

MATERIALS LICENSE

Amendment No. 09

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated January 29, 1997	
1. Children's Health Care d/b/a Children's Health Care - Minneapolis		3. License Number 22-20499-01 is amended in its entirety to read as follows:	
2. 2525 Chicago Avenue South Minneapolis, MN 55404		4. Expiration Date April 30, 2005	
		5. Docket or Reference No. 030-18449	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed	
C. Any byproduct material identified in 10 CFR 31.11	C. Prepackaged Kits	C. As needed	
D. Cesium-137	D. Sealed sources (CEA-ORIS-LAP1B Model 437C)	D. 5,100 curies	
E. Iodine-125	E. Sealed sources as identified in 10 CFR 35.400	E. As needed	

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
B. Medical use described in 10 CFR 35.200.



110104

9704140058 970303
PDR ADOCK 03018849
C PDR

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

22-20499-01

Docket or Reference Number

030-18449

Amendment No. 09

- C. In vitro studies.
- D. To be used in a CIS-US, Inc., Compagnie ORIS Industries Model IBL-437C irradiator for irradiation of blood and blood products (excluding explosives and flammable material).
- E. Medical use described in 35.400, limited to iodine-125 for interstitial treatment of cancer.

CONDITIONS

10. Location of Use: 2525 Chicago Avenue, South, Minneapolis, Minnesota.
11. Radiation Safety Officer: Karen Blumberg, M.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

- | | |
|-----------------------------|--|
| A. Shashikant M. Sane, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| B. Richard Patterson, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| C. Karen Blumberg, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| D. Judy Wenzel | Subitem 6.D. |
| E. Tae H. Kim, M.D. | 10 CFR 35.400, limited to iodine-125 for interstitial treatment of cancer. |
| F. David J. Monyak, M.D. | 10 CFR 35.400, limited to iodine-125 for interstitial treatment of cancer. |
| G. James E. Crowe, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
13. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

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14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
- B. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.
- C. The licensee is authorized to collect leak test samples for analysis by Stan A. Huber Consultants. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
15. Sealed sources containing licensed material shall not be opened or removed from the irradiator by the licensee.
16. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
17. The procedures contained in the CIS-US, Inc. instruction manual for the Model IBL 437C device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

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19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 31, 1994; and
- B. Letters dated February 22, 1995, October 16, 1996, and January 29, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 3/3/97

By James Mullane
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 3E 2B
Exp. Date: 20050430
Fee Comments: 3E ADDED 8/5/88
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: CHILDREN'S HEALTH CARE
Received Date: 970213
Docket No: 3018449
Control No.: 302313
License No.: 22-20499-01
Action Type: Amendment

2. FEE ATTACHED

Amount:
Check No.:

3. COMMENTS

Signed D. Hershey
Date 2-18-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ☒)

1. Fee Category and Amount: (7C) 3E 2B \$440

2. Correct Fee Paid. ☒ Application may be processed for:

Amendment
Renewal
License

3. OTHER

Signed SC
Date 3/23/97

APR 01 1997

Log	Feb 8 III
Remitter	
Check No.	118664
Amount	\$440
Fee Category	(7C) 3E 2B
Type of Fee	AMD
Date Check Rec'd	3/25/97
Date Completed	3/25/97
By:	SC

1997 FEB 20 PM 1:20



Children's Health Care Minneapolis
2525 Chicago Avenue South
Minneapolis, Minnesota 55404
(612) 863-6100

* January 29, 1997

* U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137

NCR Representative:

I am requesting an amendment to NRC license number 22-20499-01 to relocate our Cesium-137 self-contained biological irradiator used in our Blood Bank for the irradiation of blood and blood products. Our irradiator is a Model IBL-437C distributed by CIS-US, Inc., 5 DeAngelo Drive, Bedford, Massachusetts. A table of the IBL-437C technical specifications is attached. The relocation plan is as follows:

1. Location of Use

* The irradiator will be moved to a small room next to the relocated Blood Bank. The room has been outlined in red on the attached diagram. The room is being remodeled to provide a fourth wall and a locked door access to prevent access to the irradiator by unauthorized personnel. The walls are constructed of dry wall material. Please refer to the attached letter for construction specifics. The room is already equipped with an automatically operated fire detection and control (sprinkler) system.

2. Relocation Procedure

The relocation process will be conducted under the guidance of personnel from CIS-US.

- a. Prior to the move, the irradiator's power key will be turned "off" with the canister chamber left in the "load" position which shields the source. The canister will be removed and the protective door in front of the chamber will be closed.
- b. CIS-US will conduct area surveys around the source housing unit to ensure the source is in the "off or shielded" position prior to the move and after relocation. Internal and external wipe tests of the irradiator will also be done by CIS-US before and

302313
RECEIVED

FEB 13 1997

REGION III

* pm: 2-12-97

* FEB 13 1997

Page 2

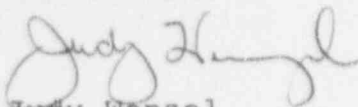
after the move. Attached is a copy of the CIS-US survey report from the irradiator relocation move in July of 1994. CIS-US will conduct similar surveys during this move. All survey records will be maintained by the Blood Bank.

- c. A Ludlum Model 5 Geiger Counter, Serial #557760, is available in the Blood Bank at all times. It has a detection range of 0.01 MR/HR to 2000 MR/HR.
- d. Paul Be...ssi, Director of Children's Facilities Management, will supervise the physical move of the IBL-437C.
- e. When the physical move has been completed and the specified area surveys have been conducted and reviewed, the irradiator will be turned back on and recalibrated as needed.

Please review our application and reply as soon as possible. The Blood Bank is scheduled to relocate by March 1, 1997, with or without relocation of the irradiator.

If you have questions or require clarification on any of this information, please contact Dawn Hansen or myself at (612) 813-6824.

Sincerely,



Judy Wenzel
Transfusion Service Manager

JW/ctf

TABLE 1. Technical Specifications of IBL 437 C IrradiatorRADIATION

Source :	Nature	cesium 137
	Number	1 to 3
	Activity per source (approximately)	63 TBq (1700 Ci)
	Dose rate at the center of the	12 Gy per minute
	chamber in the case of 3 unitary	1200 rad
		per minute
	sources of 63 TBq each (1700 Ci)	$\pm 10 \%$

GEOMETRY

a)	Aluminum Irradiation Canister :	cylindrical in shape
	Diameter	130 mm
	Total height	290 mm
	Total volume	3.8 liters
		(1 U.S. gallon)
	Rotation speed	18 revolutions per minute
b)	Irradiator	
	Depth	670 mm
	Width	650 mm
	Height	1500 mm

TOTAL WEIGHT

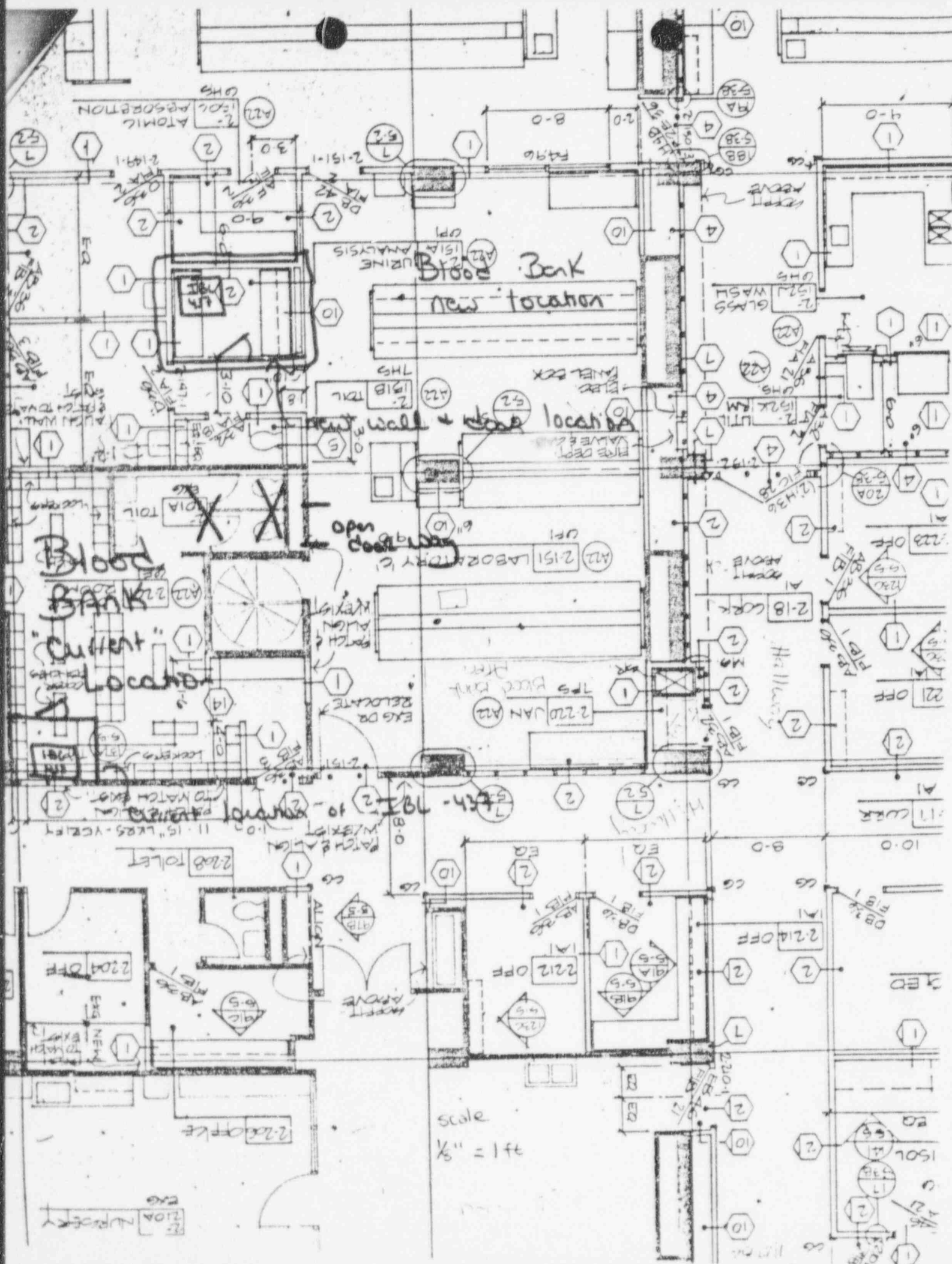
2150 kg - floor loading of 5.2 tons per square meter (on 0.4 m²)

RADIOLOGICAL SAFETY

Exposure rate in contact with the machine averages less than 25 micro Sv per hour (2.5 mR per hour)

ELECTRICAL POWER REQUIREMENT

Standard :	220/230 V about 50 Hz
	Standard wall outlet three prong plug
Optional :	110/120 V about 60 Hz
	Standard North American wall outlet three prong plug
Battery :	24 V direct current





PALANISAMI & ASSOCIATES, INC.
CONSULTING ENGINEERS

January 29, 1997

Mr. Paul Benassi
Minneapolis Children's Hospital
2525 Chicago Avenue South
Minneapolis, MN 55404

REF: Children's Hospital
Interior Remodeling - MRI Unit
PAI Job No. 97020

Dear Paul:

I have investigated the load carrying capacity of the slab through field observations and reviewing existing structural drawings. The data sheet of irradiator indicates a weight of 4,775 lbs. The post tensioned slab is 9" in depth and is safe to place the irradiator at the new location on 2nd floor between grids D and E and between grids 5 and 6.

Sincerely,

Palanisami & Associates, Inc.

P. Palanisami, P.E.
President

PP/dat

cc: Kent Vogue/Jordan Architects

(97020-MRI)



IBL 437C BLOOD IRRADIATOR

INSTALLATION QUALITY ASSURANCE PROCEDURE

IBL
move
to
new
location

DATE: July 20, 1994
CUSTOMER: Minneapolis Children's Hospital
ADDRESS: 2525 Chicago Ave Sath
CITY/STATE: Minneapolis, MN 55404
CONTACT/TITLE: Dawn Hansen
TELEPHONE #: 612 863 6824
IBL SERIAL #: 87-255

External Radiation Survey for the unopened cask with meter:

SIDE 1 IBL Move mR/Hr
SIDE 2 Soft Dawn mR/Hr
SIDE 3 Corridor mR/Hr
SIDE 4 _____ mR/Hr

External Radiation Survey of the IBL 437C Irradiator:

Maximum Measurement at surfact contact with the Irradiator:

Chamber Area 0.07 mR/Hr
(front)
Right Side 0.02 mR/Hr B.B. 0.19 mR/Hr
Left Side 0.02 mR/Hr B.B. 0.20 mR/Hr
Back of Unit 0.15 mR/Hr
Top 0.06 mR/Hr
Bottom 0.09 mR/Hr

SURVEY BY: John Precupio DATE: 7/20/94
METER: TBM-3 S/N: 34052 LAST CALIBRATION: 8/16/93

Wipe Test Survey:

- Before move { 1. ~~CASK EXTERNAL~~: IBL external
2. ~~CASK INTERNAL~~: IBL internal
After move { 3. IBL 437C EXTERNAL:
4. IBL 437C INTERNAL:

To be faxed by
_____ uCi Cs-137 ^{Paul} Tyree
_____ uCi Cs-137 RSO
_____ uCi Cs-137 CIS-US
_____ uCi Cs-137

WIPE SURVEY BY: John Precupio DATE: 7/20/94

METER: _____ S/N: _____ LAST CALIBRATION: _____

COUNTER: _____ CALIBRATION: _____ STD.No. _____

VISUAL INSPECTION of the IBL:

DAMAGE REPORT: OK

CHECK LEVEL of the IBL in the FINAL POSITION: OK

LEVELING FEET ADJUSTED:

FRONT RIGHT: 6 number of turns

FRONT LEFT: 2 number of turns

Page 3
Installation Q A Procedure

BACK RIGHT: 4 number of turns

BACK LEFT: 4 number of turns

Remove the shipping blocks securing the Drum Rotation: OK

Manually Rotate the Drum checking for smooth operation: OK

Check that the Canister Detector does not hit the Drum:

Run out of the Canister Shelf 0.012 in.

Run out of the Canister Drive Top Bearing 0.006 in.

Run out of the Upper Drum Bearing 0.0 in.

Run out of the Lower Drum Bearing 0.0 in.

Attach and secure the AC line cord: OK

Install the Electronics Panel and Control Panel: OK

Power up the IBL: OK

Check the AC outlet Voltage: 118.2 VAC

Check and adjust the 24V Power Supply: 25.56 VDC

Check the input of all Digits on the Timer: OK

Install 30 seconds on the Timer and Run a Cycle: OK

Install and secure the Back and Front Covers: OK

Check the Irradiation Position of the Drum: OK

Adjusted switch actuator: NO

Adjusted switch: NO

Page 4
Installation Q A Procedure

Check the clearance of the Canister Shelf to the Drum side wall.

Right Side 0.099 in.

Left Side 0.064 in.

Back 0.045 in.

Check the Load position of the Drum:

Adjusted switch: OK

Install the Top Cover:

OK

Check battery backup for proper operation:

OK

Check the operation of the Emergency Switch:

OK

Check the Door Interlock:

OK

Check Lamp Test:

Lamps replaced:

1 Lamp (Mains) OK

Set the Timer for 300 seconds, 5 minutes, and check with a stop watch:

OK

Install the Computer:

OK

Check the Dose Time Relationship with the Calibration Certificate:

Calibration Certificate: 1 minute 9.01 Grays

Computer Calculation: 1 minute 9.01 Grays

Set the Computer for 300 seconds, 5 minutes, and check with a stop watch:

OK



REPORT OF CONTAMINATION/LEAKAGE TEST

IBL 437C GAMMA IRRADIATOR

Serial No. 87-255

At: Minneapolis Childrens Hospital
2525 Chicago Ave. So. Minneapolis

MN

55404

License No. 22-20499-01

Tested: 20-Jul-94

By: John J. Precopio, III, Field Service Engineer

Test Method: Wipe (dry) per ANSI N542-1977; method A2.1.2

Date of Analysis: 25-Jul-94

Counter:	Eberline SRM100
Detector:	HP-210L (15 s.cm. G-M)
Set-up(1):	SH4A Sample Holder
Calibration Source(2):	LMRI EBSB30, s/n 2724, Cs-137 Beta
Efficiency (CPM+dpm):	0.274
Background CPM:	38.0
Ld CPM:	31.7
MDA(3) Cs-137 (μ Cl):	5.2E-05

Survey Location:	Internal (Canister Drum)		
Count Gross CPM:	41		
Sample Net CPM:	3.0	\pm	17.8
Test Activity (μ Cl)(4):	5.2E-05		

Survey Location:	External (Shield Body)		
Count Gross CPM:	48		
Sample Net CPM:	10.0	\pm	18.5
Test Activity (μ Cl)(4):	5.2E-05		

(1) Sample geometry/counter set-up, as appropriate to reproduce measurement.

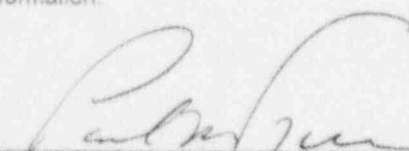
(2) NIST traceable source used to derive measurement efficiency.

(3) Minimum Detectable Activity at 5% false positive/negative confidence level.

(4) Minimum Detectable Activity when sample net CPM < lower detection level (Ld) CPM.

The irradiator was found to be negative for contamination and/or leakage of Cs-137 at the above test sensitivity (MDA). The maximum test radioactivity for acceptance of the Irradiator is 5E-03 μ Cl. A test for contamination/leakage must be performed at each six month interval, as specified in the applicable license. See section 6.5 of the Operator's Manual for further information.

Analysis and report by:


Paul M. Tyree, Radiation Safety Officer

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001CHILDREN'S HEALTH CARE
ATTN: JUDY WENZEL
TRANSFUSION SERVICE MANAGER
2525 CHICAGO AVENUE SOUTH
MINNEAPOLIS, MN 55404

TYPE OF ACTION

- ☐ NEW LICENSE
☐ RENEWAL OF LICENSE
☒ AMENDMENT TO LICENSE

REQUESTED DATE

1-29-97

LICENSE NUMBER

22-20499-01

CONTROL NUMBER

302313

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	440.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

SIGNATURE -- LICENSE FEE ANALYST

SHIRLEY CRUTCHFIELD

LFDCB

2/25/97

LFDCB

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
☐ ACCOUNT CLOSED
☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your license program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

Distribution:

Pending Fee File OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) Region 5

DATE

Feb. 25, 1997

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001CHILDREN'S HEALTH CARE
ATTN: JUDY WENZEL
TRANSFUSION SERVICE MANAGER
2525 CHICAGO AVENUE SOUTH
MINNEAPOLIS, MN 55404

TYPE OF ACTION

- ☐ NEW LICENSE
☐ RENEWAL OF LICENSE
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FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	440.00

- ☒ Your request was received without the prescribed application fee.
- ☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.
- ☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

SIGNATURE -- LICENSE FEE ANALYST

SHIRLEY CRUTCHFIELD

LFDCB

2/25/97

LFDCB

Distribution:

Pending Fee File OC/DAF/SF(LF-3.2.7)

LFARB R/F (2)

Region 5

DATE

Feb. 25, 1997

APR 01 1997

Karen Blumberg, M.D.
Radiation Safety Officer
Children's Health Care d/b/a
Children's Health Care - Minneapolis
2525 Chicago Avenue South
Minneapolis, MN 55404

Dear Dr. Blumberg:

Enclosed is Amendment No. 09 to your NRC Material License No. 22-20499-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

302313

4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

K. Blumberg

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prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No.: 22-20499-01
Docket No.: 030-18449

Enclosure: Amendment No. 09

DOCUMENT NAME: M:\03018449.CL7

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DATE	03/3/97								

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

February 19, 1997

Karen Blumberg, M.D.
Radiation Safety Officer
Children's Health Care
d/b/a Children's Health Care - Minneapolis
2525 Chicago Avenue South
Minneapolis, MN 55454

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE (Letter Dated 01/29/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

It appears that your request is nonroutine and has been assigned to James Mullauer for an expedited review. If you should have any questions please contact Mr. Mullauer at (630) 829-9887.

Incomplete information is as follows: In order for us to complete your amendment request the required fee is necessary. Please contact our License Fee & Debt Collection Branch, as referenced below, to obtain the correct fee amount.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however under timely filing (before expiration) you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302313
License No. 22-20499-01