

February 25, 1985

Mr. Steven Baggett  
Material Certification  
and Procedures Branch  
United States Nuclear  
Regulatory Commission  
Washington, D.C. 20555

Dear Mr. Baggett:

This letter is an answer to the questions you asked in your January 28, 1985 letter.

- 1) We will continue to use the current method to identify the source heads for our Iodine -125 models.
- 2) TA31 model is only for the Americium-241 isotope. Apparently you did not receive all the information we provided with our original application to Region III. Therefore we have included a copy for your file. It fully explains our model number system.
- 3) Table A page 16 of our users manual is a reference guide for medical users only. The Americium-241 isotope has no application in a medical imaging device because of its inadequate photon output. The radiation exposure levels from scatter are less than those reported for 500 mCi of Iodine-125 in our current units. Please reference paragraph one on page 8 of our application.
- 4) There are no special instructions for using the T-series heads on the current hydraulically controlled units. Please reference paragraph two items (a) through (i) on pages 7 and 8 of our application for operating instructions of the T-series (manual) source holder heads.
- 5) When a user no longer needs an Americium-241 source it may be returned to Lixi, Inc. for disposal. Since the useful life of an Americium-241 source is over four hundred years, Lixi will retain any returned sources for possible redistribution to other users. If disposal is necessary Lixi will dispose of the material as specified in our license.
- 6) You stated that our new source holder did not have an indicator that quickly showed the unit was in the exposed position. Apparently you based this comment on your evaluation of the prototype head.

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we furnished and not on the final drawings that we sent with our amendment application. The exposure control handle on the top of the head was changed from the design you observed on our prototype. After evaluating the prototype our engineer rotated the handle so that when the unit was turned to the exposed position, the handle's blade with an etched arrow on the top pointed at the lixiscopes scintillator screen. We also fitted into the body of the source head (Ref: Drawing H 50098) an "ON" and "OFF" position with their respective arrow indicator. We will also incorporate your suggestion of marking these positions on the label we wrap around the head so that the exposed position will be even more noticeable to the operator. One further point to note is the fact that the padlock hole is blocked when the device is in the exposed position. This is not only visually noticeable but it also makes it impossible for the operator to lock the device after use as he is instructed to do by the operator's manual.

- 7) Thank you for returning our Prototype source head.
- 8) Lixi has developed special fixtures and handling procedures to be used in conjunction with standard radiation handling equipment for the purpose of loading and unloading our source holder heads. Part of our procedure includes checking each I-125 isotope for purity. Specifically, we are checking for I-126 content. Amersham's source model IMC.P2 has a maximum I-126 concentration of 0.2%. Due to the design of our source holder, the radiation level at surface would be in excess of 20R/hr. when the I-126 level was 0.2%. Lixi's special handling of the Amersham source includes our standard procedure with the following addition. Lixi assembles a source holder with an Amersham capsule and then allows it to decay in a storage area until the surface radiation reading of our head declines to 0.1R/hr. When this level is reached (in approximately 30 days) then Lixi will ship the isotope to the customer. Amersham's process consistently yields isotopes with the 0.2% level of I-126. Therefore Lixi would have to order a 565mCi isotope to fill a customer's order for 400 mCi. Because of the cost and inconvenience of this procedure, Lixi would only use it when I-125 was unavailable from Atomic Energy of Canada, Ltd. Amersham could correct this problem by changing their process. However, until that time when Amersham or any other supplier of I-125 will guarantee to furnish sources with the same purity as AECL, we believe that it is in the best interests of all lixiscopes users that


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someone monitors the distributor of isotopes into Lixi's equipment. The only ones qualified to do this would be Lixi, Inc. or organizations which possess the proper equipment and handling training from Lixi, Inc.

If you have any further questions please call me at (312)620-4646.

Sincerely,

Lixi, Inc.



Robert J. Savini  
Executive Vice President

RJS/jaw

cc: Bruce Willett, Region III



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

JAN 28 1985

Mr. Robert Savini  
Lixi, Inc.  
1438 Brook Drive  
Downers Grove, IL 60515

Dear Mr. Savini:

This refers to your letters dated November 16, November 20 and December 14, 1984 requesting an amendment to your device registration sheet No. NR-422-D-101-S. We need clarification and/or additional information on the following points for us to continue with the evaluation process.

1. Will you continue to use the current method to identify the source head models?
2. Will the source head model number TA31 be used only with the Americium-241 isotope? If not, please provide us with a list of the model numbers.
3. In Table A Page 16 of your users manual, you gave dose rates for various activities and at various distances from a source head containing Iodine-125, please provide a similar listing for the Americium-241 isotope.
4. We need a copy of the instructions that will be given to the users of the Lixiscope. These instructions need to show the proper use of the new source holders, and any special notes that are needed to use the new holder on the current hydraulically controlled unit.
5. Americium-241 is very difficult to dispose of. What provision has Lixi, Inc made to handle the disposal problem? Do you plan on taking back all Americium-241 source holders that the user no longer needs?
6. Your current source holder has a very good indicator as to whether the source is exposed or not. The new holder design does not quickly tell persons around the device that it is on. We need an alternate plan to label the holder. Please call to discuss this issue before you reply.

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JAN 28 1985

Bert Savini

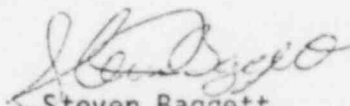
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7. The sample source holder you supplied to us is being returned to you in a separate package. We thank you for its use.
8. This refers to your December 14, 1985 letter. Please explain your special handling procedures for the Amersham Source Model IMC.P2. Additionally, please explain what is covered in your source loading training course.

We will continue with the evaluation upon receipt of your answers.

If you have any questions, please call me at (301) 427-9005.

Sincerely,



Steven Baggett  
Material Certification  
and Procedures Branch

cc: Bruce Mallett, Region III