12-18215-01

January 28, 1983

Mr. Paul Guinn
U.S. Nuclear Regulatory
Commission
Radioisotopes Licensing
Branch
Division of Material Safety
and Fuel Cycle Licensing
Washington, D.C. 20555

Re: Amendment to License 12-18215-01 and
Lixiscope Product Certification

Dear Mr. Guinn:

We request amendment to our above referenced license and product certification to add the following:

1. Increase possession limit on I-125 sealed sources as listed in our license, from 500mCi each to "Nominal 500mCi each, ± manufacturer's tolerances". For example, Amersham, as one of our I-125 sealed source suppliers, has a tolerance of -10%, + 50%.

2. Authorize Lixi, Inc. to transfer leak test date from I-125 sealed source supplier's certificates onto our own leak test certificates, or on Stan Huber Consultant's Inc. leak test certificates, when we send this test certification with Lixiscopes to customers. Our reason for doing this is to avoid customer confusion as to where they are to send subsequent leak test kits for assay, as well as to avoid the possibility that a customer may return a Lixi, Inc. source head to our sealed source suppliers, such as Amersham or AECL. A sample of a SAHCI leak test certificate is enclosed, which is already on file with the NRC Product and Certification Branch. Stan Huber has authorized us to use these leak test certificates for this purpose, subsequent to NRC approval of this item.

3. We wish to change our Lixiscope registration data to reflect the following different model series and descriptions:

30-14668

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Lixi, Inc. 1438 Brook Drive Downers Grove, Illinois 60515 (312) 620-4646 Telex 6871077 DKROB TWX 910-991-3903

a) Model LS-80 Series for industrial use, with a stainless steel scope body and source head. This description is already on file with the NRC Product Certification Branch.

b) Model LS-82 Series for industrial use, with an aluminum body shell casing and stainless steel source head. Drawings are enclosed.

c) Model LSM-80 Series for medical use. This unit is identical to the LS-80 industrial scope, except for the required different labeling for medical use. These medical labels are on file with Joe Del Medico of the NRC Medical License Branch.

d) Model LSM-82 Series for medical use. This unit is identical to the LS-82 industrial scope, except for the different labeling for medical use. These medical labels are also on file with Joe Del Medico. The medical labels are the same for both the LSM-80 and LSM-82 models.

The same tests were conducted on the LS-82 and LSM-82 models as were done on the LS-80 and LSM-80 models in our original product certification and application. There was no significant difference in test results. See the attached "Test Data for LS-82 and LSM-82 Series Lixiscopes".

4. We have added an electronic audible timer alarm to the LSM-80 and LSM-82 series for medical use, at the request of the FDA. This alarm system is activated and shut off by the Lixiscope trigger. The alarm is sounded ten seconds after the trigger is pulled and every ten seconds thereafter, as long as the trigger is in the "on" position. Please reference the new Lixiscope Instruction Manual (enclosed) which includes instructions for medical users. The alarm is discussed in item nine of this new manual. A schematic of the alarm system is enclosed for your file and the NRC Product Certification Branch records.

5. On bench mount models of the industrial LS-80 and LS-82 series, the "on-off" mechanism is a key switch instead of a trigger. Please see the enclosed print.

6. We have improved the source head designs to match collimation of the radiation beam to the field size of the detector scopes. In other words, the internal collimation design is dependant on the length of the distance bar with each Lixiscope. We have now assigned model numbers to the source heads to reflect this relationship. Each source head (holder) model has a pin located in such a manner as to allow only the positioning of a source head designed for the particular combination of distance bar length and detector scope field diameter. The source head has a mating hole matched up with the locating pin of the distance bar arm. The following are the source head description and models we intend to use:

Source Head Model #32 = 3" distance bar with 2" diameter detector.
Source Head Model #42 = 4" distance bar with 2" diameter detector.
Source Head Model #62 = 6" distance bar with 2" diameter detector.
Source Head Model #82 = 8" distance bar with 2" diameter detector.
Source Head Model #21 = 2" distance bar with 1" diameter detector.
Source Head Model #31 = 3" distance bar with 1" diameter detector.

The first digit in the source head model number is the length in inches of the distance bar. The second digit in the source head model number is the field diameter of the detector in inches. Enclosed is a drawing showing the collimator configurations of the above listed source head models.

The collimator has been changed to tungsten instead of stainless steel, although we wish to reserve the option to use either material with these I-125 source heads. The reason for our anticipated total change over to tungsten was to permit possible later use with higher energy radionuclides, when our research results indicate we may be able to apply for licensing of an additional type of radionuclide in the source heads.

We believe we have now detailed all changes or clarifications to update our Lixiscope descriptions on file with the NRC, and to aid in the NRC communicating with Agreement States about the different Lixiscope Series model numbers.

Please call if there are any questions. Enclosed is our check for the license amendment processing fee. Thank you for your assistance in expediting this request.

Sincerely,

Lixi, Inc.

Robert J. Savini
Executive Vice President

RJS/kp
CC: Earl Wright (NRC)
Stan Huber (SAHCI)

Enclosures:
1) Sample SAHCI Leak Test Certificate
2) Drawing for Model LS-82 and LSM-82 series Lixiscopes.
3) Test Data for Model LS-82 and LSM-82 series Lixiscopes.
4) New Lixiscope Instruction Manual (including medical users).
5) Schematic of Model LSM-80 and LSM-82 electronic audible timer alarm.
6) Print of bench mount models of the industrial LS-80 and LS-82 series with key switch "on-off" mechanism.
7) Drawing of collimator configurations for Lixiscope source head models.

γ and primary X-ray sources — Iodine-125

Iodine-125

Iodine-125 incorporated in an ion-exchange resin bead in a beryllium capsule sealed with epoxy resin and mounted in a stainless steel holder with a titanium window.

This design of source produces a highly collimated beam. Principal emissions: Te K X-rays and 35.4keV γ-rays.

The maximum concentration of ^{126}I is <0.2%; principal emissions from ^{126}I:
Te K X-rays, γ-rays 386keV (34%) and 667keV (33%).

type	capsule	activity* mCi	photon output in photons/sec per steradian Te K X-rays	code
point	X.105	10	2.5×10^7	IMC.24
		50	1.2×10^8	IMC.26
		100	2.5×10^8	IMC.27
		200	5×10^8	IMC.29
		400	1×10^9	IMC.32
		500	1.2×10^9	IMC.33

*activity tolerance −10, +50%

Availability: D6

Sources can be supplied without the holder.

Quality control
Wipe test A
Bubble test D

Photon emission checked using a Si(Li) detector. γ-impurities (^{126}I) content checked using a Ge(Li) detector.

Mixed nuclide source

This americium-241/iodine-125 source has been developed for use in bone densitometry but has other industrial applications.

The source comprises a point source of ^{241}Am, the radiation from which passes through a 'bucket-shaped' ^{125}I source.
The two photon energies (59.5keV from ^{241}Am and 27-32keV Te K X-rays from ^{125}I) enable the differentiation of bone and tissue in bone densitometry studies, eliminate the need to surround the limb in a constant thickness of tissue-equivalent material and allow measurement of bone mineral content in inaccessible areas such as the hip or spine.

Americium-241 source
The americium-241 is incorporated in a sintered pellet sealed in a welded stainless steel capsule (X.102/3)
Nominal activity: 100mCi
Principal photon emission: 59.5keV γ-rays
output: ~2.2×10^7 photons/sec per steradian

Combination source
The americium-241 and iodine-125 sources are designed to be used in combination, mounted in a stainless steel holder (X.265) which has a removable plug to facilitate regular exchange of the iodine-125 source. This exchange can be carried out by the user or at Amersham.

Iodine-125 source
The iodine-125 is incorporated in an ion-exchange resin bead in an aluminum alloy 'bucket' capsule sealed with epoxy resin
Nominal activity: 200mCi

Principal photon emission:
Te K X-rays (27-32keV) and 35.4keV γ-rays
output (from Te K X-rays) ~5×10^8 photons/sec per steradian
Maximum concentration of ^{126}I is <0.2%

Product codes
Mixed nuclide source (^{241}Am and ^{125}I sources in holder)—**DNC.26512**
Replacement iodine-125 source—**IMC.10909**
Exchange service (removal of old ^{125}I source, insertion of new ^{125}I source)—**S2**
Holder—**X265**

Quality control
Constituent sources:
Wipe test A
Bubble test D
Immersion test (for ^{241}Am source only) L
Emission intensity: checked using a Si(Li) detector
Spectral purity: checked using a Ge(Li) detector

Combination source:
Wipe test A

Prototype testing
^{241}Am source:
ANSI Classification: C64444
IAEA Special form: SFC.59

^{125}I source:
ANSI Classification: C34343

Availability: D8

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Enclosure 1

SEALED GAMMA SOURCE - LEAK TEST CERTIFICATE

Leak Test Report Date: 11-08-82

Facility: LIXI INC City: DOWNERS GROVE State: IL

Facility Radioactive Material Lic. No.: 12-18215-01

☒ NRC ☐ STATE

Source Identification

Radionuclide: I-125 Activity: 100 mCi

Calibration Date: 10-25-79 Manufacturer: AMERSHAM

Model No.: IMC.P2 X105 Serial No.: 0899 LJ

Assay Results:

	GROSS COUNTS/MIN	NET COUNTS/MIN	uCi
WET WIPE			
DRY WIPE	10	0	<9.1E-07
	5	0	<9.1E-07

Background @ time of assay 16 CPM

Analysis of Results: Source is not leaking at this time. Removable activity is less than 5×10^{-3} uCi.

NEXT LEAK TEST DUE: MAY 1983

Leak Test Performed by: BRUCE VAN PELT Date: 11-05-82

Analysis Performed by: STAN HUBER SAH Date: 11-08-82

sahci STAN A. HUBER CONSULTANTS, INC.

235 ESSEX LANE ◻ NEW LENOX, ILLINOIS 60451

(815) 722-8009

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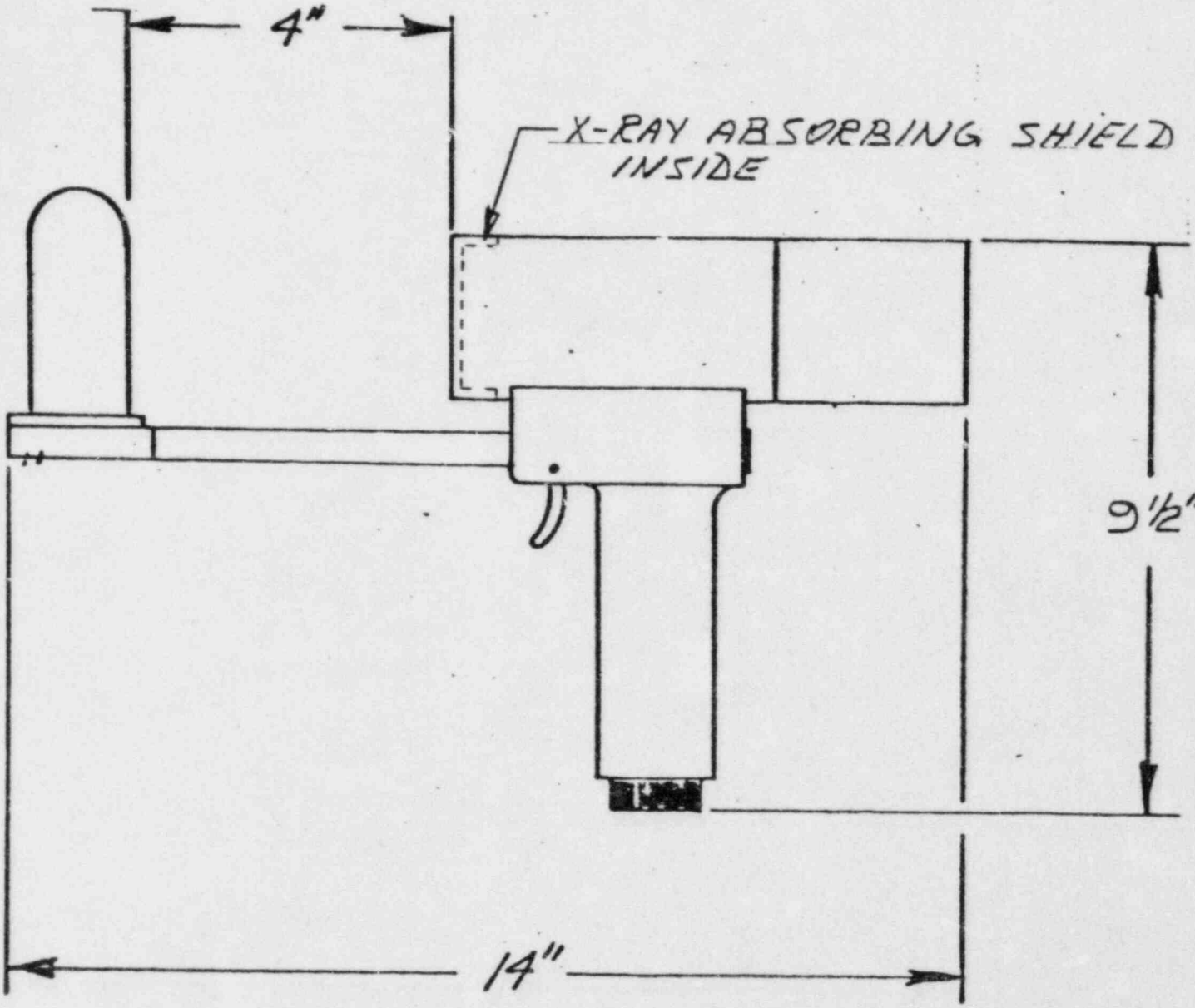

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .015		SCALE ½	DRAWN BY SPS APPROVED BY
FRACTIONAL ± 1/16	TITLE		
ANGULAR ± 1°	DATE 9/8/82	DRAWING NUMBER LS-82-X (PORTABLE)	

SPECIFICATIONS

Method of Operation:	Hand-held trigger actuator
Object Field of View:	50mm diameter
Max. Object Size:	4" depth
Output Viewing:	Direct viewing of 50mm screen with image inverted
Housing Material & Finish:	ALUMINUM, ANODIZE.
Weight:	5LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-rays)
Power Source:	Two 1.5V alkaline "C" size batteries
Resolution:	$3 \frac{lp}{mm}$
Special Features:	Not Available

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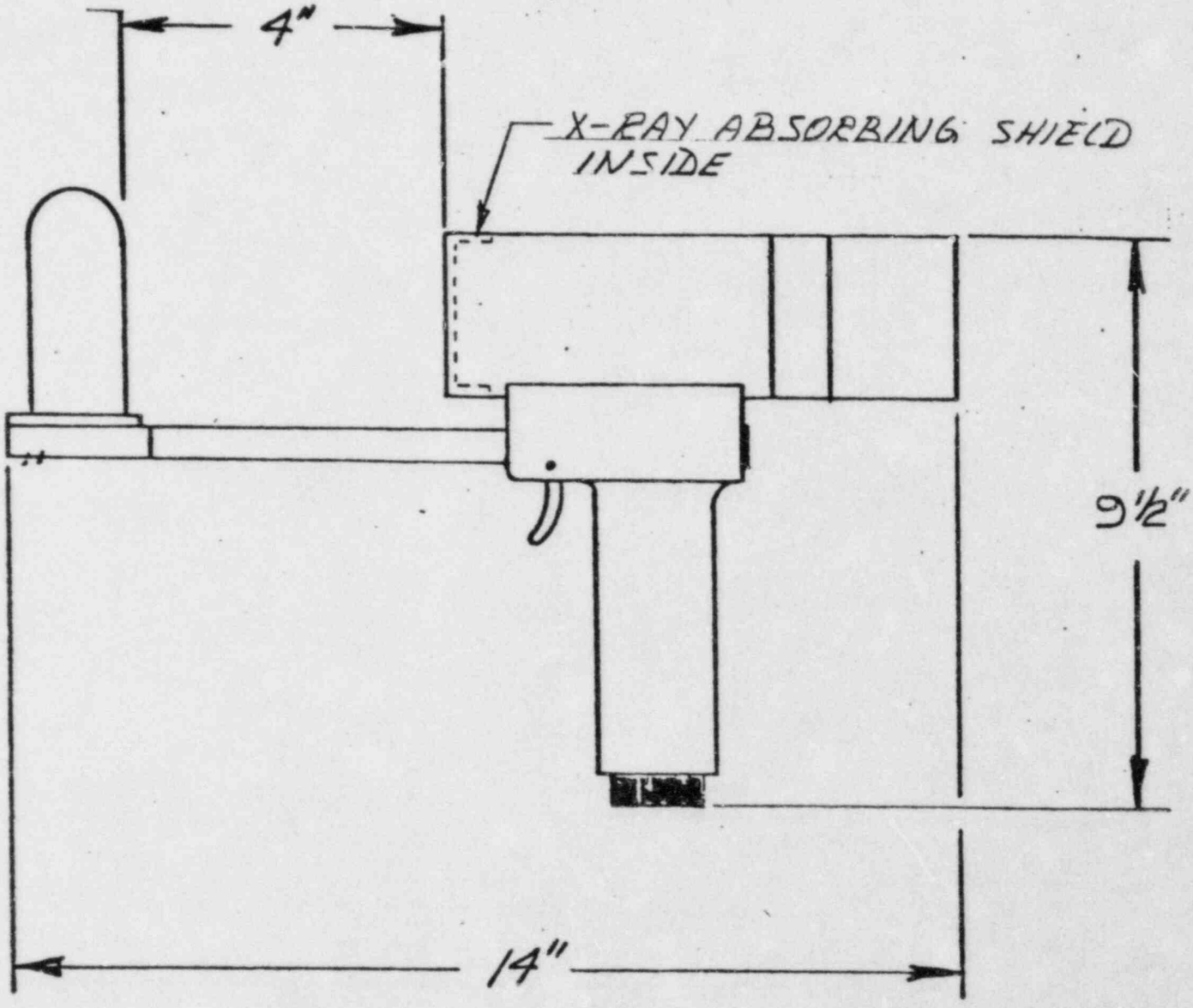

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .015		SCALE ¼	DRAWN BY SPS
FRACTIONAL ± 1/16	TITLE		APPROVED BY
ANGULAR ± 1°	DATE 9/8/82	DRAWING NUMBER LSM-82-X (PORTABLE MEDICAL)	

SPECIFICATIONS

Method of Operation:	Hand-held trigger actuator
Object Field of View:	50mm diameter
Max. Object Size:	4" depth
Output Viewing:	Direct viewing of 50mm screen with image inverted
Housing Material & Finish:	ALUMINUM, ANODIZE..
Weight:	5LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-rays)
Power Source:	Two 1.5V alkaline "C" size batteries
Resolution:	$\frac{3\ lp}{mm}$
Special Features:	10 SECOND INTERVAL TIMER/ALARM WHICH IS TRIGGER ACTUATED LABELING FOR MEDICAL USE ONLY

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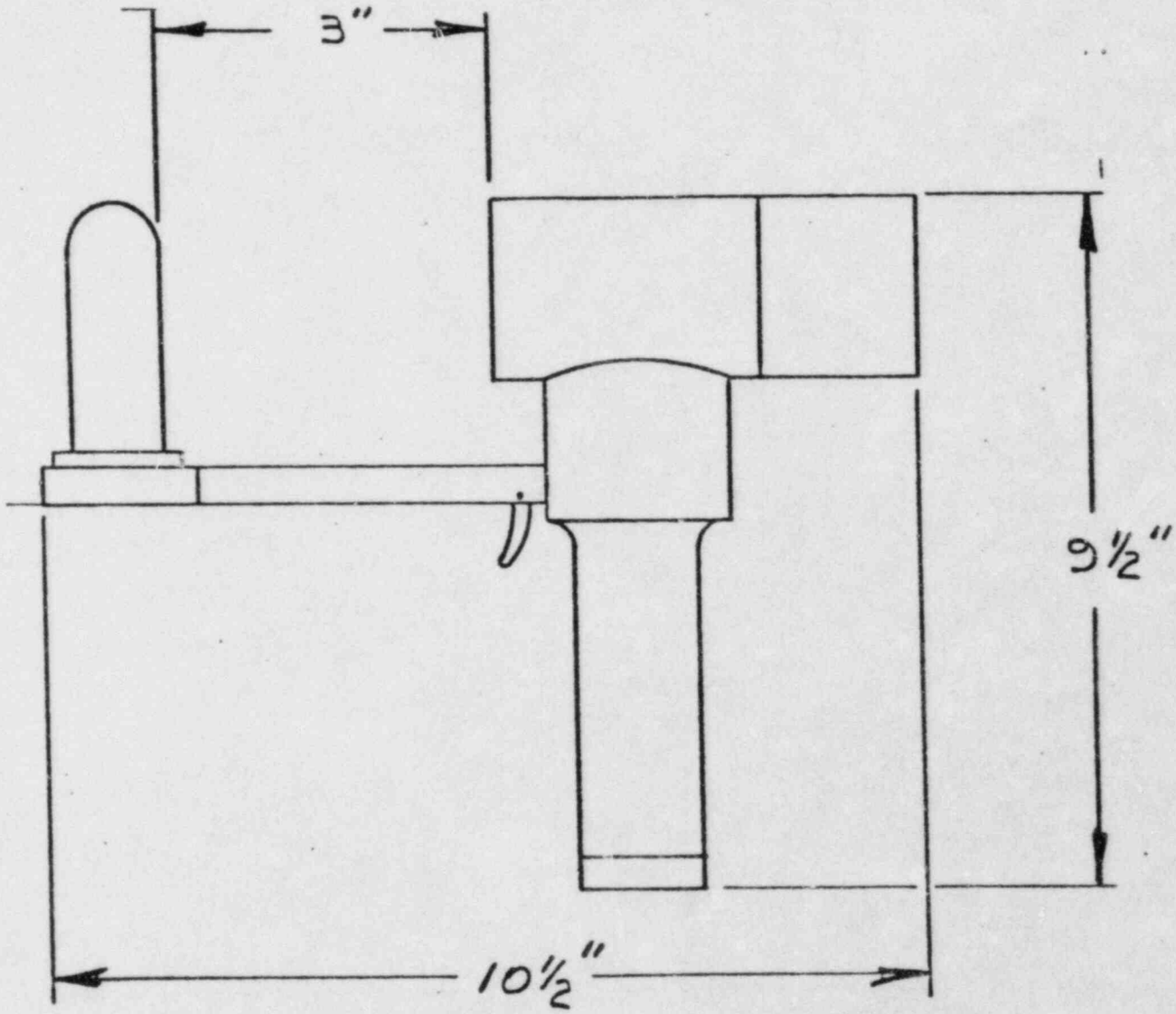

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
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			APPROVED BY
FRACTIONAL ± 1/16	TITLE		
ANGULAR ±1°	DATE 8/18/82	DRAWING NUMBER LSM-80-X (PORTABLE MEDICAL)	

SPECIFICATIONS

Method of Operation:	Hand-held trigger actuator
Object Field of View:	25mm diameter
Max. Object Size:	3" depth
Output Viewing:	Direct viewing of 25mm screen with imag inverter
Housing Material & Finish:	Non-corrosive stainless steel
Weight:	5LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-rays)
Power Source:	Two 1.5V alkaline "C" size batteries
Resolution:	$3 \frac{lp}{mm}$
Special Features:	10 SECOND INTERVAL TIMER/ALARM WHICH IS TRIGGER ACTUATED LABELING FOR MEDICAL USE ONLY

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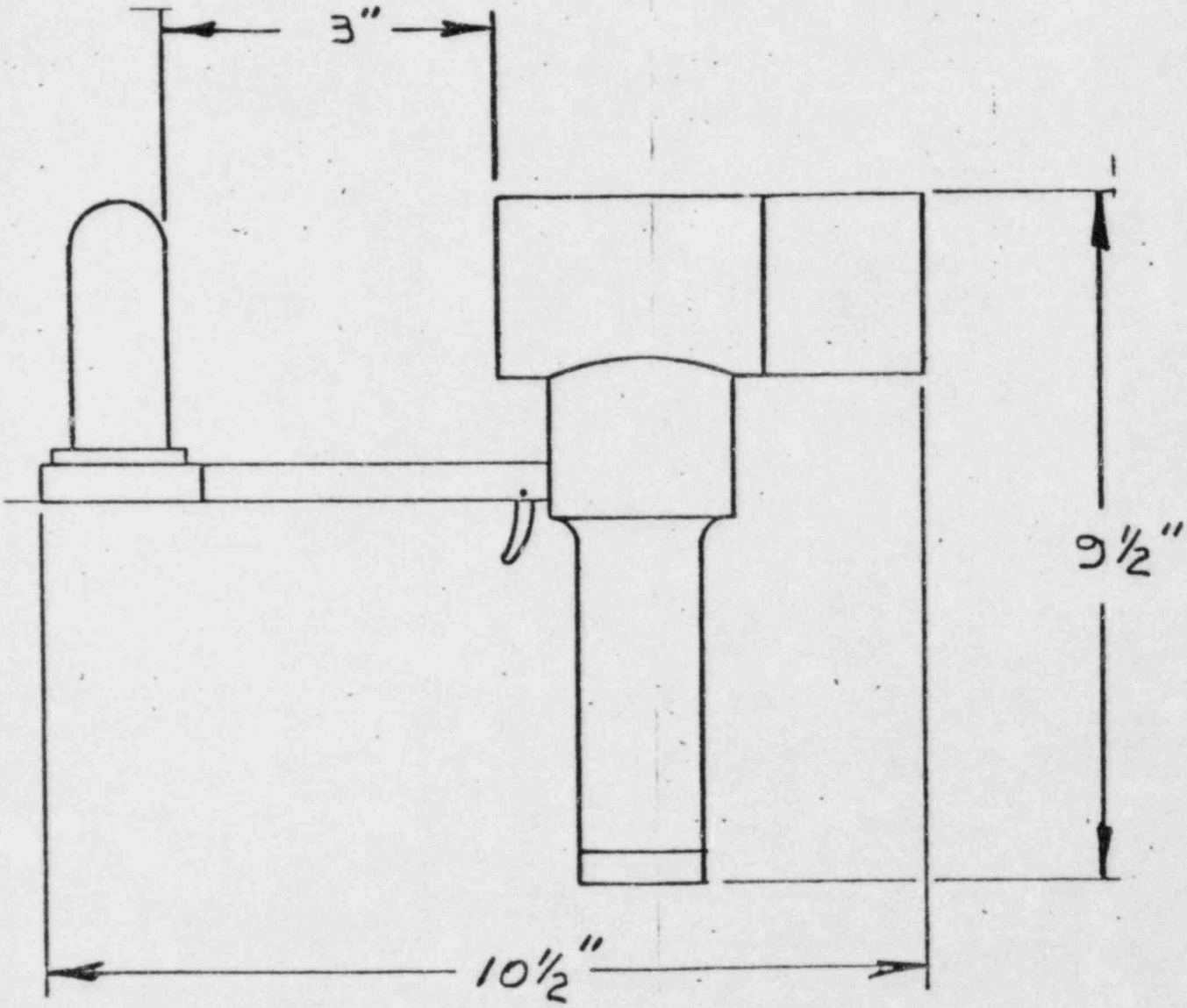

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ±.015		SCALE ~	DRAWN BY S.P.S.
			APPROVED BY
FRACTIONAL ± 1/16	TITLE		
ANGULAR ±1°	DATE 8/18/82	DRAWING NUMBER LS-80-X (PORTABLE)	

(1)

SPECIFICATIONS

Method of Operation:	Hand-held trigger actuator
Object Field of View:	25mm diameter
Max. Object Size:	3" depth
Output Viewing:	Direct viewing of 25mm screen with image inverter
Housing Material & Finish:	Non-corrosive stainless steel
Weight:	5LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-rays)
Power Source:	Two 1.5V alkaline "C" size batteries
Resolution:	$3 \frac{lp}{mm}$
Special Features:	Not Available

Enclosure 3

Test Data for Model LS-82 and LSM-82 Series Lixiscope

1) The LS-82 and LSM-82 models of the Lixiscope are identical in design principle to the LS-80 and LSM-80 series. The only basic difference is that aluminium has been used as the housing material instead of stainless steel. The purpose of this charge was to reduce the carrying weight of the unit. The source holder head is still manufactured out of stainless steel.
2) There have been no charges in the two capsules (Amersham's No. IMC P2 and Atomic Energy of Canada Limited's No. C-324) that were specified for use in the LS-80 series. Therefore, there are no changes from the performance standards in our previous letter of February 2, 1981.
3) The following ANSI N432 tests were performed on the aluminium designed Lixiscope and the new Tungsten/Stainless Steel source holder heads. The same test procedures outlined in our February 2, 1981 letter were used.
   A) Horizontal Shock Test: After 20 shocks no apparent physical damage was sustained except for some scuff marks on the housing. There were no dimensional changes to the Lixiscope or damage to the isotope capsule itself. The hydraulic exposure system functioned normally. There was no changes in the radiation level at the surface of the holder head (see attached sketch for design of test).
   B) Vertical Shock Test: The Lixiscope was dropped 100 times. After the test the device was visually and mechanically inspected. There were no dimensional changes. The hydraulic exposure system funtioned normally and the radiation level at surface remained < 0.07mr/hr (see attached sketch for diagram of test).
   C) Accidental Drop Test: For drop 1, after five consecutive drops from 5.5 meters slight abrasion marks were found on the surface. The spring system for holding the capsule in the shielded position remained functional. This test was performed on the new Tungsten/Stainless Steel source holder head with all accessories removed as specified. The external radiation exposure rate was < 0.05mr/hr at one meter from the external surface of the exposure device after the test.
   For drop 2, the source holder head (exposure device) was allowed to free-fall one meter onto the target as specified. There was no damage to the device and the radiation level at surface was < 0.07mr/hr.

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Lixi, Inc. 1438 Brook Drive Downers Grove, Illinois 60515 (312) 620-4646 Telex 6871077 DKROB TWX 910-991-3903

D) Endurance Test: This test setup cycled the trigger from one extreme position to the other is one second. After 100,000 cycles the unit still performed within specifications.

4) Maximum Exposure vs Distance from Source Holder: Exposure measurements were taken with an Eberline RO-5B ion chamber detector. This instrument was calibrated on 1/8/82 for Cs-137 and corrected for 28keV and altitude by using a correction factor of 1.1 as recommended by the manufacturer. The measurements were taken along the beam centerline of a model 42 Lixiscope head loaded with an A.E.C.L. 253 mCi I-125 capsule. The activity was calculated for the day of test. Measurements were taken with the detector scope removed to permit different distance-exposure measurements with the ion chamber meter. The corrected data is shown on the accompanying graph normalized to an effective 500mCi source (see Enclosure 3E). $E = C/r^2$, (where E is the exposure, r is the source to detector distance, and C is proportionality constant), C is 199.2 Rcm^2/hr using the 40cm point as the reference. The 40 cm point was chosen because it is the approximate midpoint of the attached graph. The calculated exposure results and observed readings are both plotted on the graph. Good agreement is seen between the calculated curve and the observed data points. The two curves become increasingly divergent as they approach the 20cm mark. This is explained by the ion chamber seeing a less uniform radiation field. At 70cm a check was made with a GM probe detector. The corrected reading was 30% above the extrapolated exposure from the equation, which is considered reasonable agreement. This exposure rate would then be 5.53r/hr or 1.54 mR/sec at 5cm from the head. Please reference our license amendment application dated September 19, 1980 and table A of the enclosed Lixiscope Instruction Manual, which reports 3.2mR/sec at the 5cm distance, normalized for 500mCi activity. Our new calculated exposure rate is about 50% of the previous reported exposure rate. This can be explained by the fact that this latest test used a two mm I-125 bead while the previous test used a one mm bead, so the specific activity difference explains this apparent discrepancy. The Table A (listed on page 16 of the Lixiscope Instuction Manual), therefore, is still applicable as being representative of "worst case" dose rates.

5) Shielding Efficiency Test: A 242mCi source calibrated on the date of measurement was used. The readings obtained were normalized to 500mCi. At the surface of the device with isotope on stored (shielded) position the maximum reading was 0.1mr/hr. At 5cm it was < 0.05mr/hr.
In the open position the following measurements were taken in those areas immediately outside the exposure zone of the Lixi, which were considered critical:

A) At the trigger the maximum reading was 0.1mr/hr.
B) Around the circumference of the intensifier tube at the exposure end the maximum reading was 1.8mr/hr.
C) Around the circumference of the intensifier tube at the viewing end the maximum reading was <0.05mr/hr.
D) At the viewing screen opening the maximum reading was <0.05mr/hr.

There was no significant difference from our measurements in our letter of February 2, 1981.

6) Radiation Scatter Test:
The measurements were taken with several different objects in the beam of the Lixiscope. The first test object was a plastic handle of a screw driver with a steel shaft through it. The second test object was a 3mm diameter plastic water bottle. This object was chosen because it gives the worse case scatter rate of all the objects we used. The third test object was a bone phantom. The results were as follows:

Model 42 Isotope Holder Head
(Observed maximum mr/hr readings for a 242 mCi isotope)

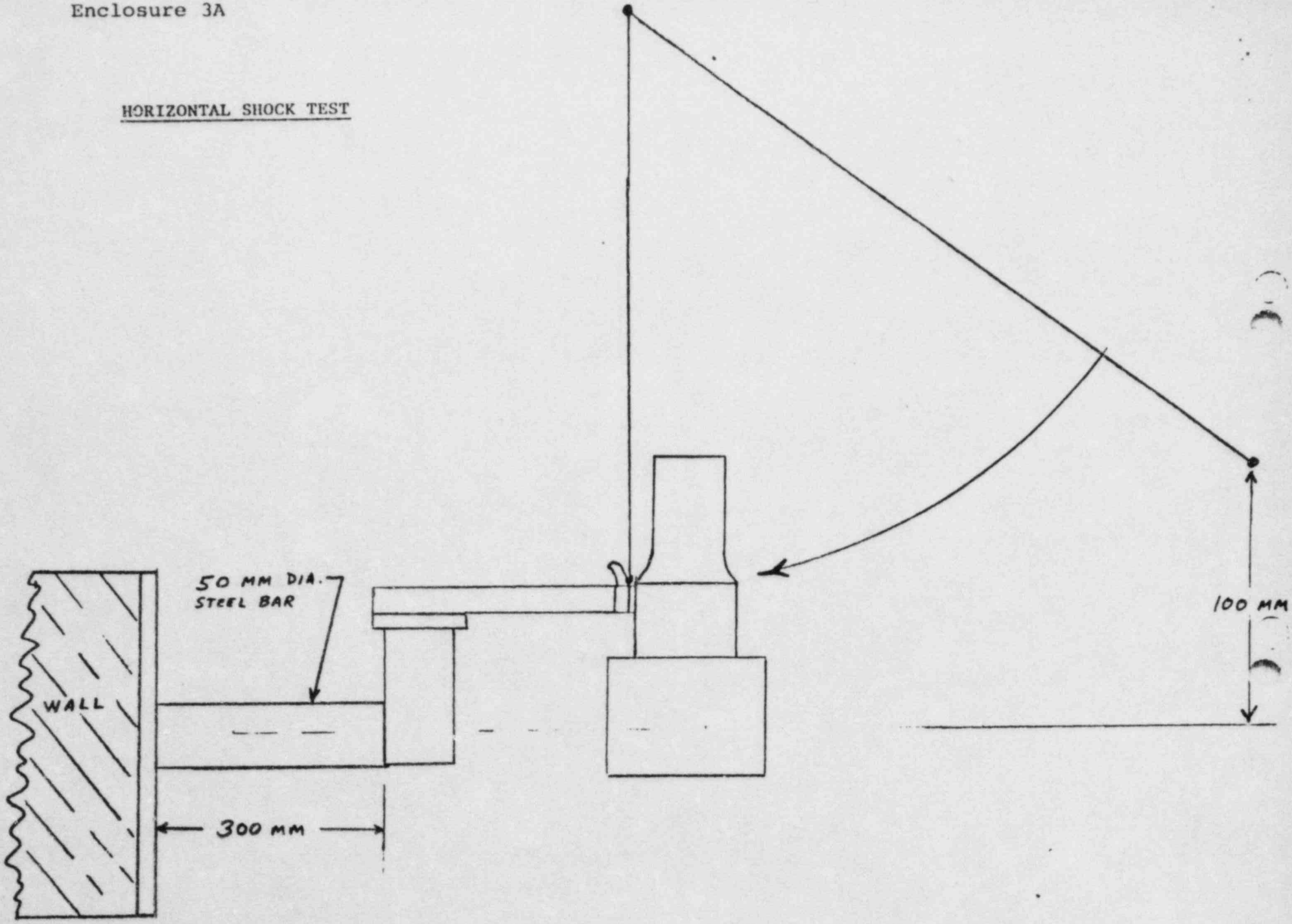
Lixiscope in open position

Object	5cm	30cm	100cm
1	8.0	0.4	0.05
2	15.0	0.6	0.07
3	2.5	0.1	0.05

If we normalize the reading for the worse case (Object 2) for 500mCi the results would be: 5cm = 31mr/hr; 30cm = 1.2mr/hr; 100cm = 0.14mr/hr.
The above readings were observed at a 90° angle from the object.
The radiation readings at the viewing end of the Lixiscope were <0.05mr/hr during the test.
These test results are well within safety levels for workers as specified by the NRC regulations.

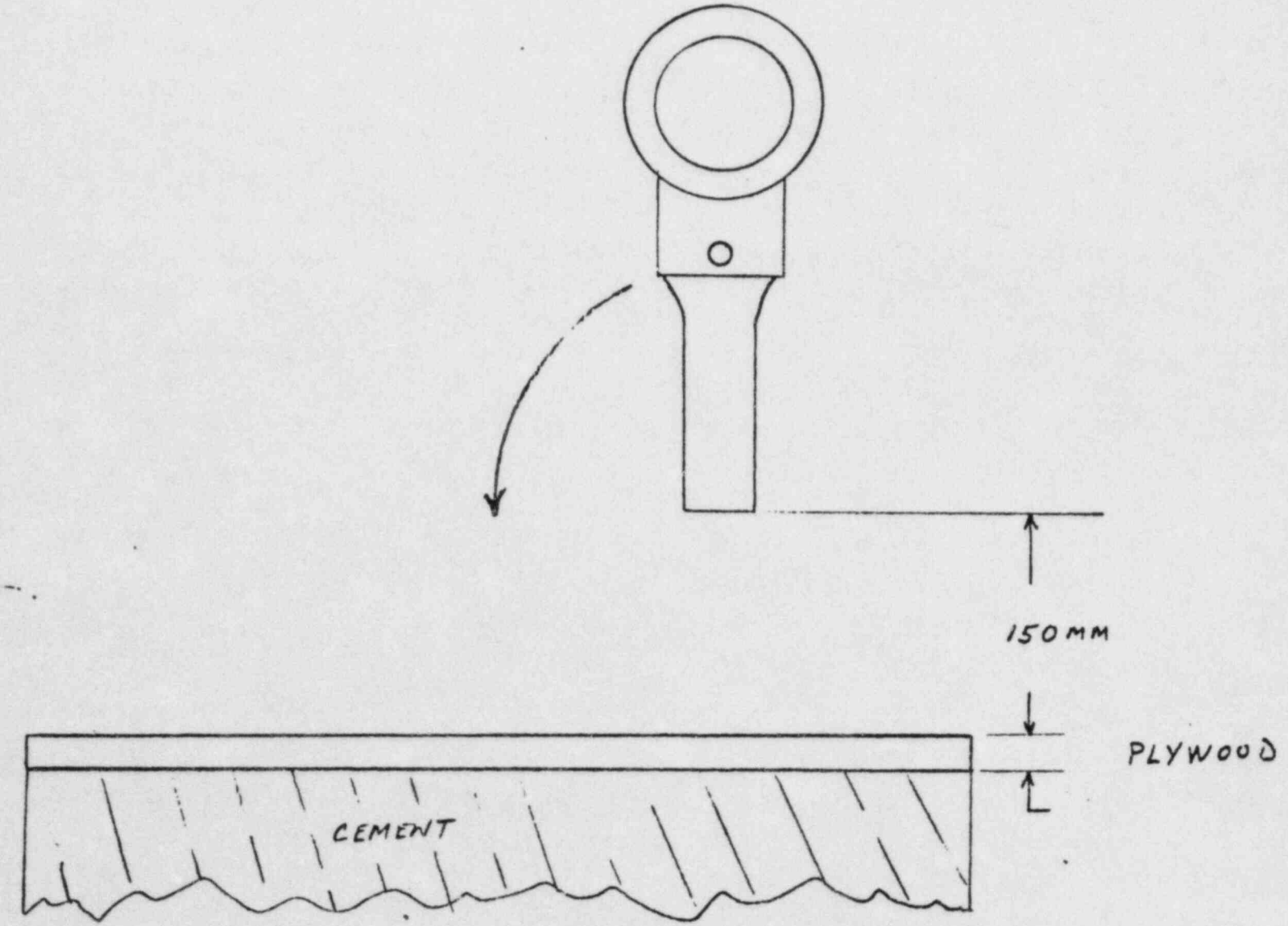
Enclosure 3A

HORIZONTAL SHOCK TEST



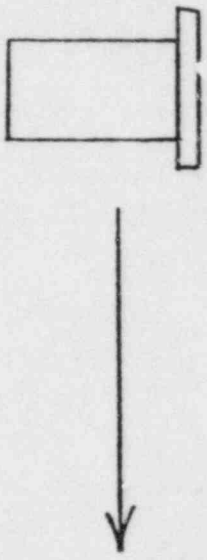
Enclosure 3B

VERTICAL SHOCK TEST



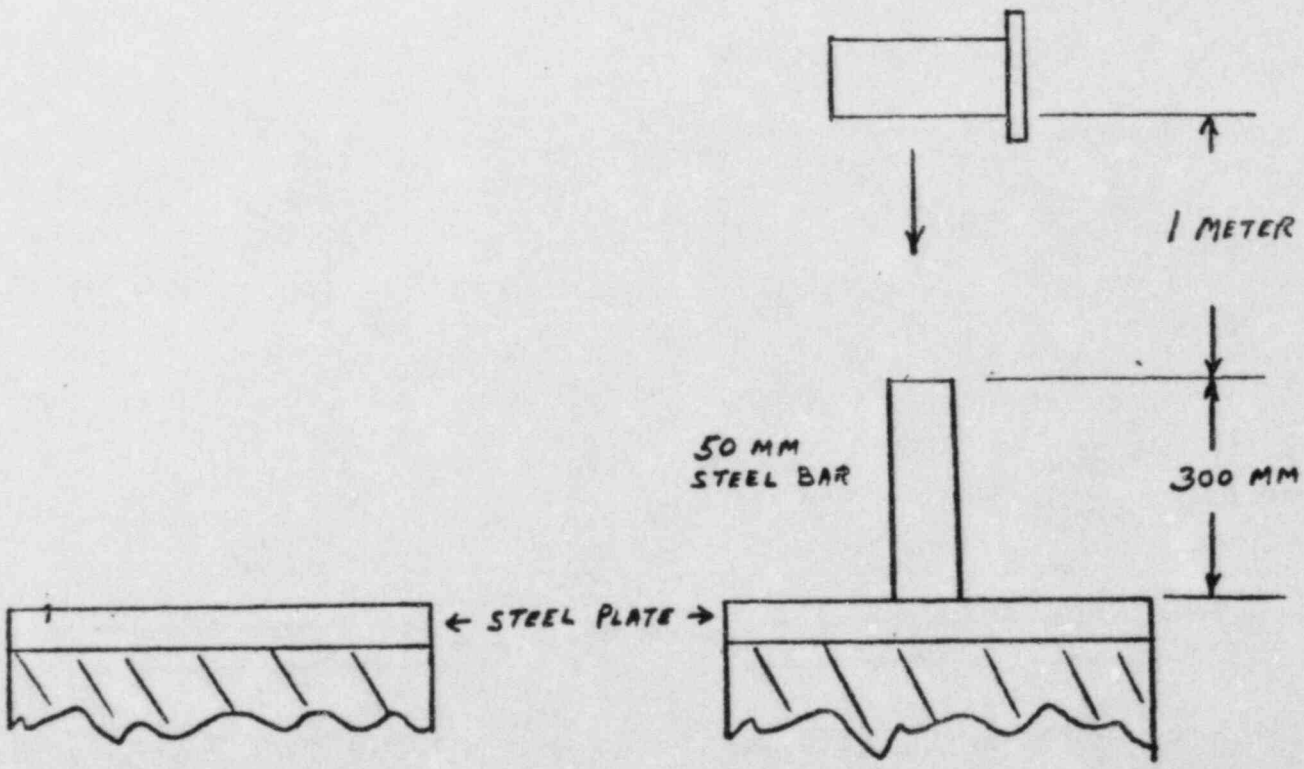
ACCIDENTAL DROP TEST

DROP TEST 1



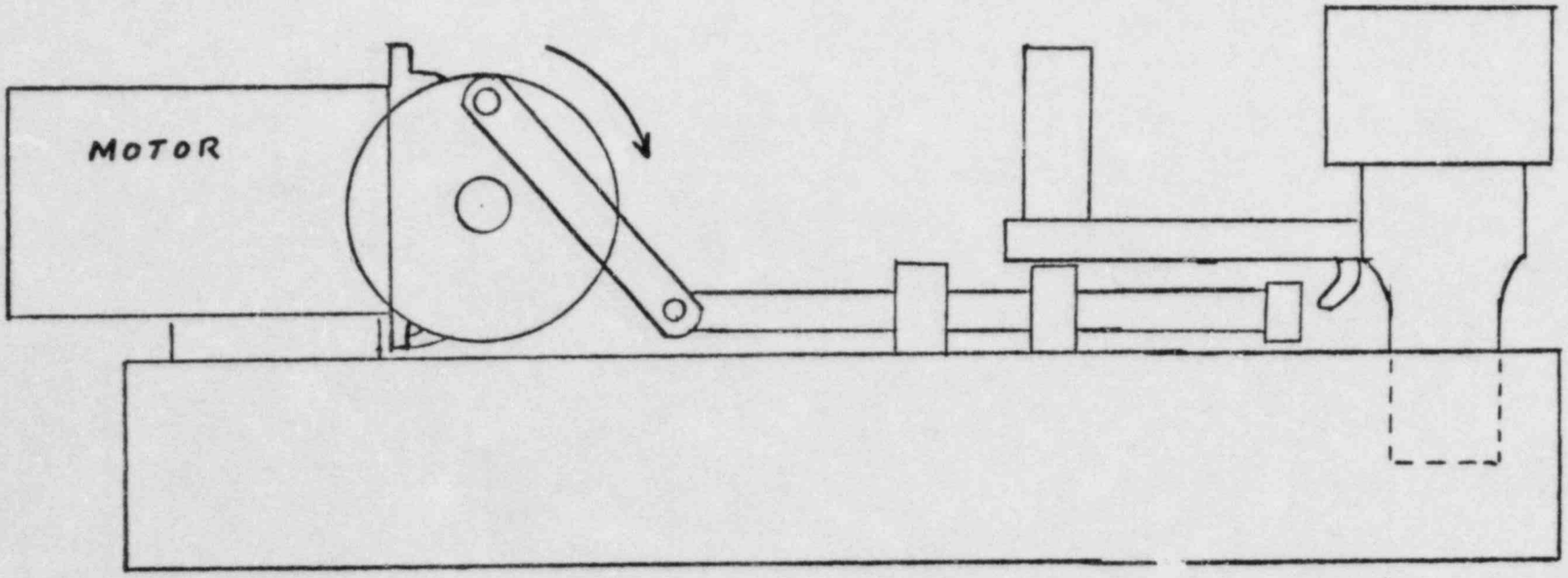
5.5 METERS

DROP TEST 2

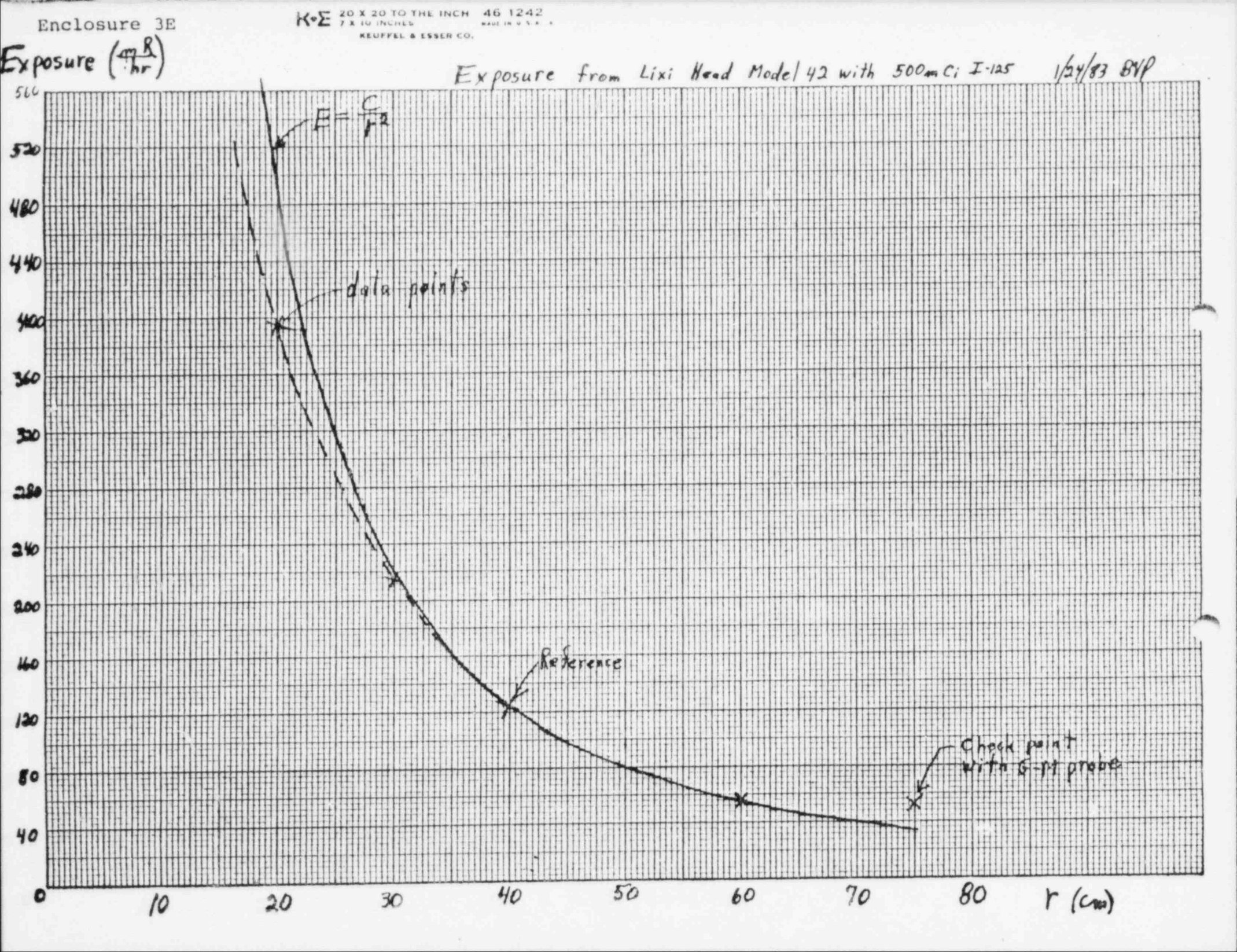


Enclosure 3D

ENDURANCE TEST



Enclosure 3E



DATE	SYM	REVISION RECORD	DR.	CK.
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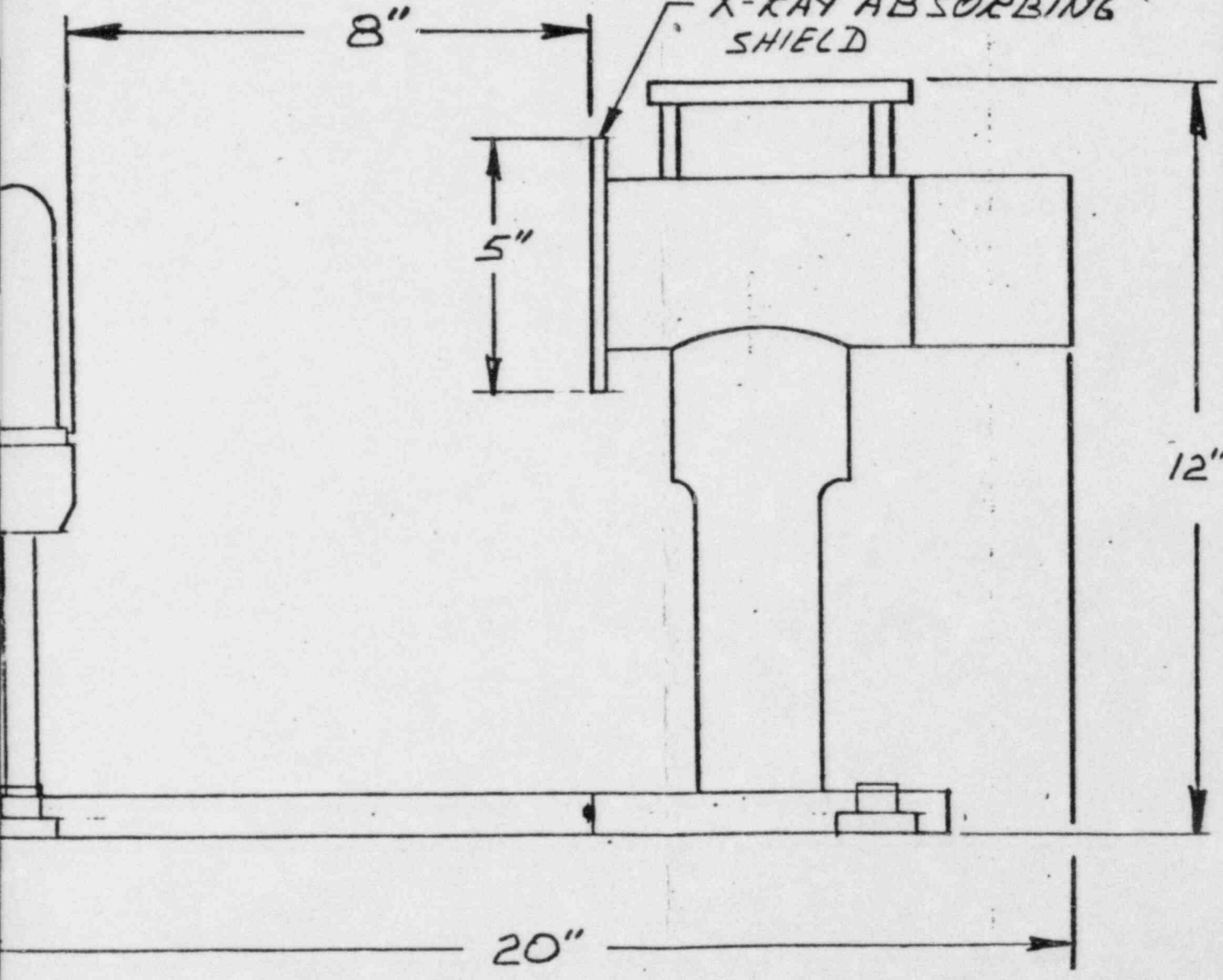

TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .015		SCALE ~	DRAWN BY SPS APPROVED BY
FRACTIONAL ± 1/16	TITLE		
ANGULAR ± 1°	DATE 8/18/82	DRAWING NUMBER LS-82-X (BENCH MOUNT)	

SPECIFICATIONS

Method of Operation:	Hand-held or base mounded on/off key actuator
Object Field of View:	50mm diameter
Max. Object Size:	8" depth
Output Viewing:	Direct viewing of 50mm screen with image INVERTED
Housing Material & Finish:	ALUMINUM, ANODIZE
Weight:	8LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-rays)
Power Source:	Two 1.5V alkaline "C" size batteries
Resolution:	$3\ \frac{1p}{mm}$
Special Features:	Carring Case

DATE	BY	REVISION RECORD	DR	CK
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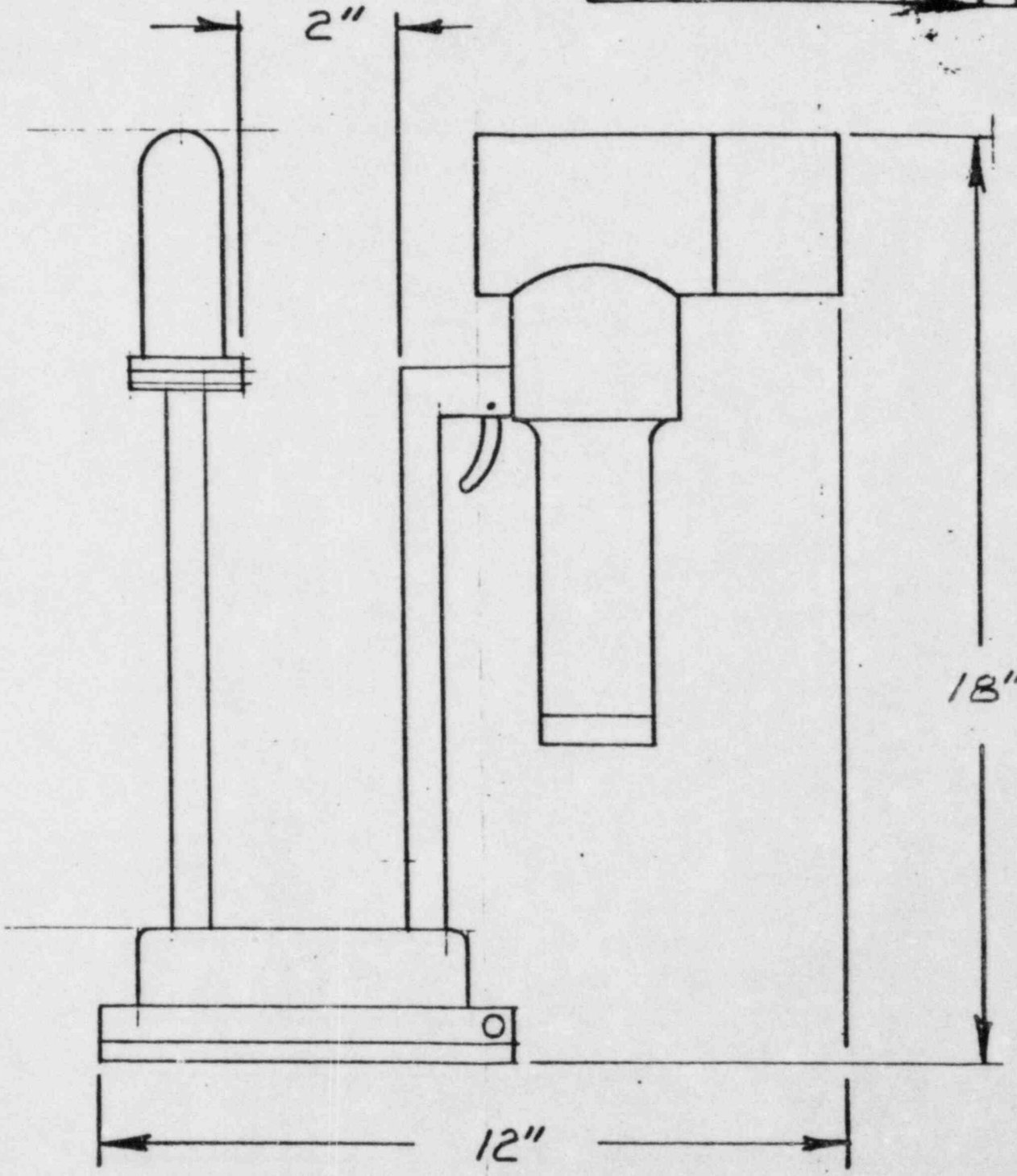


TOLERANCES (EXCEPT AS NOTED)	LIXI INC.		
DECIMAL ± .015		SCALE 1/4	DRAWN BY SPS APPROVED BY
FRACTIONAL ± 1/16	TITLE		
ANGULAR ± 1°	DATE 8/19/82	DRAWING NUMBER LS-80-X (BENCH MOUNT)	

SPECIFICATIONS

Method of Operation:	Base mounded trigger actuator
Object Field of View:	25mm diameter
Max. Object Size:	2" depth
Output Viewing:	Direct viewing of 25mm screen w image inverted
Housing Material & Finish:	Non-corrosive stainless steel
Weight:	14LBS Approx.
X-Ray Source:	Radioactive Iodine (28keV x-ray
Power Source:	Two 1.5V alkaline "C" size batt
Resolution:	$3\ \frac{lp}{mm}$
Special Features:	Not Available

LABELS FOR LIXISCOPES

MEDICAL USE

H50053

Licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States. See instruction manual for safe handling and storage procedures.

CAUTION
RADIOACTIVE
MATERIAL
SEALED GAMMA
SOURCE
RADIONUCLIDE: I^{125}

HANDLE CAREFULLY
Activity: _____ mCi
Assay Date: _____
Manufactured by Lixi, Inc.
Downers Grove, IL 60515

ALL MODELS

H50055

Made for:
Model:

LIXI

Serial No.

USED C
CARRYING

H50054

RADIOACTIVE MA
SEALED
GAMMA SOUF
RADIONUCLIDE

HANDLE CAREF
See instruction ma
safe handling and
procedures.

MEDICAL MODEL

H50050

CAUTION: Federal law restricts this device to sale by or on the order of a doctor.
WARNING: Operator should not place hands in area of radiation beam to avoid unnecessary radiation exposure.

INDUSTRIAL USE

H50080

CAUTION: Federal law restricts this device to sale by or on the order of a veterinarian.
WARNING: Operator should not place hands in area of radiation beam to avoid unnecessary radiation exposure.

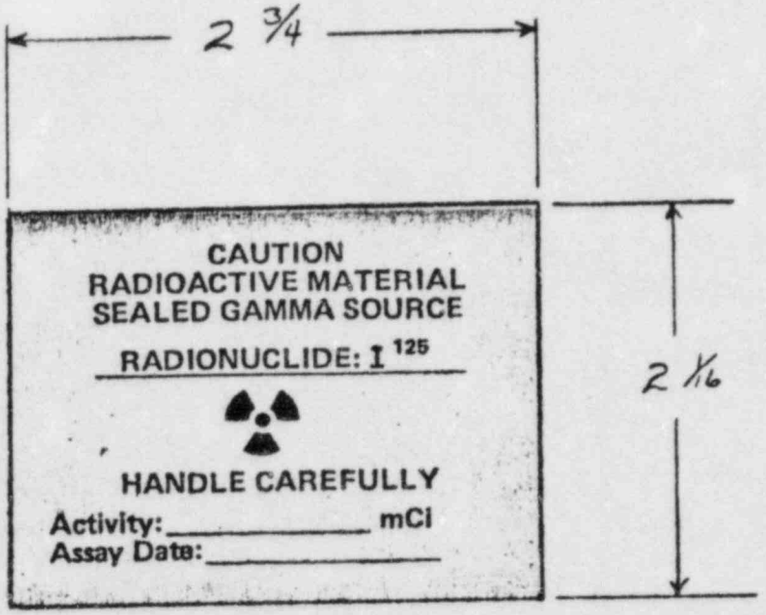
INDUSTRIAL USE

H50081

WARNING: Operator should not place hands in area of radiation beam to avoid unnecessary radiation exposure.

DATE	SYM	REVISION RECORD	DR.	CK

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 RTS
			APPROVED BY
FRACTIONAL ± 1/32	TITLE RADIOACTIVE LABEL INDUSTRIAL USE		
ANGULAR ±	DATE 1/15/81	DRAWING NUMBER H50089	

BRUNING 40-21