

JUN 14 1984

*file*

Biotec Biomedical Tech., Inc.  
ATTN: James M. Raue, Jr.  
320 South Main  
Bartlett, IL 60103

Dear Mr. Raue:

We are in receipt of your application dated April 30, 1984 for an NRC License to demonstrate the Lixiscope, a portable real-time imaging device containing iodine-125. Additional information is needed in support of your request. Please respond to the following:

1. Your application contains a sketch of the area where the Lixiscope will be stored when not in use. However, it is not clear whether this sketch depicts the office floor plan at 320 South Main in Bartlett or the floor plan at some other address. Neither can we determine from the sketch the type of building in which your office facilities and the Lixiscope will be housed. Please clarify.

(We do not normally authorize the possession and use of radioactive materials in residential dwellings, however, we will consider such a request if the applicant can demonstrate that the material will be located in a "restricted area" within the residence in accordance with Section 20.3(a)(14) of Title 10 Code of Federal Regulations, Part 20. We are particularly concerned how the applicant will insure that children and other unauthorized personnel do not have access to the area in which the radioactive material will be used or stored. The applicant will also need to verify that possession of the material in the residential dwelling does not conflict with local codes or zoning laws and that emergency support personnel, e.g., fire department, will be informed of its location.)

2. Since you are requesting authorization to use the Model LSM82-209 Lixiscope, it appears that you will be demonstrating the device to medical personnel, however, this is not addressed in your application. Please clarify.
3. Please inform us if your demonstrations of the Lixiscope will include training end-users (e.g., physicians) on radiation safety related procedures associated with the possession and use of the device.
4. If you will be instructing end-users as described above:
  - a) Please describe in greater detail the additional training, supervision, etc. that you received from Mr. Wieselmann which qualifies you to instruct potential users of the Lixiscope. Include the time period in which the training was conducted and a discussion of your experience(s) using and instructing others on the use of the Lixiscope. Please be specific in your response.

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- b) Describe the training that will be given to end-users including the duration of the training and the method that will be used to determine competency.
5. Describe the types of locations where you will be demonstrating the Lixiscope, e.g., doctors' offices, hospitals, conventions, etc. Please be as specific as possible since these locations will be specified on your license.
  6. Describe your means for preventing unauthorized access to the Lixiscope when the device is in storage at temporary job sites.
  7. What provisions have you made for obtaining access to a properly calibrated survey meter in the event of suspected source leakage?

We will continue the review of your application upon receipt of this information. Please reply in duplicate within 30 days and reference Control No. 76700.

Sincerely,

B. J. Holt  
Materials Licensing Section

R111

Holt/bm  
06/04/84

pg  
6/12/84

## 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.

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  $4\frac{1}{2}$  to  $5\frac{1}{2}$  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.

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