American Bentley

Subsidiary of
American Hospital Supply
Corporation

P.O. Box 19522
Irvine CA USA 92713-9522
17502 Armstrong Avenue
Irvine CA USA 92714

Telephone 714 261-8363
Telex 68-5503 BENT LAB IRIN

October 4, 1985

Mr. Earl White
U.S. Nuclear Regulatory Commission,
Region II
Material Radiation Protection System
101 Marietta St., Suite 2900
Atlanta, GA 30323

Dear Mr. White:

Here is the information that you requested for our material license.

1) LIXI Scope Model # LS-82-102.

2) Leak Test Procedure (see enclosure).

3) Please send the license to the attention of Luis Maldonado, Quality Assurance Supervisor, at our Puerto Rico address.

Sincerely,

Jack Sowin

Jack Sowin
Quality Assurance Engineer

JS:po

Rec'd 10/7/85

Supplemental Information
American Bentley

Leak Test Kit and Certificate File

Every LIXI source head will be accompanied by a Leak Test Certificate. A leak test kit is provided with the original LIXI Scope. The certificate and kit will be placed in this leak test file. A leak test will be performed on the I-125 source head within 6 months of the date on the original leak test certificate. Leak test kits are normally provided by the testing company when a leak test certificate is returned. Maintaining the leak tests on the required schedule is the responsibility of American Bentley.

Iodine-125 source heads exchanged at intervals of less than 6 months, do not require leak testing. A sample of the Leak Test kit instructions and a sample Leak Test Certificate are attached.

MODEL LT-2

LEAK TEST KIT

FACILITY _____

CITY _____ STATE_____

FEDERAL NRC LICENSE NO. _____

AGREEMENT STATE LICENSE NO. _____

RADIONUCLIDE _____

ACTIVITY _____ ON ORIGINAL CALIBRATION DATE

ORIGINAL CALIBRATION DATE_____

MANUFACTURER _____

MODEL NUMBER _____

SERIAL NUMBER _____

ANY OTHER DESCRIPTION _____

TEST DATE_____

SOURCES WIPED BY _____

NEXT TEST DUE _____

REMARKS: _____

sahci STAN A. HUBER CONSULTANTS, IN

235 ESSEX LANE □ NEW LENOX, ILLINOIS 60451

(815) 722-8009

Note any special billing or other instructions in the "Remarks" section on the back of this kit.

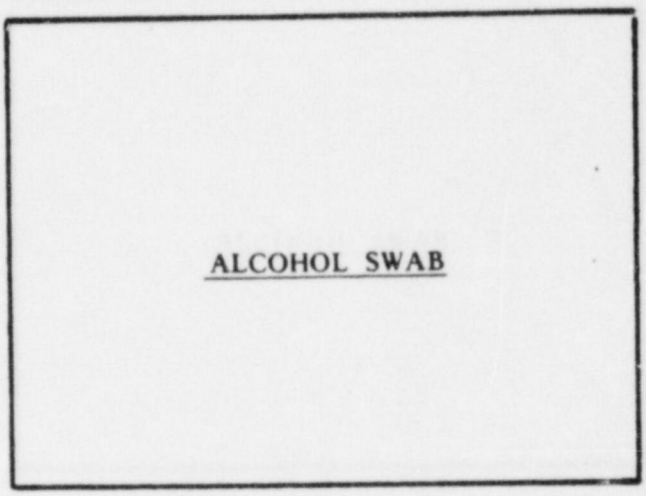
PREREQUISITES

a) Follow any manufacturer instructions or specific license conditions for proper access and wipe testing of the sources.

b) Use time, distance and shielding to reduce radiation exposure as low as reasonably achievable.

c) Use rubber gloves & remote handling devices in handling or working near radiation source containers, or when working with any potentially contaminated materials.

d) Wipe tests should only be performed by the licensed users, Radiation Safety Officer or their trained designates.



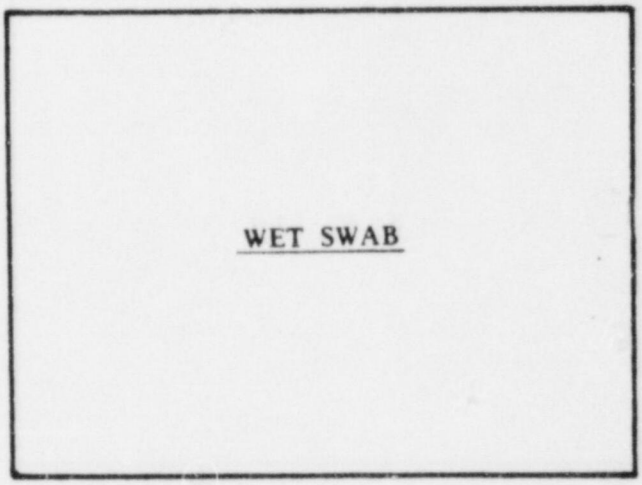
PROCEDURE

1) Place source behind shielding (if applicable) or check that direct radiation exposure is not possible.

2) Remove alcohol swab from packet to soak the "wet swab" cotton applicator.

3) Wipe all accessible surfaces of the source with wet swab. (Or nearest the source container, as applicable.)

4) Place wet swab cotton applicator in plastic sleeve marked "WET SWAB", seal open end. (Tape or staple)



5) Remove the "dry swab" cotton applicator and wipe all accessible surfaces of the source or container.

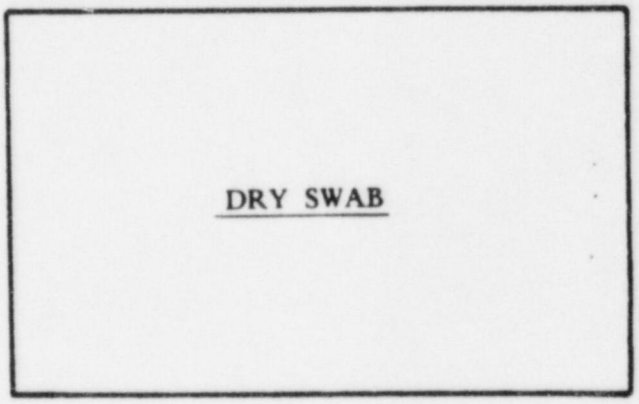
6) Place the "dry swab" cotton applicator in plastic sleeve marked "DRY SWAB" and seal open end.

7) Return source to storage (if applicable) or check that device is in proper safeguard mode.

8) Survey each swab with G-M survey meter. If reading is above normal background note this on back of kit and call Stan A. Huber Consultants, Inc. for further instructions.

9) Assuming the survey meter reading indicates no detectable activity, return kit to Stan A. Huber Consultants, Inc. in a standard size envelope.

10) You should receive the leak test certificate within 2 weeks after the sample kit is received by SAHCI. If not, please call our office.



- LEAK TEST CERTIFICATE
CERTIFICAT D'ESSAIS D'ETANCHEITE

CUSTOMER-*CLIENT/E*

DATE 1982 AUGUST 13

LIXIE INC.

ORDER NO.
NO. DE COMMANDE P.S. 86253

DESCRIPTION OF SOURCE(S) TESTED
DESCRIPTION DE(S) SOURCE(S) VÉRIFIÉE(S)

IODINE 125 POINT SOURCE NOMINAL 500 mCi IN A WELDED A.E.C.L. C324 CAPSULE.

SERIAL NO(S). *DE SÉRIE* 1669

RESULTS OF TESTS
RÉSULTATS DES ESSAIS

LEAK TEST(S) PERFORMED
ESSAI(S) D'ÉTANCHÉITÉ EFFECTUÉ(S)

☒	1. Hot liquid test, Procedure DG-0050. *Essai au liquide chaud, procédure DG-0050.*	ACCEPTABLE
☐	2. Vacuum liquid leak test, Procedure DG-0052. *Essai d'étanchéité au liquide sous vide, procédure DG-0052.*	
☐	3. Helium pressurization test, Procedure DG-0056. *Essai de mise sous pression d'hélium, procédure DG-0056.*	
☐	4. Wet wipe test, Procedure DG-0063. *Essai au frottement humide, procédure DG-0063.*	
☐	5. The immersion test, Procedure DG-0064. *Essai d'immersion, procédure DG-0064.*	
☒	6. The dry wipe test, Procedure DG-0065. *Essai au frottement à sec, procédure DG-0065.*	NEGATIVE
☐	7. Dry wipe test - 'ACTIVE' inner/'INACTIVE' outer encapsulation, Procedure DG-0161. *Encapsulation 'ACTIVE' intérieure/'INACTIVE' extérieure, procédure DG-0161.*	
☐	8. Removable contamination test on equipment utilizing depleted uranium alloy, Procedure DG-0070. *Essai de contamination amovible sur appareillage utilisant un alliage d'uranium appauvri, procédure DG-0070.*	
☐	9. Other test(s) as described below. *Autre(s) essai(s) décrit(s) ci-dessous.*	

Note: All tests performed meet specified requirements.
À noter: Tous les essais effectués répondent aux exigences.

DATE OF COMPLETION OF TEST(S):
ESSAI(S) COMPLÉTÉ(S) LE:

1982 AUGUST 13

FOR THE COMPANY
POUR LA COMPAGNIE

J. Simpson, P. Eng.

SPECIAL PRODUCTS GROUP
PRODUCTION

Atomic Energy of Canada Limited
Commercial Products
P.O. Box 6300
Postal Station J
Ottawa, Canada
K2A 3W3

L'Énergie Atomique du Canada, Limitée
Produits Commerciaux
C.P. 6300
Succursale Postale J
Ottawa, Canada
K2A 3W3

AECL-CP 1975 F 18.06

NRC FORM 218 (4-76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE: 10/4/85

TIME: ☐ A.M. ☑ P.M.

☐ INCOMING CALL ☑ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Earl D Wright		
PERSON CALLED	**OFFICE/ADDRESS**	**PHONE NUMBER / EXTENSION**
Jack P. Sowin	American Bentley Irvine Ca	714-261-8363

CONVERSATION

SUBJECT: control 50749

SUMMARY

called + Ask him for model # of device and leak test procedures.

E Wright

10/8/85

Notified Luis Maldonado that Lic issued this date

E Wright

REFERRED TO:

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

American Bentley

Subsidiary of
American Hospital Supply
Corporation

P.O. Box 19522
Irvine CA USA 92713-9522
17502 Armstrong Avenue
Irvine CA USA 92714

Telephone 714 261-8363
Telex 68-5503 BENT LAB IRIN

Received 10:30A
10/3/85 EEC

October 2, 1985

Mr. Earl ~~White~~ Wright
U.S. Nuclear Regulatory Commission,
Region II
Material Radiation Protection System
101 Marietta St., Suite 2900
Atlanta, GA 30323

Dear Mr. White:

This letter is a follow up to our phone conversation on Wednesday, October 2, 1985.

Because of the incorrect information that we received from LIXI inc., we assumed that we could operate LIXI Scopes at our manufacturing plant in Puerto Rico prior to obtaining our industrial material license. Our production line for several medical products is presently shut down until we get approval of our license application. I appreciate your efforts in expediting the processing of our application.

When we do receive our license, only American Bentley personnel who have passed the LIXI training course will be allowed to use the LIXI Scope. This will be done under the supervision of the RSO. A complete list of Puerto Rican employees that pass the test, including a permanent RSO, will be added to our license at a later time.

If at all possible, please notify me or our Quality Assurance Supervisor in Puerto Rico, Luis Maldonado by phone as soon as our license is approved. The phone number is (809)826-3131.

If you have <u>any</u> questions or problems regarding this application, please call me. I will be at our Irvine California location until Wednesday, October 16.

Thank you for your assistance.

Sincerely yours,

Jack Sowin

Jack Sowin
Engineer

JS/js

T0749
21106
030-28943

~~85 10 13054~~ 1p

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER ______
- [ ] C. RENEWAL OF LICENSE NUMBER ______

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

American Bentley
17502 Armstrong Ave.
Irvine, CA 92714

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Bentley AHS Del Caribe
Km. 1.4, State Road 402
Anasco, Puerto Rico 00610

P.O. Box 1577
Phone (809) 826-3131

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jack P. Sowin Quality Assurance Engineer

TELEPHONE NUMBER
(714) 261-8363

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3P
AMOUNT ENCLOSED $ 230.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Jack P. Sowin	Jack P. Sowin	Radiation Safety Officer	10/1/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Oct - III	3P	~~8512130513~~	17PP Jackson
AMOUNT RECEIVED	CHECK NUMBER			DATE
$230	019989			10/8/85

PRIVACY ACT STATEMENT ON THE REVERSE

SUPPLEMENTAL INFORMATION
American Bentley

5. a) Iodine - 125
   b) Solid, Sealed Source LIXI Scope Model LS- with AECL C-324 or Amersham IMC P2.
   c) 500 mci per source, maximum possession will be two sources per LIXI Scope. We presently have two LIXI Scopes.

6. The LIXI Scope will be used for non-destructive x-ray inspection of manufactured medical products. It will be the responsibility of the RSO or the Assistant RSO to train the inspectors or assemblers in the safe handling procedures of the LIXI Scope which will be used under the supervision of the RSO or the Assistant.

7. Jack Sowin - RSO, Quality Assurance Engineer.
   Kathleen Shaw - Assistant RSO, Inspector.
   Kathleen Monday - Inspector.
   Francis Roustan - Inspector.

   All of the above individuals have completed the LIXI Radiation Safety Training Course. Their certificates are attached along with a resume of their education and work experience.

8. Not applicable - there are no restricted areas with the use of the LIXI Scope.

9. Facility sketch and equipment description are attached.

10. The Radiation Protection Program is attached.

11. All spent or depleted radiation sources will be returned to the manufacturer (LIXI) for disposal.

FACILITIES AND EQUIPMENT

Ref: NRC 313

Item 9

Storage Facilities

The LIXI scope(s) defined in this application will be kept locked in their individual carrying cases (marked with "Caution Radioactive Material" labels), when not in use and stored in the area as shown on the attached sketch. This is a locked and secured area at the licensee's address. When the LIXI scope is in transit to temporary job sites, in the main plant area of our building, the LIXI scope will be kept locked in its individual carrying case and under the supervision of the licensed users listed herein, until it is returned to the above designated storage area. LIXI scopes must be signed out and in by each licensed user so the location of the device(s) is accounted for at all times. The Radiation Safety Officer is responsible for these records being maintained on a current and complete basis and available for inspection at any time.

Containers and Special Shielding

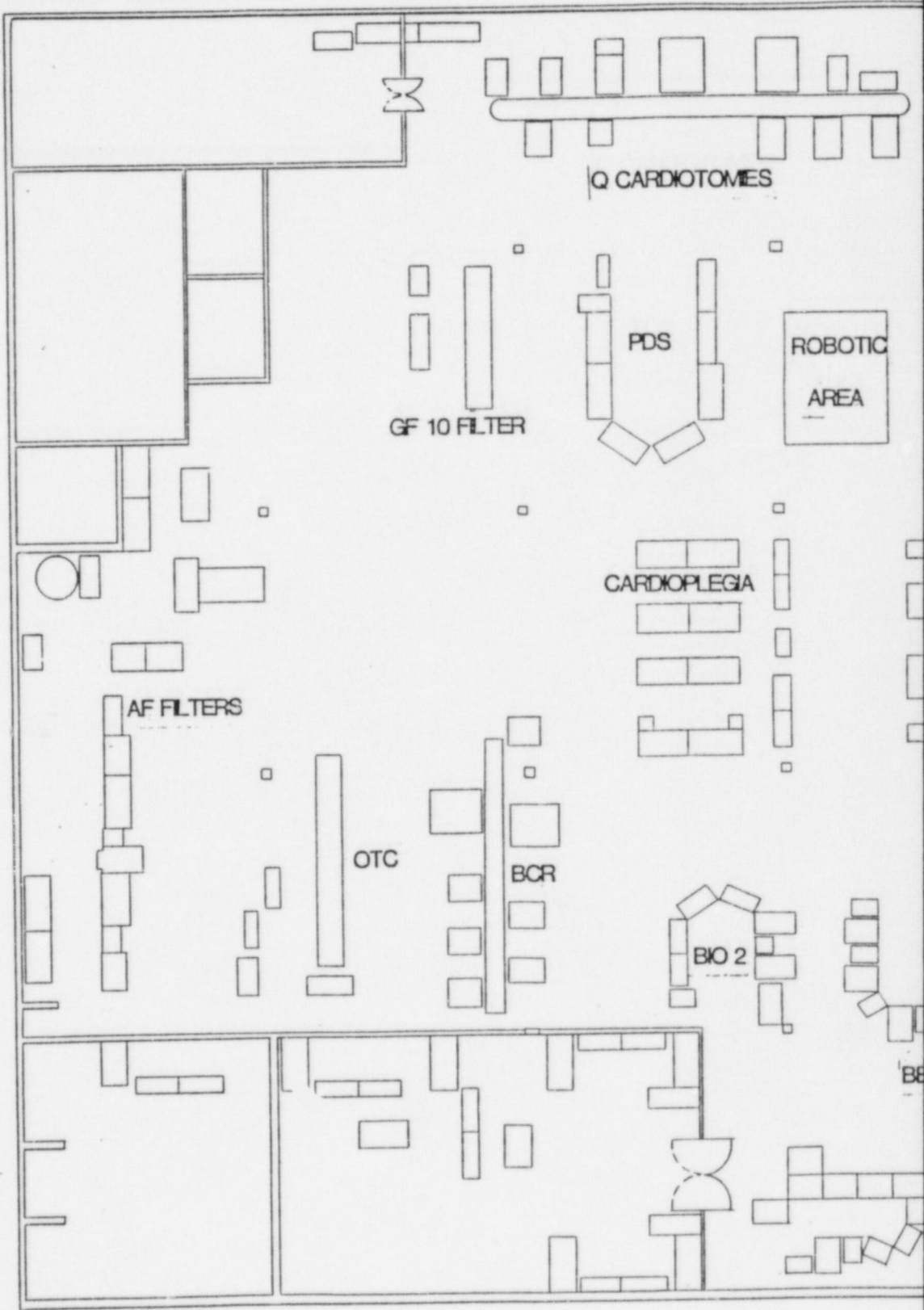
The LIXI scope is a self shielded device and there is no radiation above normal background (about 0.05 mR/hr when the LIXI scope is in its carrying case. The primary concerns are that the device must only be used by, or under the direct supervision of, trained and licensed users and that the LIXI scope be accounted for and secured at all times to prevent any unauthorized use, loss or theft of the device.

Remote Handling Equipment and Safety Procedures

The LIXI scope Instruction Manual directions will be followed. Remote handling devices, such as tongs or forceps, will be used when indicated to avoid any licensed user from ever placing their hands in the LIXI scope radiation beam.

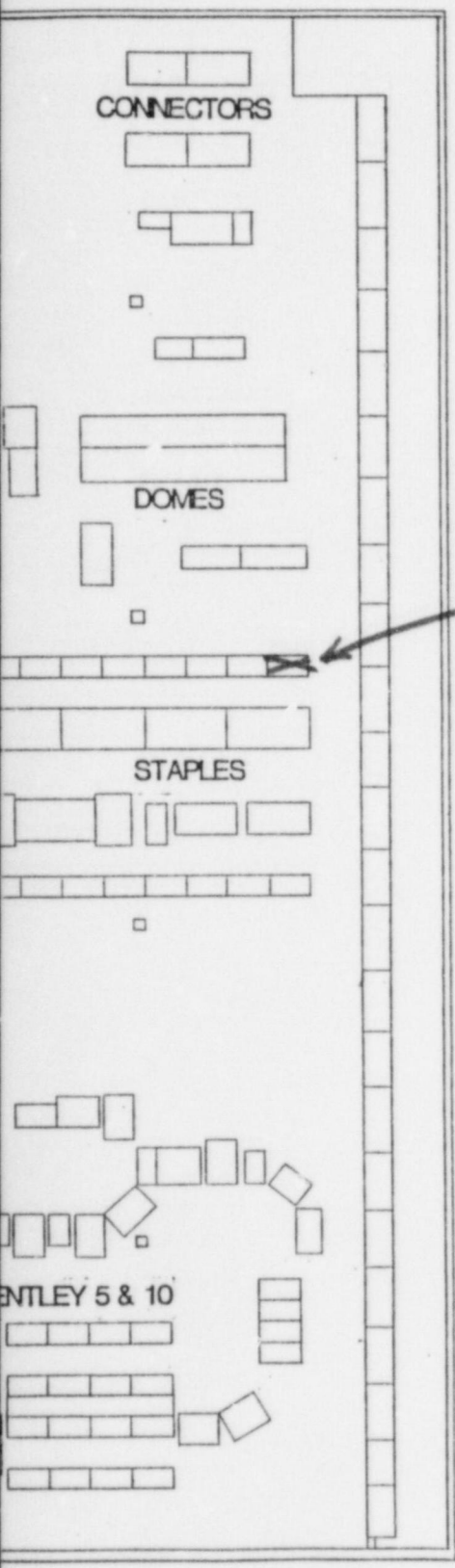
Survey measurements are taken by the manufacturer (Lixi, Inc.) prior to shipment. When shipped by the manufacturer, NO UNIT EXCEEDS 0.5 mR/hr at surface, therefore no radiation detection instruments are necessary. Also personnel monitoring devices (ring badges) are not necessary. In spite of this, for additional safety, we will be implementing a monitoring system with badges in the near future.

The LIXI scope is classified as Radioactive Material Instrument and Articles UN2911 per 49 CFR 173.422, 173.424. It is therefore exempt from labeling and marking requirements. We will follow the manufacturers instructions for return shipments of isotopes.



GENERAL NOTES: UNLESS OTHERWISE SPECIFIED

RELEASE STATUS	REV	ECN	DWN	CHK	APPD	DATE



Storage cabinet with LIXI scope

Dupe
85 1213054 2-01

QTY	ITEM NO.	PART NO.	NOMENCLATURE

UNLESS OTHERWISE SPECIFIED
DIM. LIMITS
ONE PLACE OR FRACTION ± .015
TWO PLACES .XXX ± .010
THREE PLACES .XXXX ± .005
ANGULAR DIMENSIONS ± 1/2°
FINISH ▽ ± .005 T.I.R.
⊥ .005 T.I.R. // .005 T.I.R.
BREAK SHARP CORNERS .010 x 45°
ENGINEERING DEPARTMENT APPROVAL REQUIRED ON SUBSTITUTIONS.

MODEL NO.

American Bantley
Subsidiary of [illegible]

APPD:
CHK:
DWN: D. YOUNG 8/[illegible]/15
SCALE: 1/8" = 1' SHT C

CLEAN ROOM #3
PUERTO RICO

CERTIFICATE OF TRAINING

RADIATION SAFETY

This is to certify that Jack Sowin

has completed the LIXI™ Radiation Safety Training Course on file with the U.S. Nuclear Regulatory Commission.

This training was completed on: August 28, 1985

This training course was developed by Lixi, Inc. and S.A. Huber Consultants Inc. for the purpose of providing the necessary training in radiation safety and experience for LIXI™ scope users. The training was given as approved by the NRC under License Nos. 12-17503-01 and 12-18215-01.

This also certifies that the trainee has personally operated a working LIXI™ scope, under supervision, in the aforementioned course.

A copy of this certificate is to be provided to the NRC or Agreement State as proof that the trainee has the necessary experience to make a specific application for a Byproduct Material License to possess and use a LIXI™ scope.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and all information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Lixi, Inc.

Instructor: Jeff Gipe

Signature: Jeff Gipe

Under License No: 12-18215-01

Date: August 29, 1985

Radiologic Health Branch
744 P Street
Sacramento, California 95814

STATEMENT OF TRAINING AND EXPERIENCE

(Use additional sheets as necessary)

Instruction: Every individual proposing to use radioactive material is required to submit a Statement of Training and Experience in duplicate to the address given above. Physicians should request Form RH 2000 A when applying for human use authorizations.

1. Name of proposed user: Jack Sowin Position title: QA Engineer
   Address: 89 Greenfield City: Irvine CA Zip: 92714
   To be included on Lic. No. _____ in name of American Bentley

2. Description of proposed use
   Use the LIXI Scope (Model # LS-82-102) for non-destructive x-ray inspection of medical products.

---

3. Training:
   a. High School Graduate: Yes ✓ No ____
   b. College or University: Name and location California State Polytechnic Univ., Pomona
      Years completed 4 Degree BS Course of study Electronic & Computer Engr.
   c. Education specifically applicable to use of radioactive material
      Completed the LIXI training course.

4. Experience:
   a. List experience with radioactivity beginning with most recent
      (1) Dates: From 8/85 to Present
      Title and duties: RSO. I will use the equipment to inspect product and train inspectors on its use for inspection.
      Employer: American Bentley Address: 17502 Armstrong Ave. Irvine, CA 92714 (714) 261-8363
      (2) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____
      (3) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____

b. Radioactive materials previously used. Cite typical radioisotopes in appropriate box and key t Part 4.a above:

Quantities Handled

	Microcuries	Millicuries	Curies	Kilocuries
Sealed sources		Iodine 125		
Unsealed alpha emitters				
Unsealed beta-gamma emitters				
Neutron sources				

c. Describe procedures similar to those proposed in Part 2 with which you have had experience. Indicate months or years for each and key to Part 4.a above.

d. Indicate which types of facilities you have used and key to Part 4.a.

( ) Ordinary Chemical laboratories

( ) "Controlled Area" (Type B) laboratories

( ) Glove boxes

( ) Shielded glove boxes

( ) Caves with remote manipulators

(X) ~~Field~~ operations with portable equipment
In House

5. Certificate:

I hereby certify that all information contained in this Statement is true and correct.

Jack Dowin
Signature of proposed user

10/2/95
Date

CERTIFICATE OF TRAINING

RADIATION SAFETY

This is to certify that Kathleen Shaw

has completed the LIXI™ Radiation Safety Training Course on file with the U.S. Nuclear Regulatory Commission.

This training was completed on: August 12, 1985

This training course was developed by Lixi, Inc. and S.A. Huber Consultants Inc. for the purpose of providing the necessary training in radiation safety and experience for LIXI™ scope users. The training was given as approved by the NRC under License Nos. 12-17503-01 and 12-18215-01.

This also certifies that the trainee has personally operated a working LIXI™ scope, under supervision, in the aforementioned course.

A copy of this certificate is to be provided to the NRC or Agreement State as proof that the trainee has the necessary experience to make a specific application for a Byproduct Material License to possess and use a LIXI™ scope.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and all information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Lixi, Inc.

Instructor: Jeff Gipe

Signature: Jeff Gipe

Under License No: 12-18215-01

Date: August 29, 1985

Radiologic Health Branch
744 P Street
Sacramento, California 95814

STATEMENT OF TRAINING AND EXPERIENCE

(Use additional sheets as necessary)

Instruction: Every individual proposing to use radioactive material is required to submit a Statement of Training and Experience in duplicate to the address given above. Physicians should request Form RH 2000 A when applying for human use authorizations.

1. Name of proposed user: KATHleen A SHAW Position title: QA Inspector
   Address: 2080 Newport Blvd # 106 City: COSTA MESA CA Zip: 92626
   To be included on Lic. No. _____ in name of American Bentley

2. Description of proposed use
   use the Lixiscope (model # LS-80-100) for non-destructive x-ray inspection of medical products

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3. Training:
   a. High School Graduate: Yes ✓ No ____
   b. College or University: Name and location _____
      Years completed _____ Degree _____ Course of study _____
   c. Education specifically applicable to use of radioactive material
      completed the Lixi training course

4. Experience:
   a. List experience with radioactivity beginning with most recent
      (1) Dates: From 8/85 to present
      Title and duties: Asst RSO. I will use the equipment to inspect product and train inspectors on its use for Inspection
      Employer: American Bentley Address: 17002 Armstrong Irvine, CA 92714 (714) 261-8363
      (2) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____
      (3) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____

b. Radioactive materials previously used. Cite typical radioisotopes in appropriate box and key tc Part 4.a above:

Quantities Handled

	Microcuries	Millicuries	Curies	Kilocuries
Sealed sources		Iodine 125		
Unsealed alpha emitters				
Unsealed beta-gamma emitters				
Neutron sources				

c. Describe procedures similar to those proposed in Part 2 with which you have had experience. Indicate months or years for each and key to Part 4.a above.

d. Indicate which types of facilities you have used and key to Part 4.a.

( ) Ordinary Chemical laboratories
( ) "Controlled Area" (Type B) laboratories
( ) Glove boxes
( ) Shielded glove boxes
( ) Caves with remote manipulators
(X) ~~Field~~ operations with portable equipment
In house

5. Certificate:

I hereby certify that all information contained in this Statement is true and correct.

Kathleen A. Shaw — Signature of proposed user

10/2/95 — Date

CERTIFICATE OF TRAINING

RADIATION SAFETY

This is to certify that Kathy Monday

has completed the LIXI™ Radiation Safety Training Course on file with the U.S. Nuclear Regulatory Commission.

This training was completed on: August 12, 1985

This training course was developed by Lixi, Inc. and S.A. Huber Consultants Inc. for the purpose of providing the necessary training in radiation safety and experience for LIXI™ scope users. The training was given as approved by the NRC under License Nos. 12-17503-01 and 12-18215-01.

This also certifies that the trainee has personally operated a working LIXI™ scope, under supervision, in the aforementioned course.

A copy of this certificate is to be provided to the NRC or Agreement State as proof that the trainee has the necessary experience to make a specific application for a Byproduct Material License to possess and use a LIXI™ scope.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and all information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Lixi, Inc.

Instructor: Jeff Gipe

Signature: Jeff Gipe

Under License No: 12-18215-01

Date: August 29, 1985

Radiologic Health Branch
744 P Street
Sacramento, California 95814

STATEMENT OF TRAINING AND EXPERIENCE

(Use additional sheets as necessary)

Instruction: Every individual proposing to use radioactive material is required to submit a Statement of Training and Experience in duplicate to the address given above. Physicians should request Form RH 2000 A when applying for human use authorizations.

1. Name of proposed user: Kathy Monday Position title: QA. Inspector
   Address: 15529 Williams #110 City: Tustin Zip: 92647
   To be included on Lic. No. _____ in name of American Bentley

2. Description of proposed use
   Use the Lixiscope (model # LS-82-102) for non-destructive x-ray inspection of medical products.

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3. Training:
   a. High School Graduate: Yes ✓ No ____
   b. College or University: Name and location Rancho Santiago, SANTA ANA
      Years completed 2 Degree _____ Course of study A.S. - Corrections
   c. Education specifically applicable to use of radioactive material
      Completed the Lixi training course

4. Experience:
   a. List experience with radioactivity beginning with most recent
      (1) Dates: From 8/85 to Present
      Title and duties: User. I will use the equipment to inspect product.
      Employer: American Bentley Address: 17502 Armstrong, Irvine, Ca 92714 (714) 261-8363
      (2) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____
      (3) Dates: From _____ to _____
      Title and duties: _____
      _____
      Employer: _____ Address: _____

b. Radioactive materials previously used. Cite typical radioisotopes in appropriate box and key t Part 4.a above:

	Quantities Handled			
	Microcuries	Millicuries	Curies	Kilocuries
Sealed sources		IODINE 125		
Unsealed alpha emitters				
Unsealed beta-gamma emitters				
Neutron sources				

c. Describe procedures similar to those proposed in Part 2 with which you have had experience. Indicate months or years for each and key to Part 4.a above.

d. Indicate which types of facilities you have used and key to Part 4.a.

( ) Ordinary Chemical laboratories

( ) "Controlled Area" (Type B) laboratories

( ) Glove boxes

( ) Shielded glove boxes

( ) Caves with remote manipulators

(X) ~~Field~~ operations with portable equipment
IN HOUSE

5. Certificate:

I hereby certify that all information contained in this Statement is true and correct.

Kathy Monday — Signature of proposed user

12-2-85 — Date

CERTIFICATE OF TRAINING

RADIATION SAFETY

This is to certify that Frances Roustan

has completed the LIXI™ Radiation Safety Training Course on file with the U.S. Nuclear Regulatory Commission.

This training was completed on: August 28, 1985

This training course was developed by Lixi, Inc. and S.A. Huber Consultants Inc. for the purpose of providing the necessary training in radiation safety and experience for LIXI™ scope users. The training was given as approved by the NRC under License Nos. 12-17503-01 and 12-18215-01.

This also certifies that the trainee has personally operated a working LIXI™ scope, under supervision, in the aforementioned course.

A copy of this certificate is to be provided to the NRC or Agreement State as proof that the trainee has the necessary experience to make a specific application for a Byproduct Material License to possess and use a LIXI™ scope.

This document was prepared in conformity with Title 10, Code of Federal Regulations, and all information contained herein is true and correct to the best of our knowledge and belief.

Certified by: Lixi, Inc.

Instructor: Jeff Gipe

Signature: Jeff Gipe

Under License No: 12-18215-01

Date: August 29, 1985

Radiologic Health Branch
744 P Street
Sacramento, California 95814

STATEMENT OF TRAINING AND EXPERIENCE

(Use additional sheets as necessary)

Instruction: Every individual proposing to use radioactive material is required to submit a Statement of Training and Experience in duplicate to the address given above. Physicians should request Form RH 2000 A when applying for human use authorizations.

1. Name of proposed user: Frances L. Boustead Position title: QA Inspector
   Address: 2318 Granger City: Santa Ana, Calif. Zip: 92705
   To be included on Lic. No. _____ in name of American Bentley

2. Description of proposed use
   Use the LIXI Scope for X-ray inspection of Medical Product

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3. Training:
   a. High School Graduate: Yes ✓ No ____
   b. College or University: Name and location _____
      Years completed _____ Degree _____ Course of study _____
   c. Education specifically applicable to use of radioactive material
      Completed LIXI training course

4. Experience:
   a. List experience with radioactivity beginning with most recent
      (1) Dates: From 8/85 to present
      Title and duties: Inspector, Inspect medical product.
      Employer American Bentley Address: 17502 Armstrong, Irvine, Calif
      (2) Dates: From 8-2-74 to ~~present~~
      Title and duties: ~~Inspector~~
      Employer: _____ Address: _____
      (3) Dates: From _____ to _____
      Title and duties: _____
      Employer: _____ Address: _____

b. Radioactive materials previously used. Cite typical radioisotopes in appropriate box and key t. Part 4.a above:

Quantities Handled

	Microcuries	Millicuries	Curies	Kilocuries
Sealed sources		Iodine 125		
Unsealed alpha emitters				
Unsealed beta-gamma emitters				
Neutron sources				

c. Describe procedures similar to those proposed in Part 2 with which you have had experience. Indicate months or years for each and key to Part 4.a above.

d. Indicate which types of facilities you have used and key to Part 4.a.

( ) Ordinary Chemical laboratories
( ) "Controlled Area" (Type B) laboratories
( ) Glove boxes
( ) Shielded glove boxes
( ) Caves with remote manipulators
(X) Field operations with portable equipment
In house

5. Certificate:

I hereby certify that all information contained in this Statement is true and correct.

Frances L. Houston
Signature of proposed user

10/2/85
Date