



November 20, 1984

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

RE: Supplemental Information
License Amendment 12-18215-01

Dear Mr. Mallett:

We want you to include on our current license amendment dated November 16, 1984 the following item:

Remote or secondary control mechanism for LIXI scopes can be added without any increase in radiation exposure danger.

Lixi, Inc. has evaluated four basic methods of remotely controlling a LIXI source holder head on a LIXI scope. These include hydraulic actuated pistons, air actuated solenoids, electro mechanical solenoids and manual cable controls.

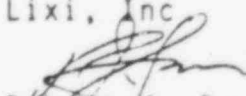
In each case the remote control either moved the LIXI trigger control or moved the piston in the LIXI source holder head. In the event of failure of any of these devices the unit would not turn "on", but would create no additional health hazard. If the device malfunctioned by not turning "off" there would be no greater danger from radiation than with normal use of the LIXI scope. The unit could be turned "off" in this event by simply unscrewing the two fasteners which hold the LIXI source holder head onto the LIXI scope. The source holder would then be padlocked as indicated in the Lixi Instruction Manual until the remote control could be repaired. For the reasons discussed above we request that the NRC permit under our certification the addition of remote control mechanisms.

We have attached example drawing of remote control devices.

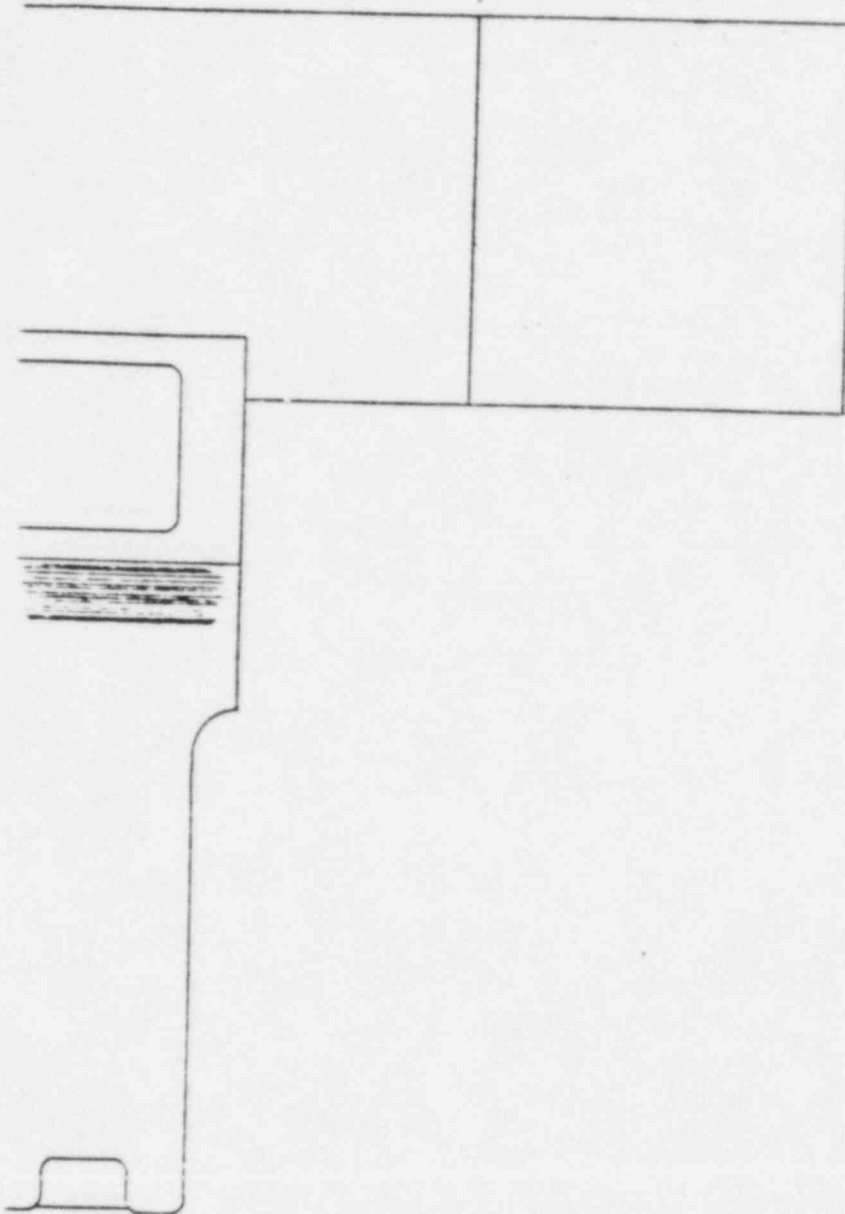
Sincerely,

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REG3 LIC30
12-18215-01 PDR

Lixi, Inc.

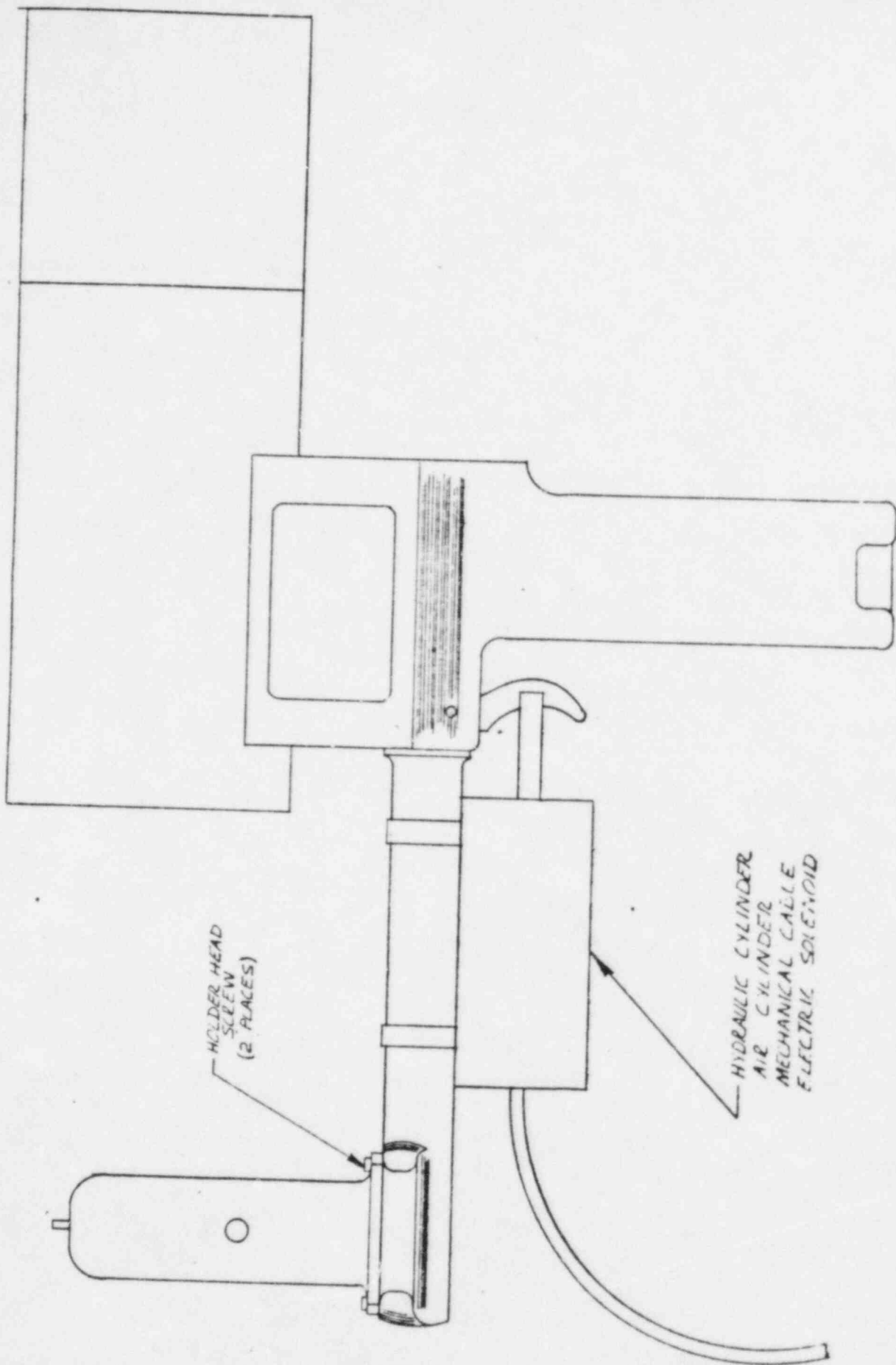

Robert J. Savini
Executive Vice President
RJS/jaw

DATE	BY	REVISION RECORD	DR	CK
10/1/84	W. J. L. P. J. J. J.			



All specifications, drawings, sketches, photographs, samples or tools and all technical or business information or data (written, oral, photographic or otherwise and including that which is stored on or in any storage medium) furnished by LIXI, INC. hereunder or in contemplation hereof shall be considered by you to be confidential, proprietary or a trade secret of LIXI, INC.

TOLERANCES (EXCEPT AS NOTED)		LIXI INC	
DECIMAL		SCALE	DRAWN BY T.A.S.
FRACTIONAL		APPROVED BY	
ANGULAR		TITLE REMOTE CONTROL MECHANISM	
	DATE 11/12/84	DRAWING NUMBER H50144	

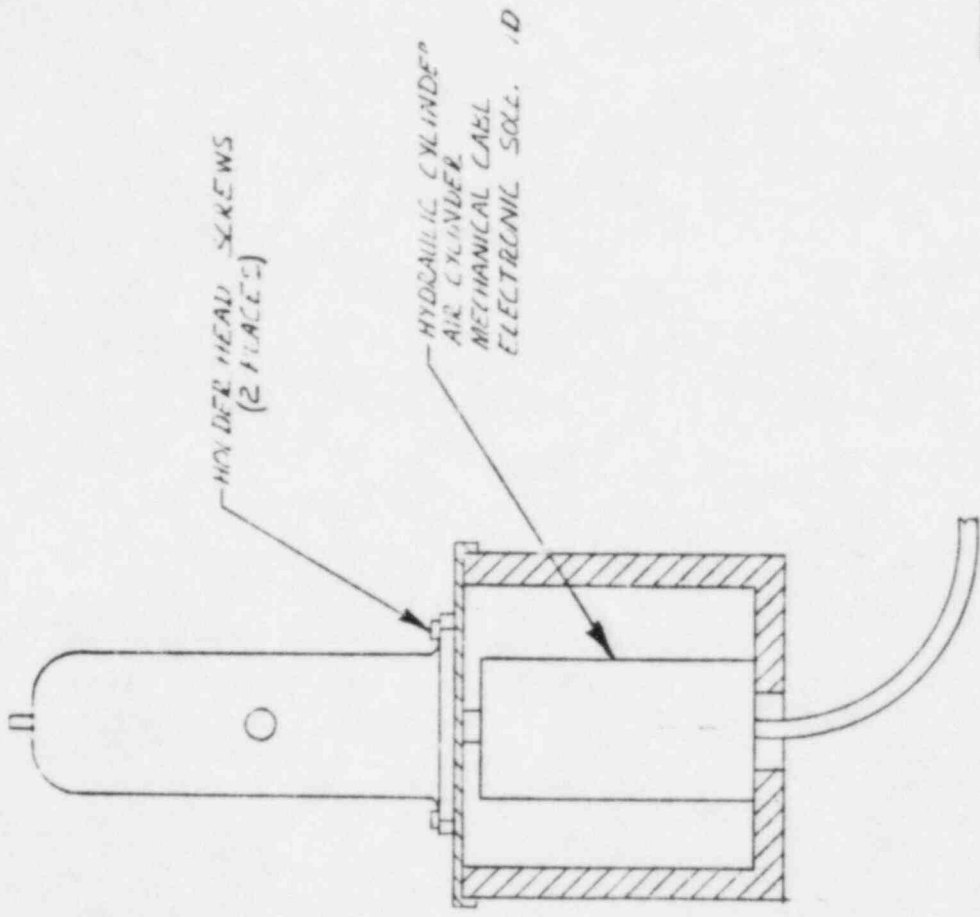


HOLDER HEAD
SCREW
(2 PLACES)

HYDRAULIC CYLINDER
AIR CYLINDER
MECHANICAL CALLER
ELECTRIC SOLENOID

DATE	BY	REVISION	RECORD

CONTROL NO. 7 9 4 1 5



All specifications, drawings, sketches, photographs, samples or tests, and all technical or business information or data (written, oral photographs or otherwise and including that which is stored on or in any storage medium) furnished by LIXI INC., hereunder or in contemplation hereof shall be considered by you to be confidential, proprietary or a trade secret of LIXI, INC.

TOLERANCES (EXCEPT AS NOTED)	LIXI INC		
DIMENSIONAL	SCALE	DATE	APPROVED BY
	1/4"	11/4/84	BT
FRACTIONAL	REMOTE CONTROL MECHANISM		
ANGULAR	DRAWING NUMBER H50143		

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21 6/15/86
A (F.P.)

November 16, 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

Re: Amendment to License No. 12-18215-01 and 12-18215-02MD

Dear Mr. Mallett:

We request that our license be amended for the following items:

- A) Add permission to transport and demonstrate at remote locations for the purpose of research and development sealed source isotopes permitted under items 6(A)(B), 7(A)(B) and 8(A)(B), to item 9(A) and (B).
- B) Certify our new manually controlled isotope exposure devices for distribution with Iodine-125 and Americium-241. This new design is designated by the model number Tx_1x_2 , where T represents the type of head (manual), x_1 is an alphabetic letter that represents the isotope (such as I=Iodine-125 and A=Americium-241), and x_2 is a number which represents the different counting and collimation designs.
- C) Add Americium-241: physical form: sealed source Amersham capsule AMC.17x92/0 maximum activity 375 mCi to items 6(C), 7(C) and 8(C), and also to authorize use 9(C).
- D) Add to our medical distributor license that our new manual Lixi source holder heads with Iodine-125 are equivalent to the models listed in License No. 12-18215-02MD.

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~~12-18215-02MD~~
77792

Current Model No.

Tx₁x₂ Model No.

31	T131
32	T132
42	T142
62	T162
82	T182

This new series of source holder heads has the same exposure and surface radiation levels as does the hydraulic controlled style of heads for 500 mCi of I-125. These new heads are interchangeable as shown above on the LS-80-X, LSM-80-X, LS-82-X and LSM-82-X series LIXI scopes. All Lixi source holder heads are loaded at the factory. Due to design and method of loading, only trained Lixi personnel can disassemble and re-load a source holder head. Industrial or medical users cannot replace or unload the isotope capsule from the source holder. In order to be licensed to load Lixi source holder heads, a person must complete a special training course at Lixi, Inc. designed for that purpose.

In support of our request in item A we submit the following information:

- 1) All prototype isotopes to be used in test at remote sites will be of metal construction and hermetically sealed by welding, or epoxy.
- 2) All source holder heads used for these temporary test site evaluations will be constructed of steel, lead or tungsten in a design similar to our current approved exposure devices. Example design drawings are attached. (H50098 and H50096)
- 3) The prototype isotopes used for these off site tests are limited to those isotopes that have a principal energy output which does not exceed 150 keV. The maximum permissible radiation level at surface of the source holder would be 30 mR/hr. Our source holders have a maximum diameter of 4 inches, therefore assuming the 30 mR/hr at surface, a user in the normal operating position would have his body located 21 inches from the surface of the holder as a minimum dimension. This would mean a worst case exposure to the user of 0.22 mR/hr. No user would receive a dose in excess of two millirems in any one hour period.

- 4) Lixi personnel will control the test area in such a manner to keep all observers at a safe distance from the unit. Lixi will comply with the provisions of Part 20 standards for protection against radiation particularly Part 20.105 on permissible levels of radiation in unrestricted areas. Lixi personnel who perform tests at remote locations will use personal monitoring devices (pocket dosimeters) during the test. All off site tests or use will be performed only by or under the direct supervision of Bruce Van Pelt or Edward Polz. Their training experience is already on file with the NRC. Lixi Inc.'s safety procedures will be used at all remote locations.
- 5) Packaging used in transporting LIXI scopes to remote locations will meet Department of Transportation (DOT) regulations for transportation of Radioactive Materials per 49 CFR 172 through 173. All isotopes so shipped will have a current leak test certificate.
- 6) Maximum activity will not exceed the limits specified for prototype isotopes in Lixi, Inc. license, or the DOT limits for A₁ and A₂ values specified in 49 CFR 173.421, 173.422, 173.423, 173.433 and 173.434 which ever is lower.
- 7) Lixi will take the normal security precautions when transporting to a test sight such as locking or sealing the container as well as locking the Lixi source holder head. The usual mode of transportation will be ground, however if air is used. Lixi will package the unit to meet DOT Type A specifications for passenger carrying aircraft. At the test sight Lixi will only leave the unit when it is in a locked or otherwise secured area (such as with a guard in a security office). When doing so, Lixi will lock or seal the transport container with the device. In the event that the test period will take more than one day and Lixi is unable to secure the device at the test sight, then Lixi will store the device at the hotel locked in the authorized users room. Since the device is kept in its locked storage container and the radiation level at surface of the container will not exceed 0.5 mR/hr there is no danger to the occupant of the room and this storage mode is within the safety regulations of Part 20.

In support of our request in item B for certification of a manually controlled exposure device, we submit the following explanation and test data. The Tx₁x₂ series exposure devices were designed to eliminate the need for a hydraulic system to activate the devices on LIXI scopes. The devices are operated by a 90° rotation of the exposure control handle. The devices incorporate a steel pin which travels in a slot over the 90° rotation and at both ends of the slot are holes that capture the pin. This results in the necessity to push downward (inward) with 3.5 kg force over a distance of 1.6 mm to uncapture the pin and then turn it 90° to change the device from the "off" to the "on" position (or vice versa). The TA31 device tested had a shorter pin that required pushing the exposure control handle vertically only 1.2 mm to be free of the pin.

Model TA31 loaded with a 300 mCi AM-241 capsule was tested and found to conform to ANSI N432 standard of May, 1980 as a Class P, type 2, type L portable exposure device with local control.

ANSI N432 paragraphs as follows:

4.0 Marking and Identification

The label will be similar to that now used on LIXI scopes with the proper radionuclide indicated.

5.1.1 Design Considerations

All materials and fasteners are the same type as those used on current model I-125 holder heads.

5.1.2 Locks

The lock and locking arrangement are the same as those currently used on I-125 holder heads.

5.1.3 Not Applicable

5.1.4 Tests

Test data follows in paragraph 8

5.2 Not Applicable

6.0 Controls

6.1.1 Control can not be removed.

6.1.2 Control is marked as per drawings H50096 and H50098 attached.

6.1.4 Not applicable; Integral control

6.1.5 Not Applicable

6.1.6 The control is an integral part of the source assembly and as such will be tested with the exposure device as a whole.

6.2 Operator will not be within the emergent beam of radiation when operating control.

7.1 All sealed sources used will conform to ANSI N542.

7.2 Not Applicable

7.3 Not Applicable

8.1 Shielding Efficiency Test

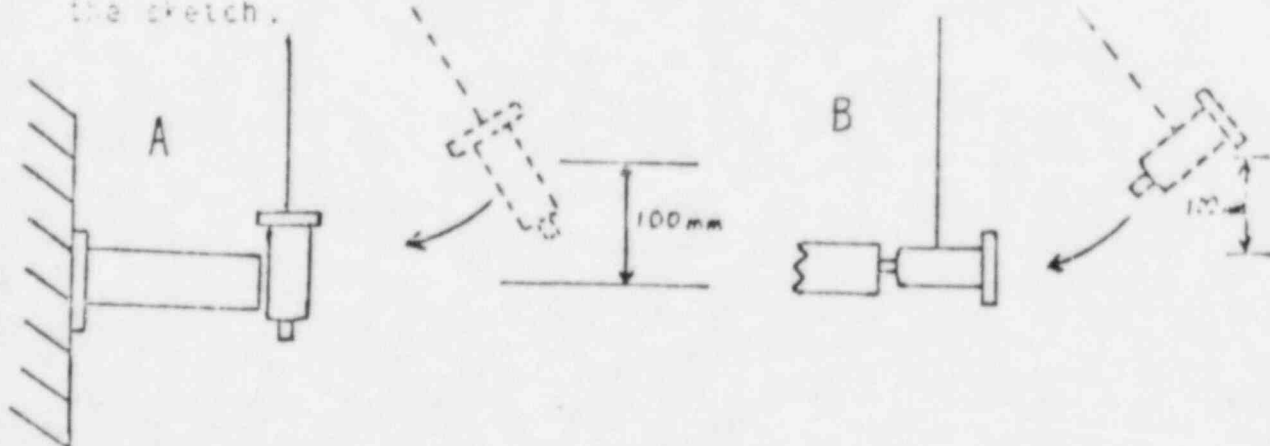
With the source in the stored position the exposure rate was as follows:

Surface of exposure device: 0.6 mR/hr

One meter from device: Less than 0.05 mR/hr

8.2 Horizontal Shock Test

This test was set up according to paragraphs 8.2.2 and 8.2.3. The exposure device fell vertically at least 100 mm 20 times in each of two positions as shown in the sketch.



Sketch B indicates what is considered the most susceptible position for damage. The impulse is applied directly to the exposure control handle which is spring loaded.

After 40 shocks the device operated normally. A few nicks and dents were evident.

8.3.2 Vertical Shock

This test was set up according to paragraphs 8.3.2.1 and 8.3.2.2 except the plywood was 3/4" and ly. After 100 drops at 50 mm there was no damage.

8.4 Accidental Drop Tests

Drop #1: The exposure device was allowed to free fall twice from a height of 5.5 meters onto a 12.4 mm thick steel plate resting on a concrete floor. 5.5 meters was used instead of 9 meters as were the original tests performed January, 1981 for the first submission by Lixi, Inc. The first drop was such that the exposure control contacted first and second was such that the side of device contacted first. The points of contact were the same as those in horizontal shock test above. The only damage suffered except for nicks and scratches was slight bowing of the bottom disc which is held by a snap ring. This ring is backed up by a roll pin. The device still functioned normally and the surface radiation level remained 0.6 mR/hr.

Drop #2: This was not performed because it was essentially the same as drop #1 because of the small size of the device.

8.5, 8.6, 8.7, 8.8 Do not apply.

8.9 Endurance Test

The device was judged most likely to wear where the steel pin contacted the groove of tungsten alloy material with the spring force of about 3.4 kg. This test was set up to move the pin back and forth over the middle 30° of the total 90° travel. The device was connected to a motorized travel cyler which operated at 2100 cycles per hour. This is 0.86

second for one 30° movement. After 21.752 cycles the unit performed normally. On closer inspection the wear on the pin was measured at 0.005 cm (.002") with no wear in the groove.

The T₁X₁ series exposure devices have the same padlock security as the current devices. This series includes devices to be interchangeable with current devices for Iodine-125 capsules. These are specifically:

<u>T₁X₁ Series</u>	<u>Current Model</u>
T131	31
T132	32
T142	42
T162	62
T182	82

The shielding effectiveness on these devices would be as good or better than the current devices. This certification would apply to our license 12-18215-02MD. Lixi, Inc.'s Operators Manual for LIXI scopes will be modified to include the following instruction procedure for manually controlled T-series source holder heads:

- a) Unlock the security padlock and remove padlock from LIXI source head. This prevents unauthorized use of the LIXI scope.
- b) Push down on the control handle located on top of the source holder head and rotate 90° until indicator on the handle aligns with the stop position marked "on". The handle will only rotate in one direction to turn "on", which is counterclockwise when viewed from above with the scope to the right of the source head.
- c) Place the object to be examined in the open space between the scintillator cover and the source holder.
- d) For best imaging quality, place the surface of the object being evaluated against the scintillator cover of the LIXI scope. For example, in viewing a patient's finger, the finger should be at the surface of the scintillator cover rather than against the source head. A finger or other small object may be rotated in contact with the detector scope surface for real time imaging in various viewing positions.
- e) Pull the trigger on the scope. This activates the electronics for the viewing screen.

- f) Small objects must be handled with forceps or other remote holding devices to avoid exposing the fingers in the collimated radiation beam. The combination of distance from the radiation source and the shielding by the LIXI scope itself keeps radiation levels at the viewing side to normal background radiation levels.
- g) Nonmedical users are never to insert their fingers, hands or other extremities, or those of co-workers into the radiation beam.
- h) Remove object from beam when viewing is completed. Release the trigger and rotate control handle 90° in a clockwise direction to the "off" position.
- i) Relock the source holder head as it was prior to item "a" in the series of instructions.

In support of our request in item C, add Americium-241 for industrial use distribution only, we submit drawings LS-82-315, LS-82-X (series) and LS-80-002 for scopes designed for Americium-241 which have a tungsten alloy front shield to restrict radiation to below 2 mR/hr at all points around the scope except in the beam area. The data submitted above for exposure device TA31 attests to the devices ability to safely contain Americium-241. There will be no need to unload an Americium-241 capsule from device TA31 because of the long half-life of this isotope. We have included a blind hole roll pin to virtually eliminate any concern over removal of the capsule from the device. The LS-82-315, LS-80-002 and LS-82-X (series) units can interchangeably use I-125 or Am-241 source holder heads. Other models of LIXI scope authorized for use with I-125 heads must be returned to the factory for modification before they can be used with Am-241.

In support of our request in item "D" for addition of the T-series Iodine-125 source holder to our medical use distributor license we offer the following:

- 1) Shielding is equivalent to the other approved models
- 2) The radiation levels at surface and scatter radiation levels around the units are the same as the approved models.
- 3) The Iodine-125 capsule and maximum activity level are the same as the approved models.

Mr. Bruce Mallett
Page Nine
November 16, 1984

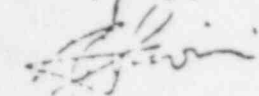
- 4) The exposure rate listed in Table A on page 16 of our Operators Manual are the same and therefore there would be no change in the exposure rate to patients.

The information contained in this application is confidential and proprietary and is therefore exempted from public disclosure per 10 CFR 2.790.

Enclosed is our check for \$820.00 for this application amendment fee for categories 3B (\$120.00), 3D (\$120.00), and 9A (\$580.00).

Sincerely,

Lixi, Inc.



Robert J. Savini
Executive Vice President

RJS/kr
Enclosures

LIXI

November 16, 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

Re: Amendment to License No. 12-18215-01 and 12-18215-02MD

Dear Mr. Mallett:

We request that our license be amended for the following items:

- A) Add permission to transport and demonstrate at remote locations for the purpose of research and development sealed source isotopes permitted under items 6(A)(B), 7(A)(B) and 8(A)(B), to item 9(A) and (B).
- B) Certify our new manually controlled isotope exposure devices for distribution with Iodine-125 and Americium-241. This new design is designated by the model number Tx_1x_2 , where T represents the type of head (manual), x_1 is an alphabetic letter that represents the isotope (such as I=Iodine-125 and A=Americium-241), and x_2 is a number which represents the different mounting and collimation designs.
- C) Add Americium-241: physical form: sealed source Amersham capsule AMC.17x92/0 maximum activity 375 mCi to items 6(C), 7(C) and 8(C), and also to authorize use 9(C).
- D) Add to our medical distributor license that our new manual Lixi source holder heads with Iodine-125 are equivalent to the models listed in License No. 12-18215-02MD.

RECEIVED BY LFMB	
Date	11/23/84
Log	200-174
By	[Signature]
Orig. To	R/T
Action Compl.	[Signature]

Applicant	2797-4320
Check No.	1720-38974
Amount	1580.44
Fee Category	
Type of Fee	1203 Paid
Date Check Rec'd	11/23/84
Received By	[Signature]

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U.S. NRC
LIC. FEES

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NOV 19 1984
REGION III

8503120488
Control # 7792 16

Current Model No.

Tx₁x₂ Model No.

31
32
42
62
82

TI31
TI32
TI42
TI62
TI82

This new series of source holder heads has the same exposure and surface radiation levels as does the hydraulic controlled style of heads for 500 mCi of I-125. These new heads are interchangeable as shown above on the LS-80-X, LSM-80-X, LS-82-X and LSM-82-X series LIXI scopes. All Lixi source holder heads are loaded at the factory. Due to design and method of loading only trained Lixi personnel can disassemble and re-load a source holder head. Industrial or medical users cannot replace or unload the isotope capsule from the source holder. In order to be licensed to load Lixi source holder heads, a person must complete a special training course at Lixi, Inc. designed for that purpose.

In support of our request in item A we submit the following information:

- 1) All prototype isotopes to be used in test at remote sites will be of metal construction and hermetically sealed by welding, or epoxy.
- 2) All source holder heads used for these temporary test site evaluations will be constructed of steel, lead or tungsten in a design similar to our current approved exposure devices. Example design drawings are attached. (H50098 and H50096)
- 3) The prototype isotopes used for these off site tests are limited to those isotopes that have a principal energy output which does not exceed 150 keV. The maximum permissible radiation level at surface of the source holder would be 30 mR/hr. Our source holders have a maximum diameter of 4 inches, therefore assuming the 30 mR/hr at surface, a user in the normal operating position would have his body located 21 inches from the surface of the holder as a minimum dimension. This would mean a worst case exposure to the user of 0.22 mR/hr. No user would receive a dose in excess of two millirems in any one hour period.

- 4) Lixi personnel will control the test area in such a manner to keep all observers at a safe distance from the unit. Lixi will comply with the provisions of Part 20 standards for protection against radiation particularly Part 20.105 on permissible levels of radiation in unrestricted areas. Lixi personnel who perform tests at remote locations will use personal monitoring devices (pocket dosimeters) during the test. All off site tests or use will be performed only by or under the direct supervision of Bruce Van Pelt or Edward Polz. Their training experience is already on file with the NRC. Lixi Inc.'s safety procedures will be used at all remote locations.
- 5) Packaging used in transporting LIXI scopes to remote locations will meet Department of Transportation (DOT) regulations for transportation of Radioactive Materials per 49 CFR 172 through 173. All isotopes so shipped will have a current leak test certificate.
- 6) Maximum activity will not exceed the limits specified for prototype isotopes in Lixi, Inc. license, or the DOT limits for A₁ and A₂ values specified in 49 CFR 173.421, 173.422, 173.423, 173.433 and 173.434 which ever is lower.
- 7) Lixi will take the normal security precautions when transporting to a test sight such as locking or sealing the container as well as locking the Lixi source holder head. The usual mode of transportation will be ground, however if air is used. Lixi will package the unit to meet DOT Type A specifications for passenger carrying aircraft. At the test sight Lixi will only leave the unit when it is in a locked or otherwise secured area (such as with a guard in a security office). When doing so, Lixi will lock or seal the transport container with the device. In the event that the test period will take more than one day and Lixi is unable to secure the device at the test sight, then Lixi will store the device at the hotel locked in the authorized users room. Since the device is kept in its locked storage container and the radiation level at surface of the container will not exceed 0.5 mR/hr there is no danger to the occupant of the room and this storage mode is within the safety regulations of Part 20.

Mr. Bruce Mallett
Page Four
November 16, 1984

In support of our request in item B for certification of a manually controlled exposure device, we submit the following explanation and test data. The Tx₁x₂ series exposure devices were designed to eliminate the need for a hydraulic system to activate the devices on LIXI scopes. The devices are operated by a 90° rotation of the exposure control handle. The devices incorporate a steel pin which travels in a slot over the 90° rotation and at both ends of the slot are holes that capture the pin. This results in the necessity to push downward (inward) with 3.5 kg force over a distance of 1.6 mm to uncapture the pin and then turn it 90° to change the device from the "off" to the "on" position (or vice versa). The TA31 device tested had a shorter pin that required pushing the exposure control handle vertically only 1.2 mm to be free of the pin.

Model TA31 loaded with a 300 mCi AM-241 capsule was tested and found to conform to ANSI N432 standard of May, 1980 as a Class P, type 2, type L portable exposure device with local control.

ANSI N432 paragraphs as follows:

4.0 Marking and Identification

The label will be similar to that now used on LIXI scopes with the proper radionuclide indicated.

5.1.1 Design Considerations

All materials and fasteners are the same type as those used on current model I-125 holder heads.

5.1.2 Locks

The lock and locking arrangement are the same as those currently used on I-125 holder heads.

5.1.3 Not Applicable

5.1.4 Tests

Test data follows in paragraph 8

5.2 Not Applicable

6.0 Controls

6.1.1 Control can not be removed.

6.1.2 Control is marked as per drawings H50096 and H50098 attached.

6.1.4 Not applicable; Integral control

6.1.5 Not Applicable

6.1.6 The control is an integral part of the source assembly and as such will be tested with the exposure device as a whole.

6.2 Operator will not be within the emergent beam of radiation when operating control.

7.1 All sealed sources used will conform to ANSI N542.

7.2 Not Applicable

7.3 Not Applicable

8.1 Shielding Efficiency Test

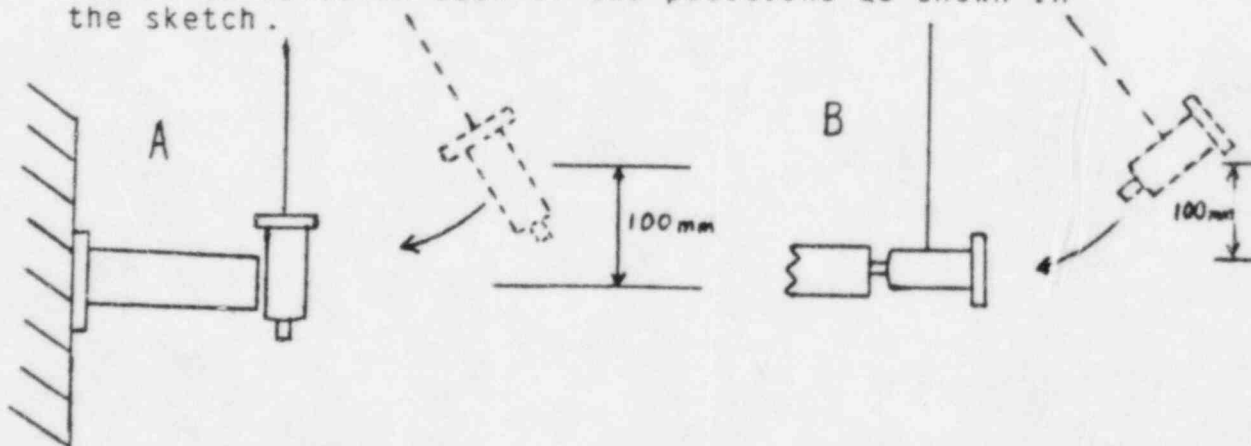
With the source in the stored position the exposure rate was as follows:

Surface of exposure device: 0.6 mR/hr

One meter from device: Less than 0.05 mR/hr

8.2 Horizontal Shock Test

This test was set up according to paragraphs 8.2.2 and 8.2.3. The exposure device fell vertically at least 100 mm 20 times in each of two positions as shown in the sketch.



Sketch B indicates what is considered the most susceptible position for damage. The impulse is applied directly to the exposure control handle which is spring loaded.

After 40 shocks the device operated normally. A few nicks and dents were evident.

8.3.2 Vertical Shock

This test was set up according to paragraphs 8.3.2.1 and 8.3.2.2 except the plywood was 3/4" and 5 ply. After 100 drops at 50 mm there was no damage.

8.4 Accidental Drop Tests

Drop #1: The exposure device was allowed to free fall twice from a height of 5.5 meters onto a 12.4 mm thick steel plate resting on a concrete floor. 5.5 meters was used instead of 9 meters as were the original tests performed January, 1981 for the first submission by Lixi, Inc. The first drop was such that the exposure control contacted first and second was such that the side of device contacted first. The points of contact were the same as those in horizontal shock test above. The only damage suffered except for nicks and scratches was slight bowing of the bottom disc which is held by a snap ring. This ring is backed up by a roll pin. The device still functioned normally and the surface radiation level remained 0.6 mR/hr.

Drop #2: This was not performed because it was essentially the same as drop #1 because of the small size of the device.

8.5, 8.6, 8.7, 8.8 Do not apply.

8.9 Endurance Test

The device was judged most likely to wear where the steel pin contacted the groove of tungsten alloy material with the spring force of about 3.4 kg. This test was set up to move the pin back and forth over the middle 30° of the total 90° travel. The device was connected to a motorized travel cyler which operated at 2100 cycles per hour. This is 0.86

second for one 30° movement. After 21.752 cycles the unit performed normally. On closer inspection the wear on the pin was measured at 0.005 cm (.002") with no wear in the groove.

The Tx₁x₂ series exposure devices have the same padlock security as the current devices. This series includes devices to be interchangeable with current devices for Iodine-125 capsules. These are specifically:

<u>Tx₁x₂ Series</u>	<u>Current Model</u>
TI31	31
TI32	32
TI42	42
TI62	62
TI82	82

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- a) Unlock the security padlock and remove padlock from Lixi source head. This prevents unauthorized use of the LIXI scope.
- b) Push down on the control handle located on top of the source holder head and rotate 90° until indicator on the handle aligns with the stop position marked "on". The handle will only rotate in one direction to turn "on", which is counterclockwise when viewed from above with the scope to the right of the source head.
- c) Place the object to be examined in the open space between the scintillator cover and the source holder.
- d) For best imaging quality, place the surface of the object being evaluated against the scintillator cover of the LIXI scope. For example, in viewing a patient's finger, the finger should be at the surface of the scintillator cover rather than against the source head. A finger or other small object may be rotated in contact with the detector scope surface for real time imaging in various viewing positions.
- e) Pull the trigger on the scope. This activates the electronics for the viewing screen.

- f) Small objects must be handled with forceps or other remote holding devices to avoid exposing the fingers in the collimated radiation beam. The combination of distance from the radiation source and the shielding by the LIXI scope itself keeps radiation levels at the viewing side to normal background radiation levels.
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- h) Remove object from beam when viewing is completed. Release the trigger and rotate control handle 90° in a clockwise direction to the "off" position.
- i) Relock the source holder head as it was prior to item "a" in the series of instructions.

In support of our request in item C, add Americium-241 for industrial use distribution only, we submit drawings LS-82-315, LS-82-X (series) and LS-80-002 for scopes designed for Americium-241 which have a tungsten alloy front shield to restrict radiation to below 2 mR/hr at all points around the scope except in the beam area. The data submitted above for exposure device TA31 attests to the devices ability to safely contain Americium-241. There will be no need to unload an Americium-241 capsule from device TA31 because of the long half-life of this isotope. We have included a blind hole roll pin to virtually eliminate any concern over removal of the capsule from the device. The LS-82-315, LS-80-002 and LS-82-X (series) units can interchangeably use I-125 or Am-241 source holder heads. Other models of LIXI scope authorized for use with I-125 heads must be returned to the factory for modification before they can be used with Am-241.

In support of our request in item "D" for addition of the T-series Iodine-125 source holder to our medical use distributor license we offer the following:

- 1) Shielding is equivalent to the other approved models
- 2) The radiation levels at surface and scatter radiation levels around the units are the same as the approved models.
- 3) The Iodine-125 capsule and maximum activity level are the same as the approved models.

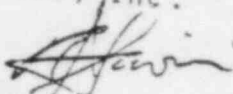
- 4) The exposure rate listed in Table A on page 16 of our Operators Manual are the same and therefore there would be no change in the exposure rate to patients.

The information contained in this application is confidential and proprietary and is therefore exempted from public disclosure per 10 CFR 2.790.

Enclosed is our check for \$820.00 for this application amendment fee for categories 3B (\$120.00), 3D (\$120.00), and 9A (\$580.00).

Sincerely,

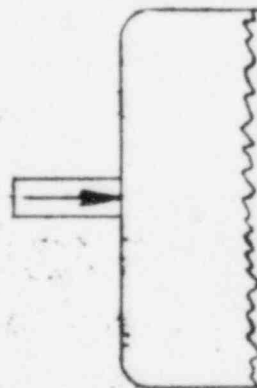
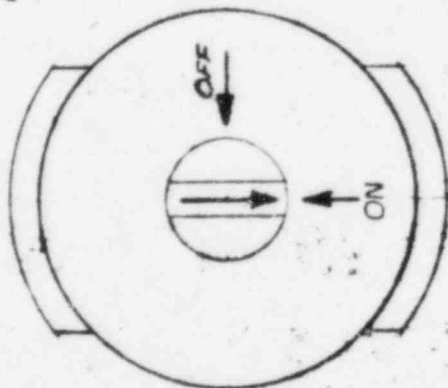
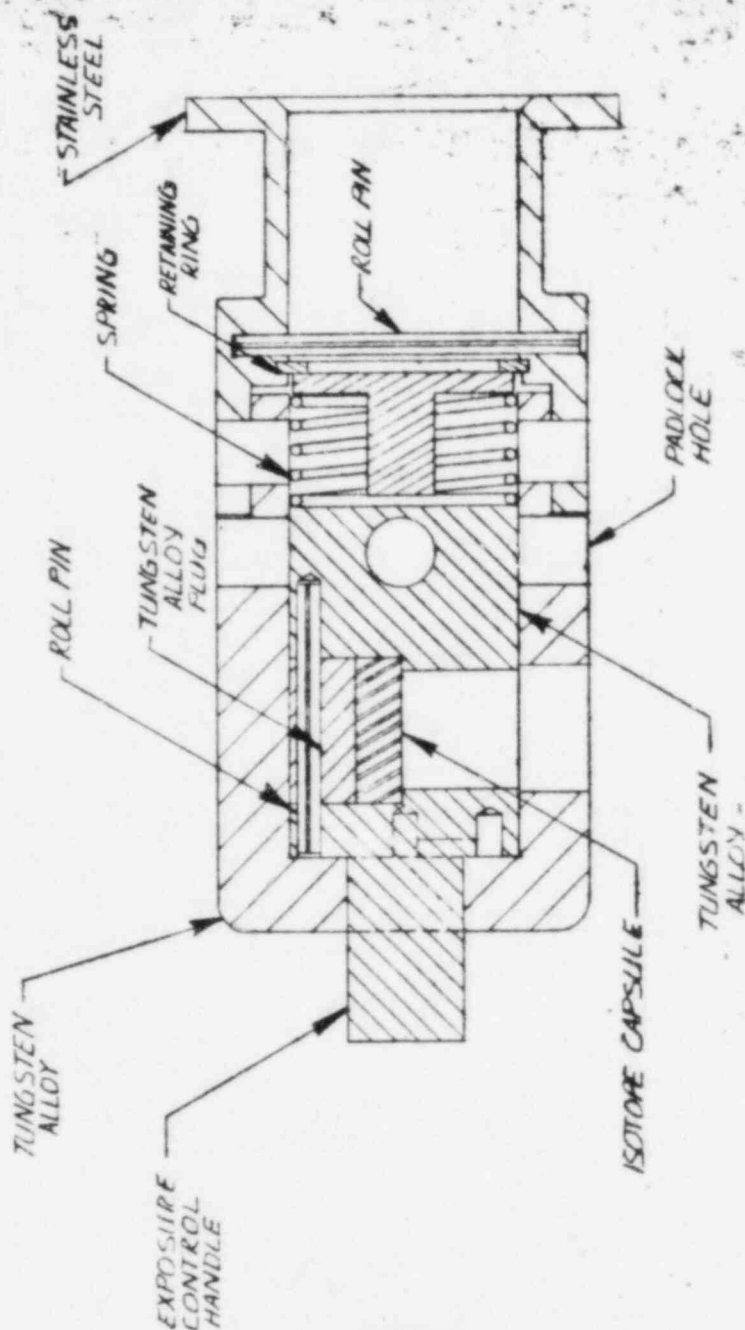
Lixi, Inc.



Robert J. Savini
Executive Vice President

RJS/kr
Enclosures

DATE	BY	REVISION	RECORD	CM
11/1/84	A	NEW	REVISION	



All specifications, drawings, sketches, photographs, reprints or books and all materials of business information or other written, oral photographic or otherwise and including that which is shown on or in any other form (film) furnished by LIXI INC. hereunder shall be confidential and shall be considered by you to be confidential, proprietary or a trade secret of LIXI INC.

TOLERANCES (UNLESS OTHERWISE SPECIFIED)	LIXI INC.
DIMENSIONAL	DATE 2/1
FUNCTIONAL	APPROVED BY JAS
ASSEMBLY	DATE 11/4/84
	QUANTITY NUMBER H 50026
	TITLE ISOTOPE EXPOSURE DEVICE
	APPROVED BY JAS

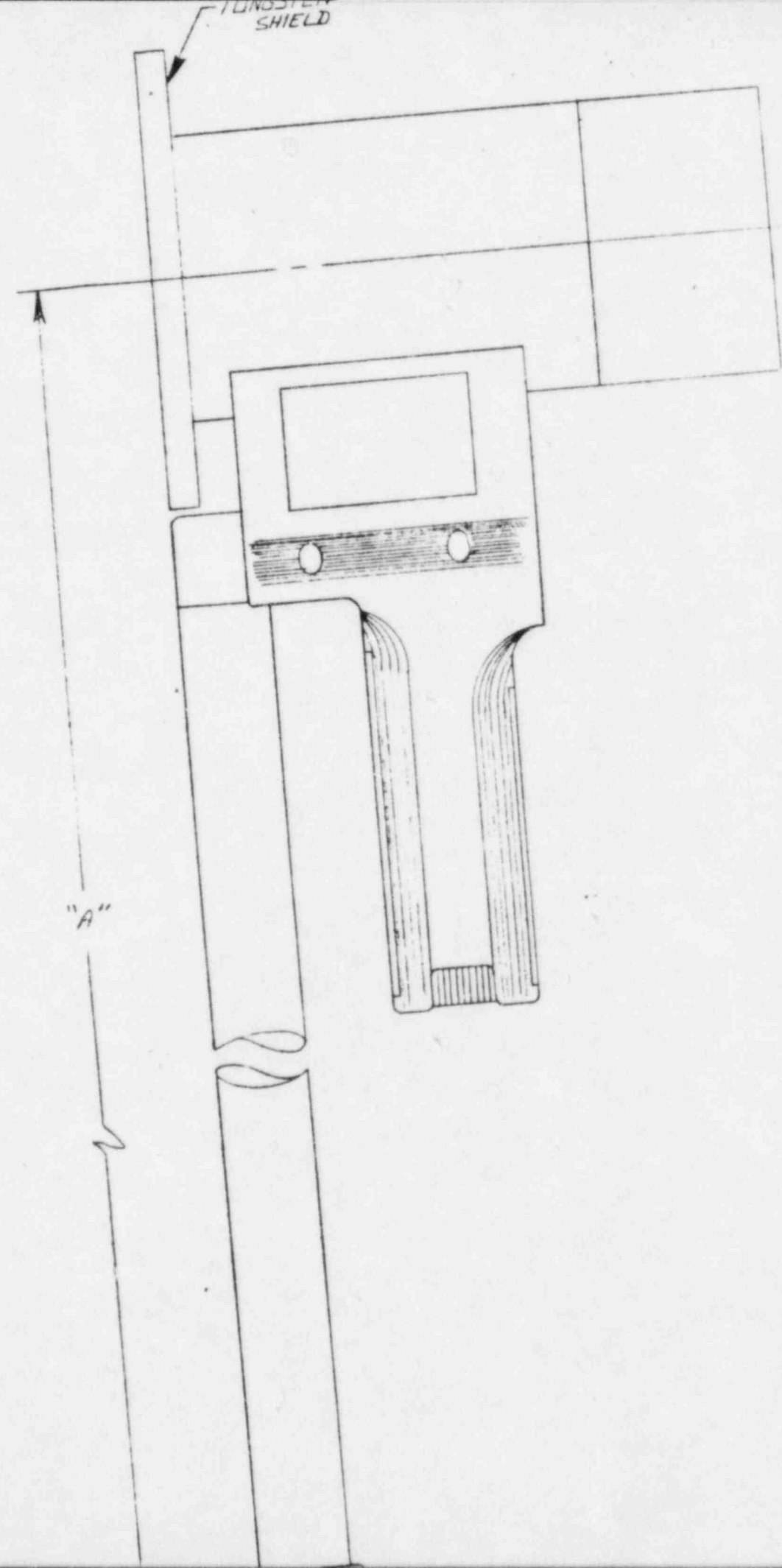
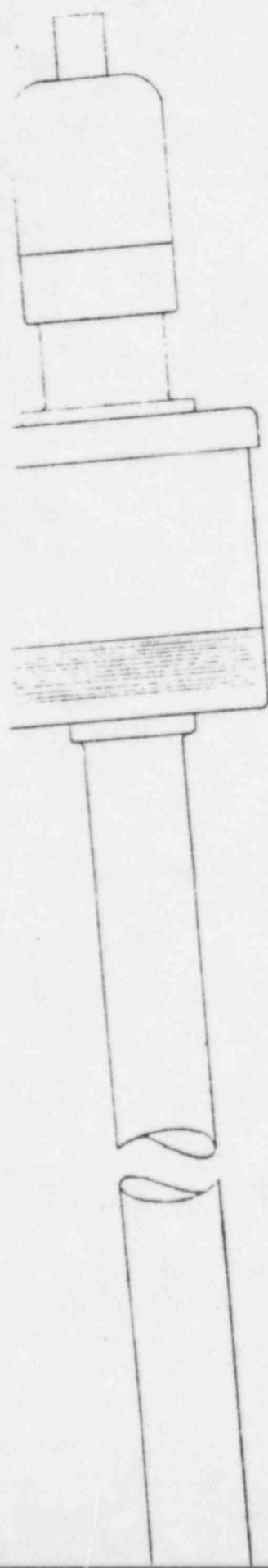
MODEL NO.	DIM "A"
LS-82-3/2	18"
LS-82-3/3	3 1/2"
LS-82-3/4	12"
LS-82-	
LS-82-	

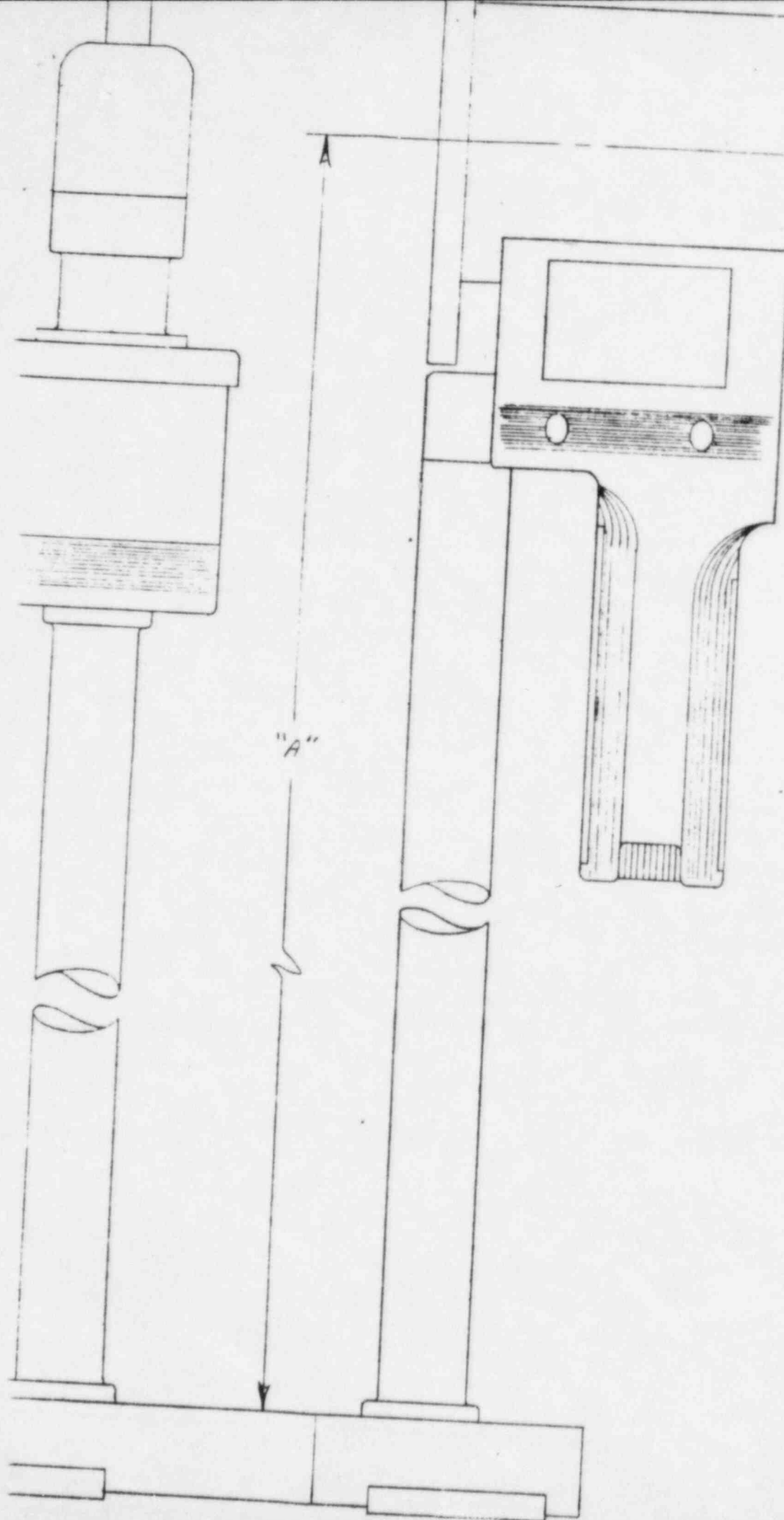
NOTE: 1 1/2" HEAD COULD BE
USED ON THIS UNIT.

All specifications, drawings, sketches, photographs, samples or tools, and all technical or business information or data (written, oral photographic or otherwise and including that which is stored on or in any storage medium), furnished by LIXI INC. hereunder or in contemplation hereof shall be considered by you to be confidential, proprietary or a trade secret of LIXI INC.

TOLERANCES EXCEPT AS NOTED:		LIXI INC.	
DECIMAL		SCALE	DRAWN BY
1		11	AS
FRACTIONAL		TITLE	APPROVED BY
2		BENCH UNIT FOR AMERICAN	st
ANGULAR		DRAWING NUMBER	
2	7-1/8"	LS-82-XXX SEE CHART	

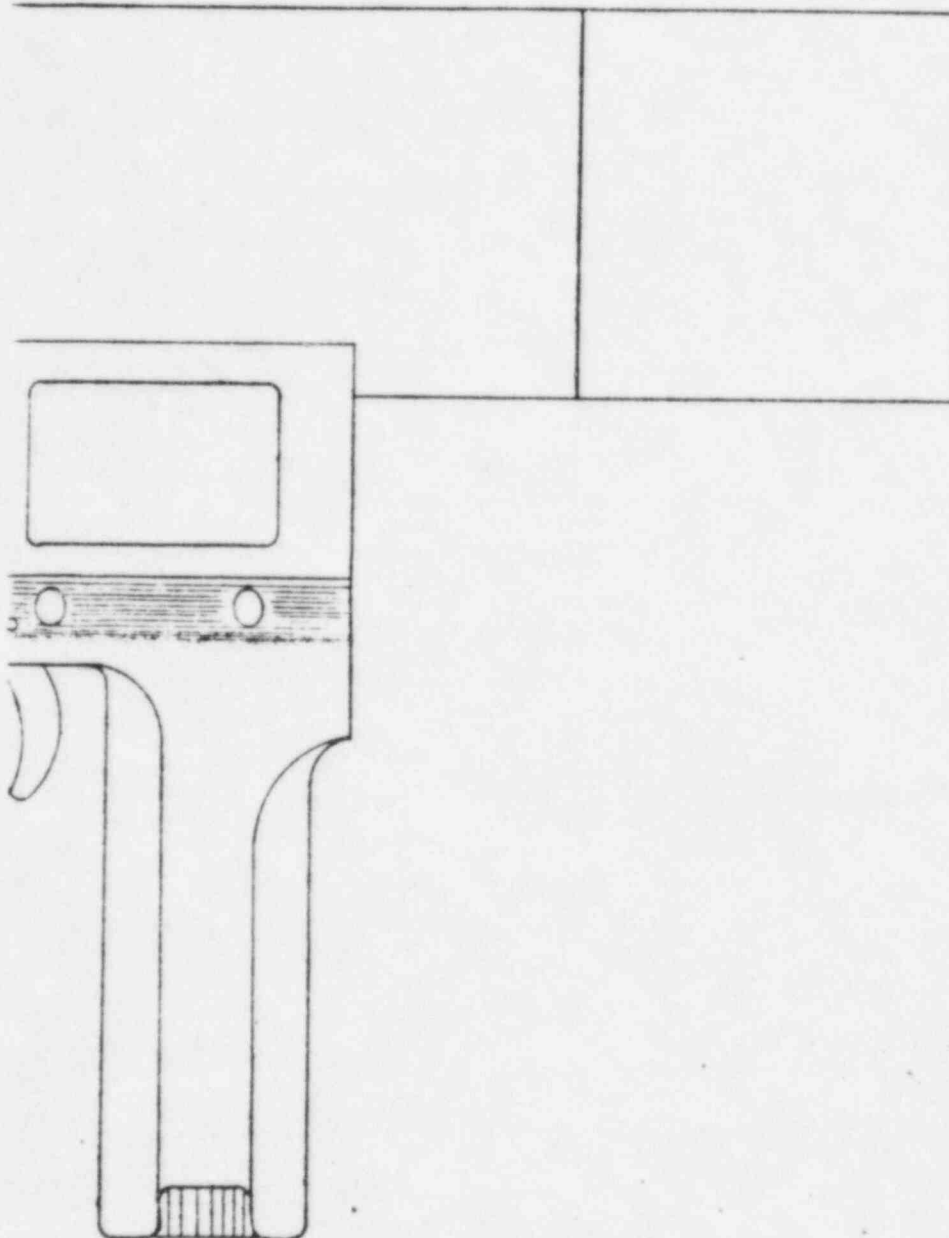
CONTROL NO. ~~XXXXXXXXXX~~





DATE	BY	REVISION RECORD	DR	CA
9/8	1	NEW DRAWING		

TUNGSTEN ALLOY SHIELD

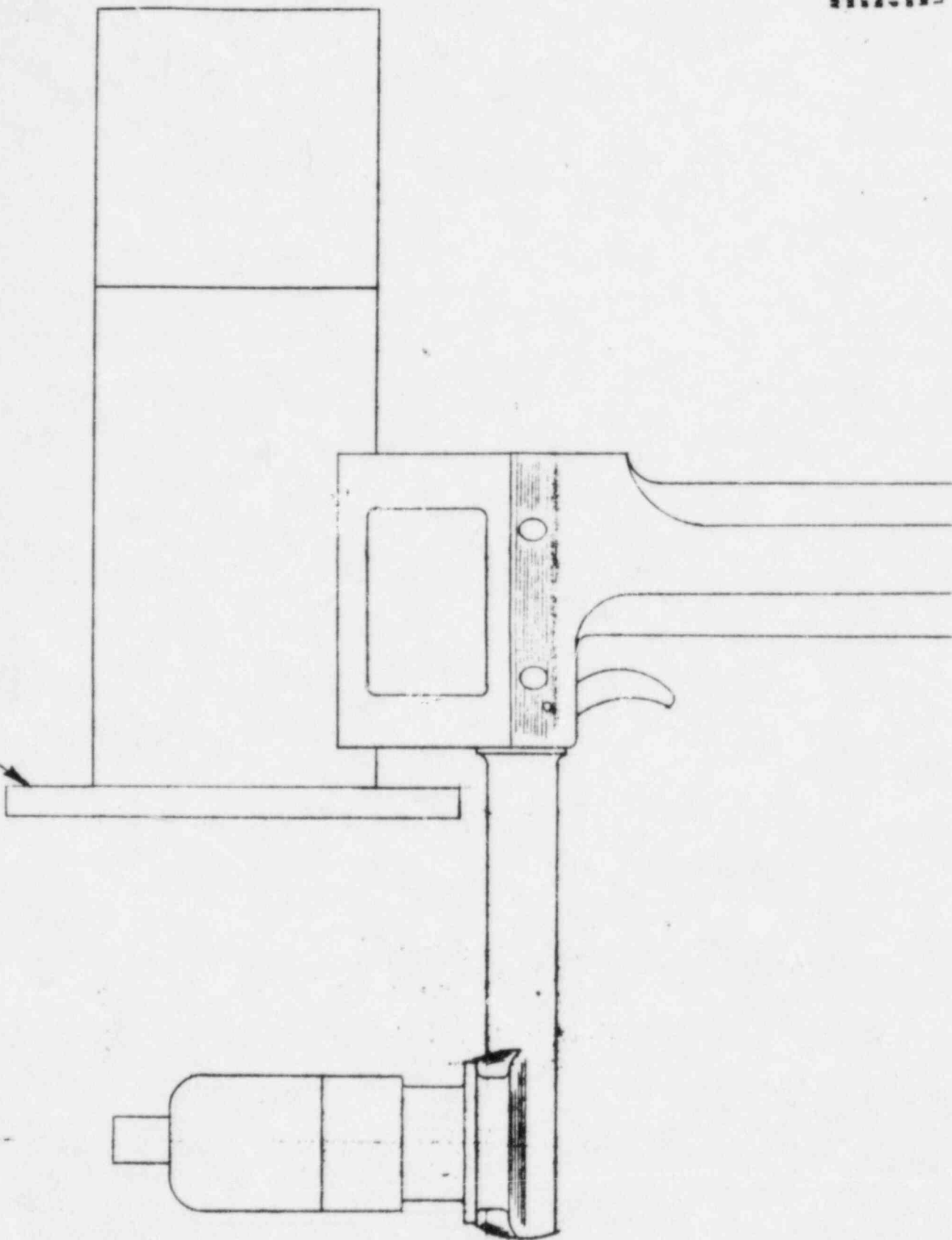


All specifications, drawings, sketches, photographs, samples or tools, and all technical or business information or data (written, oral photographic or otherwise and including that which is stored on or in any storage medium) furnished by LIXI INC. hereunder or in contemplation hereof shall be considered by you to be confidential, proprietary or a trade secret of LIXI INC.

NOTE: 1/2" HEAD COULD BE
USED ON THIS UNIT.

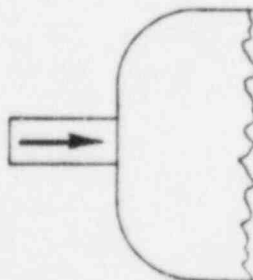
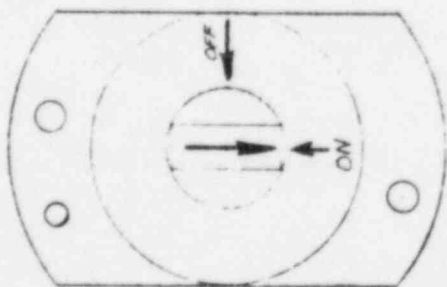
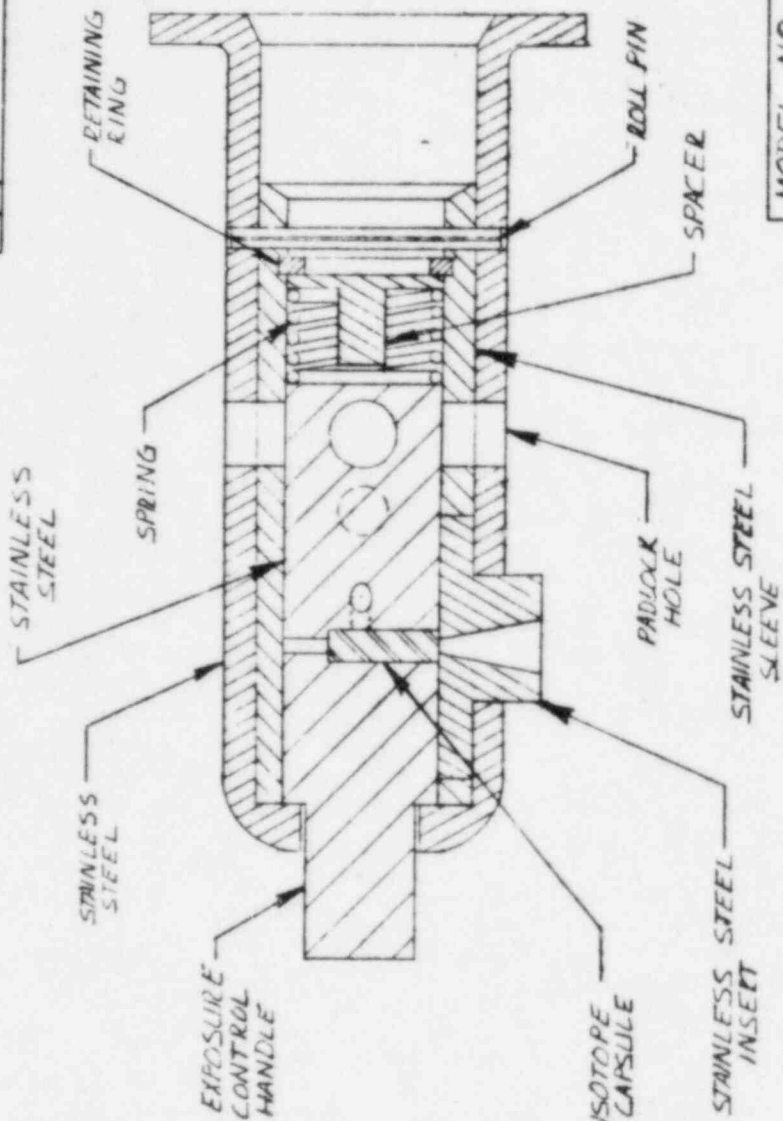
TOLERANCES (UNLESS AS NOTED)		LIXI INC	
DECIMAL		SCALE 1/1	DRAWN BY US
FRACTIONAL		TITLE HAND HELD UNIT FOR AMERICAN	APPROVED BY #
ANGULAR	DATE 11/4/84	DRAWING NUMBER LS-B2-315	

TUNGSTEN ALLOY
SHIELD



All specifications, dimensions, or tolerances, or data herein, including but not limited to, shall be furnished as in contemplation of the contract to be completed by LDO INC.

DATE	BY	REVISION	RECORD	CK
7/2/54	66	LR	10	54



MODEL NO.	
XX	TI
31	32
42	62
RE	

TOLERANCES		LIXI INC.	
UNLESS OTHERWISE SPECIFIED		DATE	7/2/54
DECIMAL		DESIGNED BY	7/2/54
FRACTIONAL		TITLE	ISOTOPE EXPOSURE DEVICE
ANGULAR		DATE	11/6/54
		QUANTITY	H 50098

All specifications, drawings, sketches, photographs, samples or data, and all information of business information or data (written, oral, photographing or otherwise) including that which is stored on or in any storage medium, for use by LIXI INC. is a trade secret of LIXI INC. and shall be held as such by you.