

LIXI.

September 14, 1984

Mr. Bruce Mallett, PhD, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
U.S. Nuclear Regulatory
Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

27 P1:19
LIC. FEE MGMT BRANCH

Applicant	LIXI
License No.	12-18215-01
Amount and Category	7126
Expiry Date	9/15/84
Date Check Rec'd	10/2/84
Received By	[Signature]

RECEIVED BY LFMP	
Date	9/21/84
Loc	ENR Sept 11
By	[Signature]
Gng To	[Signature]
Action Compl	[Signature]

Re: Amendment to License No. 12-18215-01

Dear Mr. Mallett:

We request amendment to our above referenced license for the following items:

- 1) Increase our possession limit for any byproduct material with Atomic Numbers 3-83, inclusive, from 500 millicuries per source to one (1.0) curie per source, for research and development of imaging devices.
- 2) Specify a greater possession limit for Thulium (Tm) 170 sealed sources, not to exceed 50 curies per source.
- 3) Add Ed Polz as Assistant Radiation Safety Officer.
- 4) Distribution of LIXI scopes under Private Brand Name Labels.

In support of our request for handling higher activity sealed sources, we have enclosed a statement regarding "Personnel Resources and Supplemental Radiation Safety Procedures."

At this time, we also wish to confirm our interpretation of "Authorized Use". Item 9.C.(5) which states "Distribution to veterinarians or other persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the NRC or an Agreement State". We believe this includes our authorization to ship LIXI scopes (FDA registered and NRC licensed imaging devices) to any other licensed firm, for purposes of distribution under our brand name label, or our name label, to their individual veterinarian or broad licensed customers. When LIXI distributes to a

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brand name label licensee for redistribution it will do so in accordance with the licensee's license requirements for label specification.

The same authorization appears to apply under our medical distribution license number -02MD. We realize we would need to amend our product certifications on file with the NRC for any new models of LIXI scopes or related imaging devices. However, after each product certification, we would not need to amend our -01 or -02MD distribution licenses. If this interpretation is not correct, please advise us of procedures which could be used to make license amendments automatic upon new product certification.

The information attached to this amendment is confidential and proprietary and is therefore exempted from public disclosure per 10 CFR 2.790.

Enclosed is our check for \$120.00 for this application processing fee for Category 3A. We will appreciate your assistance in expediting this amendment, so we can proceed with our cooperative research Agreement with the University of Missouri at Columbia.

Thank you.

Sincerely,

Lixi, Inc.



Robert J. Savini
Executive Vice President

RJS/kr
Enclosures

Control No. 7 7 4 7 7