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

Gentlemen:

Enclosed is Amendment No. 12 to your NRC License No. 12-18215-01, which authorizes you to utilize one thulium-170 sealed source up to 50 curies in your development of imaging devices. As per a telephone conversation between Robert Savini and me on November 8, 1984, we have issued this amendment so that you may possess a source manufactured for you by the University of Missouri; however, we have not authorized you to possess and use sealed sources with atomic numbers 3-83 and activities up to 1 curie each as requested. In order to obtain this authorization and authorization to obtain more than one thulium-170 source of up to 50 curies you will need to submit a description of:

1. The shielding you have or will have sufficient to reduce exposure levels from 1 curie, gamma emitting sources such as those containing cobalt-60 or cesium-137 to less than the limits specified in Section 20.105 of 10 CFR Part 20 for unrestricted areas. In your description, please include calculations of the maximum radiation levels that will exist in each unrestricted area adjacent to your shielded use or storage areas.
2. The general design criteria and tests performed on the finished sources to ensure integrity during use. We recommend that the sources be constructed of material that is not easily broken, punctured, or cut; the radioactive material be in a form that is easily contained if released (e.g., not in liquid or powder form); and the tests for integrity be equivalent to those outlined in the National Bureau of Standards Handbook No. 126, ANSI-542-1977.
3. The frequency and methodology utilized to calibrate the pocket dosimeters utilized as personnel monitoring devices in your radiation safety program. We recommend a frequency of 12 month intervals utilizing sources with radiation emissions similar to those used in your program.

We have not authorized you to distribute lixiscopes under private brand labels as requested in your September 14, 1984 letter. In order to obtain this authorization you will need to submit additional information on the following items:

1. Your NRC License No. 12-18215-01 specifies that 2 types of labels are placed on the lixiscopes devices as follows: One type encompasses labels on the isotope holder head and carrying case which meets the requirements of Section 20.203 of 10 CFR Part 20 and a second type encompasses labels on the back and side of the lixiscopes housing and carrying case which

identify the manufacturer (i.e., Lixi, Inc.) who has the necessary NRC license, personnel and equipment to perform service operations for the end user (e.g., source return program, repair of device and/or source holder, etc.). Please identify which labels will be modified for use in your distribution to brand label licensees and submit the modifications for our review. NOTE: The second type of labeling mentioned above, must always contain the name and address of the company offering services such as source return program and repair to the end user; and at this time, we are only aware of these services being provided by Lixi, Inc.

2. Please submit a description of any modifications that you will make in your instruction manual for this distribution program. NOTE: As above, any instructions to end users must include the name and address of the company offering services such as a source return program and repair to the end user.

In response to your statements concerning Item 9., authorized use, on your NRC License No. 12-18215-01 and amendments necessary to your NRC License Nos. 12-18215-01 and 12-18215-02MD when new models of lixiscope are placed in the product certifications on file with the NRC, we have the following comments:

1. Item 9.C.5. of your NRC License No. 12-18215-01 authorizes you to distribute the material identified in Items 6.C., 7.C., and 8.C, to any person or firm authorized to receive the material. The purpose for which the receiver uses the material is, however, dependent upon the conditions of the receiver's NRC or Agreement State license.
2. The authorization in your licenses is based upon the procedures you submitted to us as part of applications; these procedures include labeling of the device (e.g., September 19, 1980 letter). Therefore, any changes to that labeling by you or the receiver, must be authorized by the NRC.

Your medical distribution License No. 12-18215-02MD authorizes distribution to only persons licensed pursuant to Section 35.14 and Section 35.100(f), Group VI of 10 CFR Part 35, or under equivalent licenses of Agreement States; and these persons are not authorized to redistribute the material received.

3. Modification of product certification sheets for new models of lixiscope or related imaging devices would also require an amendment to your medical distribution License No. 12-18215-02MD, since this license authorizes distribution of devices specifically listed which are compatible with your product certification sheet and Group VI, Schedule 35.100(f), 10 CFR Part 35. Modification of certification sheets for new models may require an amendment to your License No. 12-18215-01, depending upon whether or not the modification reflects changes in the authorizations listed on this license. We would be glad to discuss how your License No. 12-18215-01 may be modified to allow for as few amendments as possible, when changes are made to product certifications. Please call me and we will establish a mutual time for this discussion.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address.
5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.
6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

Lixi, Inc.

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If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed  
Bruce S. Mallett, Ph.D., Chief  
Materials Licensing Section

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*Bm 11/15/84*  
Mallett/as  
11/15/84