

FEB 10 1984

FCML:PCV  
(15909)  
030-19897

Lixi, Inc.  
ATTN: Mr. Robert Savini  
Executive Vice President  
1438 Brook Drive  
Downers Grove, IL 60515

Gentlemen:

This is in reference to your September 13, 1983 letter that requests licensing action on License Nos. 12-18215-01 and 12-18215-02 MD. We note that most of the requests in your letter pertain to your -01 license; Mr. Hickey of our Industrial Section has corresponded with you on the requests pertaining to the -01 license and amended that license on January 25, 1984.

From your correspondence (i.e., your August 3, 1983 and September 13, 1983 letters), there are only two requests that pertain to your -02 MD license and they are the addition of tellurium-125m as an alternate isotope in the Lixiscope and removal of the radiation label on the outside of the carrying case. Other requests pertaining to radiation safety officer, users, training programs, changes in facility, etc., pertain only to the -01 license.

At this time we cannot approve your request for use of the tellurium-125m source in the Lixiscope because NRC's Material Certification and Procedures Branch has not received, evaluated and approved, for licensing purposes, the specific tellurium-125m sources you want to obtain from the University of Missouri, AECL or Amersham Corp. When registration of one or more of these sources has been completed and the Lixiscope device registration sheet has also been revised, you may resubmit your request.

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PDR FOIA  
GROSSMAB4-398 PDR

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SURNAME						
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Your request should be submitted in duplicate and should be accompanied by copies of correspondence with the Food and Drug Administration (FDA) acknowledging either FDA's approval of the Lixiscope with a tellurium-125m source or FDA's finding of substantial equivalence. Your request should also specify that 10 CFR 35.100(f) needs to be amended to add tellurium-125m. Your request need not be accompanied by any additional fee because we will consider our review of that request to be a continuation of our review of your September 13, 1983 letter.

With respect to your request to delete the radiation label from the carrying case, we agree with Mr. Hickey's January 24, 1984 letter (copy enclosed) to you.

Sincerely,

Patricia C. Vacca  
Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety

Enclosure: As stated

OFFICE	FCM						
NAME	PCVacca/1g						
DATE	02/10/84						