the licensee will insure that the device is attended and secured at all times by the licensee, or locked in secure storage.
    7. In the event of an accident wherein damage to the Lixiscope occurs, NRC will be notified immediately.

8. Leak test will be performed every six months using the Stan A. Huber Consultants leak test kit, LT-2.

James M Rowe
Applicant's signature

Control No. 76700

TRAINING CERTIFICATE

RADIATION SAFETY AND EXPERIENCE
Ref: NRC 3131 - Items 16 & 17

Item 16-Training

This certifies that the following individual(s) have taken the Lixi, Inc., Radiation Safety Course on file with the Nuclear Regulatory Commission:

| Names (Type or Print) | Signature(s) |
|---|---|
| James M. Raue, Jr. | James M. Raue, Jr. |
| | |
| | |
| | |
| | |
| | |

Item 17 - Experience

The applicant(s) and the instructor signing this certificate hereby attest that this document is executed in conformance to Title 10, Code of Federal Regulations and to the best of our belief, is true and correct. The applicant(s) has/have received instruction in the operation of the Lixiscope, and has operated a working model under the supervision of the instructor.

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.

Training completed: April 30, 1984
date

Certified by: Kenneth Wieselman
Instructor

Signed: Kenneth Wieselman
Instructor

Date: May 1, 1984

Under license #: 12-19730-01

Control No. 76700

INSTRUCTOR CERTIFICATION

James M. Raue, Jr. has been trained in radiation safety and has received instruction in use and demonstration of the Lixiscope in accordance with the S.A.Huber Radiation Safety Course on file with the NRC.
As a representative of Lixiscope of America, he has received additional and continued consultations regarding the Lixiscope. By virtue of this training and his experience in technical representation in the medical field he is qualified to train physicians using the S.A.Huber Radiation Safety Course materials.

This representative was trained by Kenneth Wieselman (instructor)
on April 30, 1984 (date)

Kenneth Wieselman

Kenneth Wieselman

Control No. 76700

## FORMAL TRAINING IN RADIATION SAFETY AND EXPERIENCE

**Ref: NRC 313 I - Items 16 and 17**

**Item 16 - Training**

This is to certify that the following individuals have attended the Lixiscope -Training Course in accordance with the Lixi, Inc. and S. A. Huber Consultant's Inc. course descriptions on file with the Nuclear Regulatory Commission:

| Registry Number* (For Completion by NLR) | Names (Type or Print) | Signatures |
|---|---|---|
| 030 | DAVID LEVINE | David Levine |
| 031 | [illegible] | [illegible] |
| 033 | KEN WIESELMAN | Ken Wieselman |

The above individual(s) are to be added on to the following NRC license:

Name: Lixiscope of America Inc
Address: 3000 Dundee Road
City, State, Zip: Northbrook IL 60062
Telephone #: (312) 272-1000

This training was completed on: 18 April 1981 (Date)

**Item 17 - Experience**

A brief resume is attached for each individual to be covered under items 6 and 7 on form NRC 313 I. This also certifies that such individual(s) have personally operated a working Lixiscope, under supervision, in the aforementioned course.

The applicant and any instructor executing this certificate on behalf of the 3 (number) person(s) listed above, certify that this document is prepared in conformity with Title 10, Code of Federal Regulations, and that all information contained herein, is true and correct to the best of our 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.

Certified by: Stan A Huber
Date: 18 April 1981 (signed)
Instructor Name: Stan A. Huber
NLR Registry No.: 001
Under License No.: 12-17503-01

*NATIONAL LIXISCOPE REGISTRY

NRC License #12-17503-01 S. A. Huber Consultants, Inc., New Lenox, IL

Validated by: Stan A. Huber
Name: Stan A. Huber (signed)
Title: President
Date: 4-18-81

Control No. 76700

**NOTE:** This certificate is invalid unless countersigned by the NATIONAL LIXISCOPE REGISTRY and their registry numbers are assigned.

Lixiscope - Training Course Outline

(Registration of Attendees and Introduction to Course)

1. Overview of federal NRC and Agreement State Regulations for Radiation Protection. (Special emphasis on 10CFR Parts 19 & 20)

2. General Radiation Safety Instructions to Workers.
   NRC Regulation Guide
   NRC Prenatal Exposure Instructions for any female worker

3. Need for Specific Radiation Safety Program for each Lixiscope Licensee (Regulations and License conditions)

(Question - Answer Session and Break)

4. Elements of an Effective Radiation Management Program

   a) Restricted Users (only trained personnel can use Lixiscope).
   b) Security against theft or loss of radioactive material (includes receiving procedures, key controls and return or disposal procedures).
   c) Thorough familiarity of licensed users with individual facility application to NRC for licensure, as well as the license itself.
   d) Accountability and specific secure storage area for the Lixiscope(s).
   e) Quarterly inventory and source exchange or transfer or disposal records.
   f) Semi-annual leak test records and how to use leak test kits.
   g) Discussion of radiation surveys - if required by NRC.
   h) Personnel exposure monitoring systems - film and TLD badges.
   i) Maximum permissible doses (MPD) and how to read film badge reports.
   j) "ALARA" philosophy - to keep radiation exposures as low as reasonably achievable.
   k) NRC posting and labeling requirements and DOT requirements in any transportation.
   l) Reason for R.S.O. and duties of this individual.
   m) Advantages of centralized record system (recommended type).
   n) Review of required reports and sample forms and "year at a glance" management chart.
   o) Audits, annual safety reviews and preparation for inspections.
   p) New users personnel orientation and license amendments.

(Question - Answer Session and Break)

5. Elements of an NRC license application.

   a) Discuss licensing checklist resumes and individual or special needs.

   b) Review licensing services or consultation available.

Control No. 76700

6. Review of the Lixiscope Instruction Manual and specific safety instructions.

   a) Characteristics of I-125 source and discussion of half-life.

   b) Inverse square law and basic radiation safety principles of time, distance and shielding.

   d) Demonstrate Lixiscope operation.

   e) Final Question and Answer Session.

   f) Test.

   g) Certification of Attendance or Completion.

Total Course Time = Approximately 4½ to 5½ hours with 3 ten minute breaks = 5 to 6 hours total time (not counting 15 minute test).

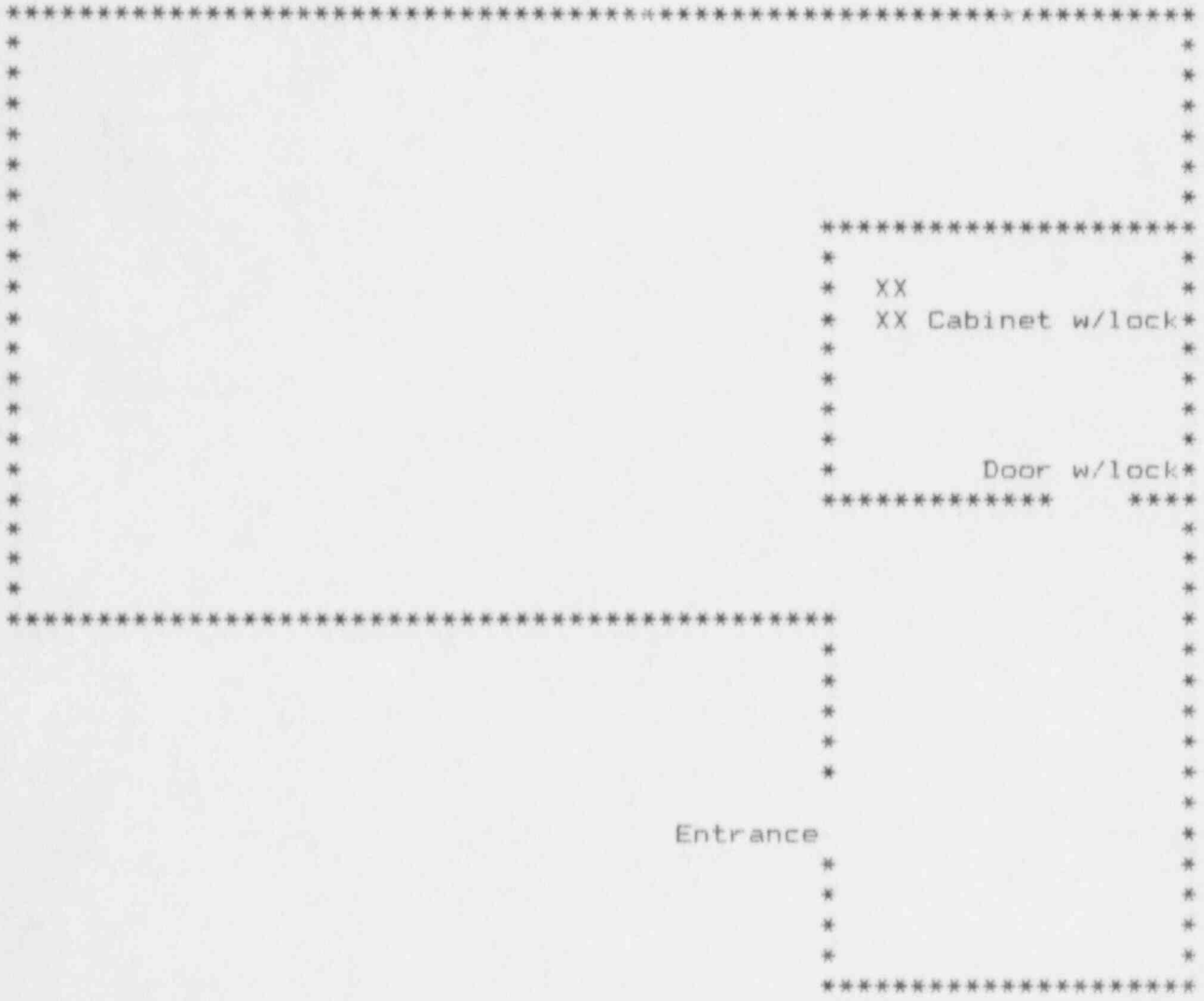
NOTE: These are very rough time estimates. With smaller classes it may be possible to complete the course in 2 or 3 hours total time.

JAMES M. RAUE JR.

PROPOSED SECURED LOCATION

FOR LIXISCOPE STORAGE

OFFICE FLOOR PLAN




Control No. 76700

JAMES M. RAUE JR.

PERSONAL DATA

BORN 11/27/46

MARRIED - 3 CHILDREN

EDUCATION - BS ACCOUNTANCY 1972

EMPLOYMENT:

4/72 TO 6/76 - PRIVATE AND PUBLIC ACCOUNTING.

6/76 TO 12/82 - IMED CORP.. SOLD INFUSION PUMPS TO HOSPITALS IN ILLINOIS, INDIANA, AND KENTUCKY. #1 SALESMAN 1978 AND 1979 AND #1 MANAGER 1980. ATTAINED SUPERQUOTA IN ALL OTHER YEARS. SALES IN 1976 = $80,000, 1982 = $10,000,000.

1/83 TO PRESENT - OWNER OF PAIN MANAGEMENT SYSTEMS. DISTRIBUTION OF T.E.N.S. UNITS (PAIN CONTROL DEVICES). CURRENTLY RETAIN OWNERSHIP BUT DO NOT PARTICIPATE IN DAY-TO-DAY OPERATIONS.

4/2/84 TO PRESENT - VICE PRESIDENT/GENERAL MANAGER "BIOTEC MIDWEST". RESPONSIBILITIES INCLUDE MARKETING FOR 7 MIDWEST STATES.

ASSOCIATIONS:

SCHOOL BOARD MEMBER - U46 SCHOOL DISTRICT (3RD LARGEST IN ILL)

BARTLETT LIONS - MEMBER SINCE 1968

BARTLETT VOLUNTEER FIRE DEPARTMENT - MEMBER SINCE 1972

NOTE TO: License Fee Management Branch, ADM

FROM: Region III

SUBJECT: VOIDED APPLICATION

Control Number 76269

Applicant Biotec Biomedical Technology

Date Voided

Reason for Void non-response to def. letter

Signature Vockulow

Attachment:
Application

16700
May 9 '84
No refund

NRC Form 782
(1-82)

U.S. NUCLEAR REGULATORY COMMISSION

# MATERIALS DATA INPUT—INDUSTRIAL, MEDICAL SOURCE/SPECIAL NUCLEAR

## A. TYPE OF ACTION AND IDENTIFICATION CODES

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | NEW LICENSE | AMENDMENT TO RENEW LICENSE | AMENDMENT TO TERMINATE | X VOID | DOCKET NUMBER | | MAIL CONTROL NUMBER | CHANGE NAME/ADDRESS ("X" box) |
| 1 | X NEW LICENSE AND NEW LICENSEE | OTHER AMENDMENT | CLERICAL CHANGE NO AMENDMENT | 2 | 030-18492 | | 76700 | |

## B. INDICATIVE INFORMATION

| | | | |
|---|---|---|---|
| 2 | INDIVIDUAL LICENSEES | NAME (Last, First, Middle) | NAME (Last, First, Middle) No response to def letter. |
| | | NAME (Last, First, Middle) | NAME (Last, First, Middle) Abandoned. |
| | | NAME (Last, First, Middle) | NAME (Last, First, Middle) |
| 3 | ORGANIZATION | ORGANIZATION NAME (Alphabetic Sequence) Biotec Biomedical Tech, Inc. | 1-12-85 Pat V. |
| 4 | LICENSEES | DEPARTMENT OR BUREAU | RIII |
| 5 | ADDRESS | BUILDING, STREET 320 S. Main | CITY Bartlett / STATE IL. / ZIP CODE 60103 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 6 | TYPE OF APPLICANT | U.S. GOVERNMENT AGENCY / INDIVIDUAL LICENSEE / X ORGANIZATIONAL LICENSEE | DATE REQUEST RECEIVED 5-3-84 | INSTITUTION CODE 24337 | PENDING PROG. CODE 03223 | ACTUAL PROG. CODE |

SECONDARY PROGRAM CODES (As required)

| #1 | #2 | #3 | #4 | #5 |
|---|---|---|---|---|
| | | | | |

| 7 | LICENSE NUMBER 12-24337-01 | DATE LICENSE ISSUED OR ACTION COMPLETED | EXPIRATION DATE | |
|---|---|---|---|---|
| | APPLICANT'S COMMUNICATION DATED | CLASSIFICATION | ASSIGNED TO | RESULTING AMENDMENT NUMBER |

ENCLOSURES

UNCLASSIFIED DESCRIPTION

DISTRIBUTION

OTHER REFERRALS

| NAME | DATE | NAME | DATE |
|---|---|---|---|
| | | | |

NRC Form 782
(1-82)

7—LICENSE FEE MANAGEMENT REFERENCE COPY