JUL 31 1985

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

Gentlemen:

Enclosed is Amendment No. 14 to your NRC License No. 12-18215-01 in accordance with your request.

We note, in your November 16, 1984 letter that you wish all the information furnished in connection with those amendments to be withheld from public disclosure per 10 CFR 2.790. As specified in a January 4, 1985 letter to all NRC Material Licensees (copy enclosed), however, you must request withholding in accordance with the procedures specified in Section 2.790. Please note that any request for withholding is subject to an NRC determination as to whether the document may be actually withheld in accordance with applicable laws and regulations. Please reevaluate what is considered to be proprietary and clearly identify these or portions thereof as required by Section 2.790.

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.

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

Sincerely,

Original Signed By
Bruce S. Mallett
Materials Licensing Section

Enclosure(s): Amendment No. 14

RIII
BSM 7/31
Mallett/cm
07/31/85

July 29, 1985

NRC Region 111
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attn: Bruce Mallett

Dear Mr. Mallett:

Enclosed are copies of our Label Print number 49987 dated 7-29-85 and our Lixi Instruction Manual that you requested.

Sincerely,

Lixi, Inc.,

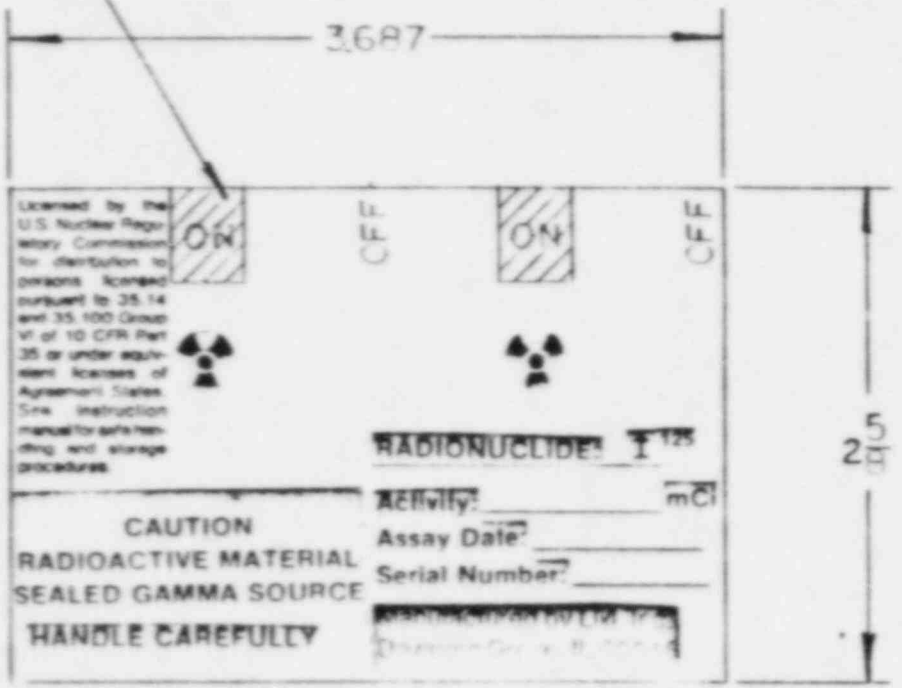
Robert J. Savini
RJS/ap
enc.

8512060084 dupe

Lixi, Inc. Telephone (312) 620-4646 Telex 6871077 OKROB
1438 Brook Drive Downers Grove, Illinois 60515

DATE	SYM	REVISION RECORD	DR.	CK.
7-29	A	NEW RELEASE	LZ	

SHADED AREA TO BE MAGENTA IN COLOR
LETTERING INSIDE SHADED AREA TO BE YELLOW BACKROUND
(2 PLACES)



MAGENTA LETTERING ON A YELLOW 3M Y-7884 COMPUTER INPRINTABLE VINYL BACKGROUND USING 3M 467 ADHESIVE

TOLERANCES (EXCEPT AS NOTED)	LIXI INC		
DECIMAL ±.010		SCALE FULL	DRAWN BY LZ
			APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL GROUP VI USE IODINE 125		
ANGULAR ± 1°	DATE 7-29-85	DRAWING NUMBER 49987	

IRUNING 40.21

June 6, 1985

Sterling W. Bell
Material Certification &
Procedures Branch
United States Nuclear
Regulatory Commission
Washington, D.C. 20555

Dear Mr. Bell:

This letter is in answer to your letter of March 29, 1985. We are sorry that the information we provided in our February 25th letter was incomplete. We have reviewed our correspondence and now submit the following revised information:

A) We have developed a reference guide for the exposure rates from Americium-241. This guide is based on a 300 mCi source at various distances from our source head. We provided only one table instead of several for different decay levels because the Am-241 long half life makes others unnecessary. We have provided a note with the guide which states that after ten years, the exposure rates would reduce by 1.7 percent. This guide table will be added to our instruction manual as Table "E".

B) We have enclosed a copy of our current instruction manual. We are adding two appendices to our manual as you requested. One covers industrial use of the T-series and key activated source heads. The other covers the medical use of the T-series source holder heads. (See appendices in attached instruction manual)

C) We are using Steve Baggett's suggestion on labeling the T-series source heads to quickly show when the unit is in the exposed position. We have enclosed drawings numbered 49983, 49984, 49985, 49986, 50305 and 50306 which show the types and positions of the labels on the T-series heads. We have modified the handle on the top of the head from the prototype that Mr. Baggett evaluated. The blade of the handle now lines up with the "ON" position of the label when the unit is in the active position.

8512060087 Aug. VIII

JUN 10 1985

RECEIVED

JUN 10 1985

CONTROL NO. 7 9 4 1 5

REGION III

Lixi, Inc. Telephone (312) 620-4646 Telex 6871077 DKROB

If there are any further questions, please do not hesitate to call me.

Sincerely,

Lixi, Inc.

Robert J. Savini
Executive Vice President

RJS/jaw
cc: Bruce Mallett, Region III
Steve Baggett
Enclosures

TABLE E

Exposure Rates (mR/sec.) at the Center of the Beam for 300 mCi of an Am-241 Loaded LIXI Source Head in the Operating Mode.

Distance from Source Head	Am-241 300 mCi
Surface	2.9
1 cm	1.00
2 cm	0.53
3 cm	0.32
4 cm	0.22
5 cm	0.15
6 cm	0.12
7 cm	0.09
8 cm	0.07
9 cm	0.06
10 cm	0.05

NOTES:

A) The above figures can be multiplied by sixty (60) to give mR per minute values.

B) Am-241 is not recommended as an imaging source for medical use.

C) This table was derived from measurements made using a 300 mCi Am-241 source in a T-Series LIXI Source Holder Head and a Victoreen 541R Dosimeter.

D) After ten years, the exposure rates will reduce by 1.7 percent.

APPENDIX I

Industrial use of T-series and Key activated source holder heads for LIXI Imaging Scopes:

There are two types of manually controlled source holder heads for use on the LIXI Imaging Scopes. The first is the key activated type which is used primarily on bench mounted LIXI systems (see Model LS-82 series on page 14). On this type of unit, a key is inserted into the control box on top of the pedestal below the source holder head. When the key is turned, it rotates a cam which raises the source to the active "ON" position. They key control units use the same source holder heads as do the hydraulic controlled units.

The key cannot be removed from the unit while the isotope is in the "ON" position. The unit must be turned "OFF" to remove the key. The users should always visually check the unit for the red "ON" indicator and the key position in order to determine whether the unit is "OFF" before placing their hands in the radiation beam area. With the exception of inserting and turning a key instead of pulling a trigger, the user should follow the Safe Operating Instructions for "Hydraulic Controlled Scopes" in section 7(A) of this manual.

The T-series source head is the second type of isotope holder head. These heads are designed to turn "ON" when you press down and rotate a handle ninety degrees. This handle is located on top of the head. When the unit is in the "ON" position, the blade of the handle and the indicator engraved on it will point at the LIXI Tube Housing. There is also a label on the source holder head with "ON" and "OFF" position marked on it.

When the unit is in the "ON" position, the padlock hole will be blocked. The unit can only be padlocked when the control handle has been returned to the "OFF" position.

The users should always visually check the handle position to determine whether the unit is "OFF" before placing their hands in the radiation beam area. With the exception of rotating the control handle, the T-series LIXI Source Holder Heads should be used in accordance with the Safe Operating Instructions in section 7(B) of this manual.

SPECIAL NOTE: All LIXI Source Heads are designed with a unique mounting system that allows only correct head types to be mounted on a scope. Thus, only heads for LS-82-209 units will mount on LS-82-209 units. For example, there is a control pin on the scope housing that mates with a hole in the source head so that one cannot interchange a head from LS-82-209 with an LS-82-205 or an LS-82-100.

INTERCHANGEABILITY CHART

Iodine-125 Sources

Hydraulic Models	=	T-Series
31	=	T131
32	=	T132
42	=	T142
62	=	T162
82	=	T182

Americium-241 Sources

T-Series
TA31*

*Americium-241 is only provided in a TA31 head and will only interchange with source heads on LIXI Imaging Scopes that have been modified for Am-241 use by the facility.

APPENDIX II

Medical use of the T-Series LIXI Source Holder Heads:

Medical users of the LIXI Imaging Scope must follow a slightly different procedure from Hydraulic Controls when using a T-Series head on their scope. It is necessary to turn thehead to the "ON" position following the instructions in section 7(B). The trigger is then to be pulled in order to turn on the electronic imaging screen. After completing these two steps, a medical doctor may place a patient's extremity into the radiation beam area and view the screen. To stop viewing, the medical doctor should first remove the patient from the beam, then release the trigger and turn "OFF" the T-series head following the instructions in section 7(B) of this manual.

The T-Series source head is the second type of isotope holder head. These heads are designed to turn "ON" when you press down and rotate a handle ninety degrees. This handle is located on top of the head. When the unit is in the "ON" position, the blade of the handle and the indicator engraved on it will point at the LIXI Tube Housing. There is also a label on the source holder head with "ON" and "OFF" position marked on it.

When the unit is in the "ON" position, the padlock hole will be blocked. The unit can only be padlocked when the control handle has been returned to the "OFF" position.

SPECIAL NOTE: All Lixi Source Heads are designed with a unique mounting system that allows only correct head types to be mounted on a scope. Thus only heads for LSM-82-209 units will mount on LSM-82-209 units. There is a control pin on the scope housing that mates with a hole in the source head so that one cannot interchange a head from LSM-82-209 with a LSM-82-205.

INTERCHANGEABILITY CHART

Iodine-125 Sources

Hydraulic Models		T Series
31	=	T131
32	=	T132
42	=	T142
62	=	T162

DATE	SYM	REVISION RECORD	DR	CK
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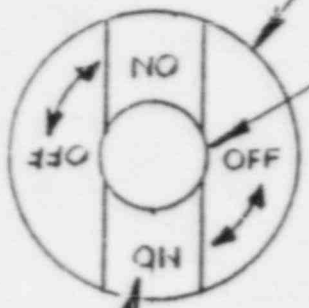

SHADED AREA TO BE MAGENTA IN COLOR. LETTERING INSIDE SHADED AREA TO BE YELLOW BACKROUND (2 PLACES)

MAGENTA LETTERING ON A YELLOW 3M Y-7884 COMPUTER IMPRINTABLE VINYL BACKGROUND USING 3M467 ADHESIVE.

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .010		SCALE FULL	DRAWN BY SK APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL (INDUSTRIAL USE) (AMERICIUM)		
ANGULAR ± 1°	DATE 4/22/85	DRAWING NUMBER 499R3	

DATE	SYM	REVISION RECORD	DR	CK
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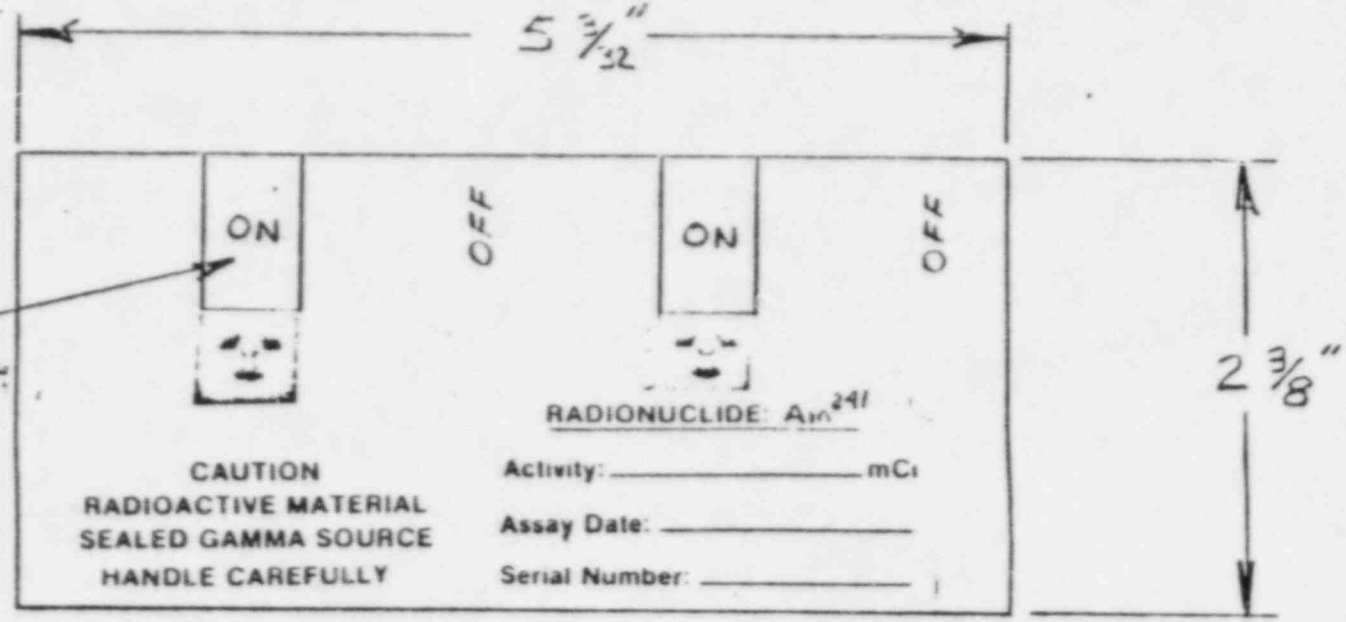

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MAGENTA LETTERING ON A YELLOW 3M Y-1264 COMPUTER IMPRINTABLE VINYL BACKGROUND USING 3M467 ADHESIVE

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .010		SCALE FULL	DRAWN BY CPS
			APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL (INDUSTRIAL USE) (AMERICIUM)		
ANGULAR ± 1°	DATE 9/22/86	DRAWING NUMBER 49984	

BRUNING 4021

DATE	SYM	REVISION RECORD	DR	CK
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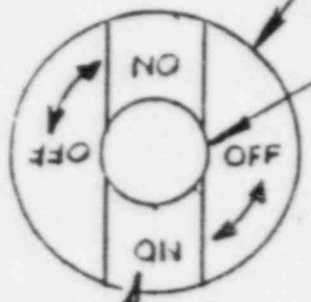

SHADED AREA TO BE MAGENTA IN COLOR. LETTERING INSIDE SHADED AREA TO BE YELLOW BACKGROUND (2 PLACES)

MAGENTA LETTERING ON A YELLOW 3M Y-7884 COMPUTER IMPRINTABLE VINYL BACKGROUND USING 3M467 ADHESIVE.

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .010		SCALE FULL	DRAWN BY SK
			APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL (INDUSTRIAL USE) (I-125/AM-241)		
ANGULAR ± 1°	DATE 4/22/85	DRAWING NUMBER 49985	

BILLING 40-21

DATE	SYM	REVISION RECORD	DR	CK
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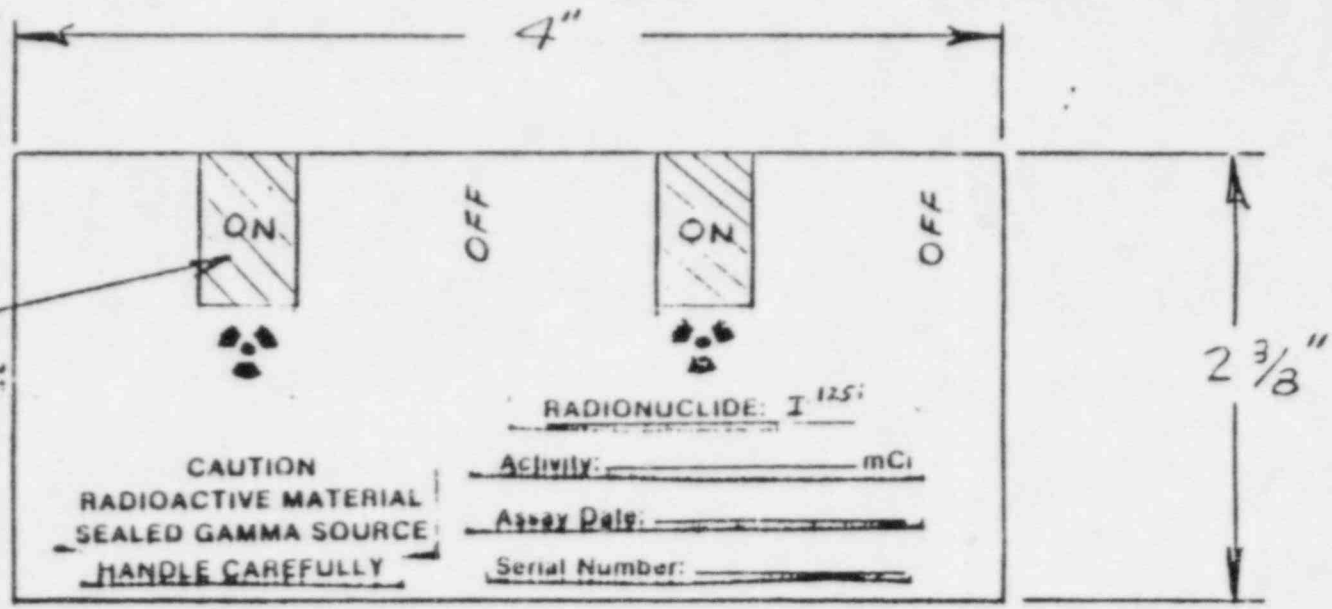


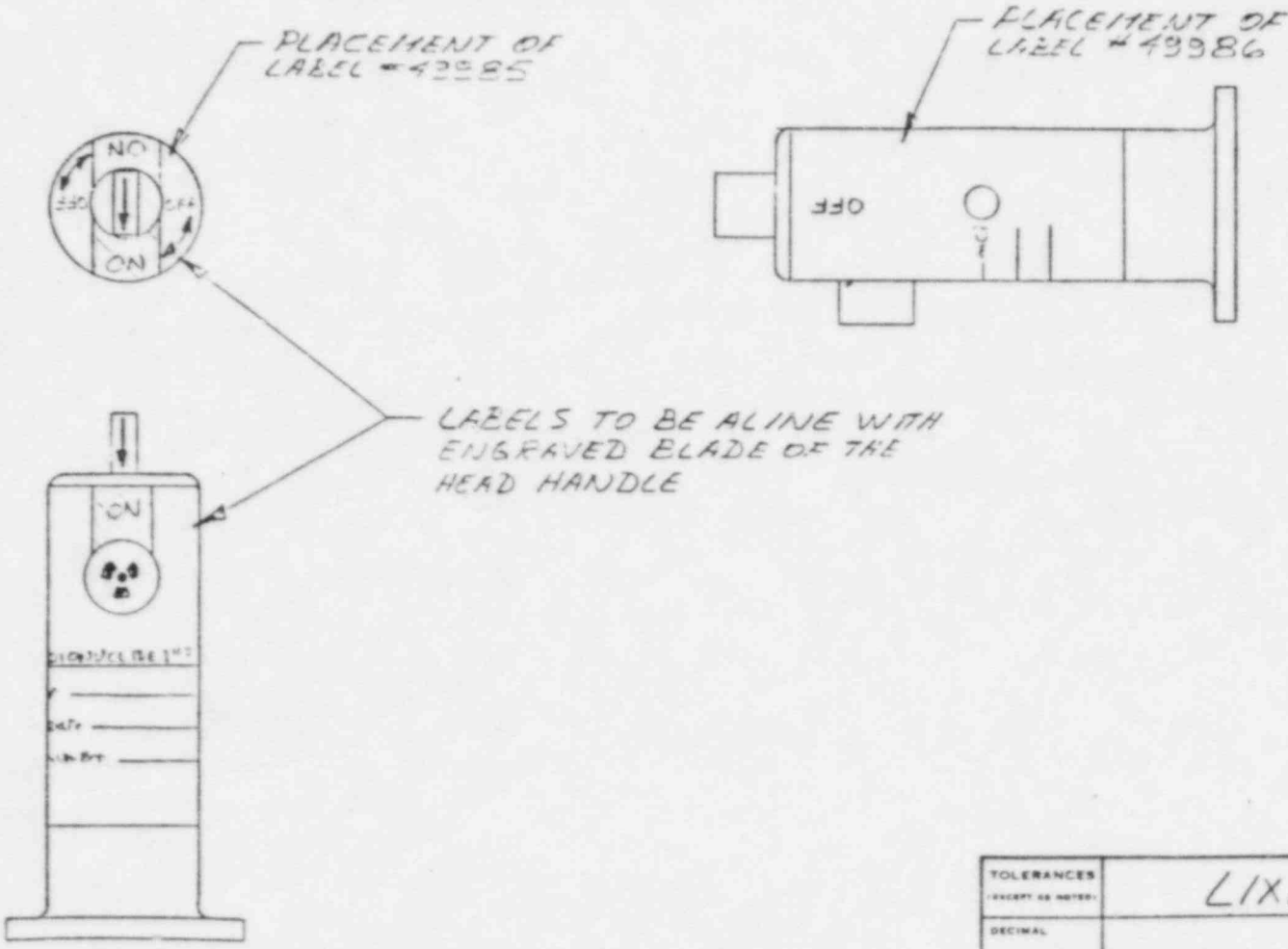
SHADED AREA TO BE MAGENTA IN COLOR. LETTERING INSIDE SHADED AREA TO BE YELLOW BACKGROUND (2 PLATES)

MAGENTA LETTERING ON A YELLOW 3M Y-7884 COMPUTER IMPRINTABLE VINYL BACKGROUND USING 3M467 ADHESIVE

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .010		SCALE FULL	DRAWN BY CPS
			APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL (INDUSTRIAL USE) (IODINE-125)		
ANGULAR ± 1°	DATE 4/22/85	DRAWING NUMBER 49986	

BRUNING 4521

DATE	BY	REVISION RECORD	OK	CK



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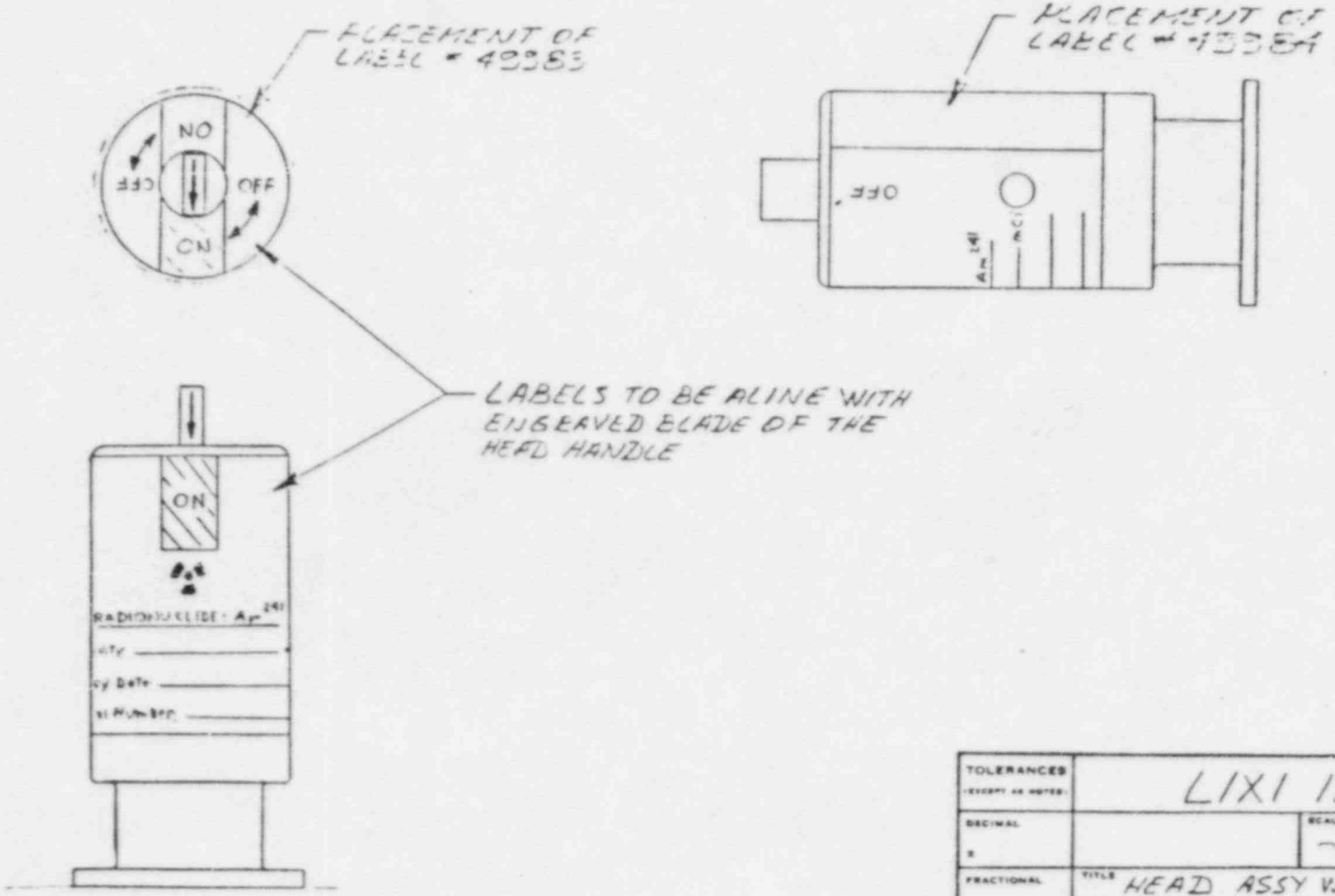
ANGULAR ±	DATE 6/5/03	DRAWING NUMBER 50306	



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FRACTIONAL ±	TITLE HEAD ASSY WITH LABELS FOR AMERICIUM-241 SOURCES T-SERIES		
ANGULAR ±	DATE 6/5/85	DRAWING NUMBER 50305	

BRUNING 40-21

MAR 29 1985

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

Dear Mr. Savini:

Mr. Steven Baggett, of our office, has requested that I respond to your letter to him dated February 25, 1984, concerning your earlier request to amend your device registration sheet No. NR-422-D-101-S.

In reviewing your correspondence, we find your paragraphs 1, 2, 5, 7 and 8 acceptable; however, your paragraphs 3, 4 and 6 are not responsive to the issues raised in our letter of January 28, 1985. Consequently, we recommend that you develop and submit a users manual which covers both medical and industrial use. This may be done as one manual for each area or one manual adequately covering both industrial and medical uses.

Your proposed "ON" and "OFF" position indicator system is not sufficient, in our opinion, to safely show the position of the source. I strongly recommend that you reconsider Mr. Baggett's recommendations sent you in his January 25, 1985 letter as an additional safety measure.

If I may be of any assistance while you are drafting a response to this letter, please do not hesitate to contact me at (301) 427-9026. We will continue with the evaluation upon receipt of your answers.

Kindest regards,

Sterling W. Bell
Material Certification and
Procedures Branch

cc: Bruce Mallett, Region III

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~~8513060088~~

CONTROL NO. 79415

APR - 2 1985

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SURNAME	SBell/sc						