

MATERIALS LICENSE

Amendment No. 11

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 March 21, 1997	
1. Columbia-CSA/HS Greater Cleveland Area Healthcare System, L.P. d/b/a Columbia St. Luke's Medical Center, a Ministry of the Sisters of Charity of St. Augustine 11311 Shaker Boulevard Cleveland, OH 44104		3. License Number 34-00398-10 is amended in its entirety to read as follows:	
		4. Expiration Date April 30, 2004	
		5. Docket or Reference No. 030-17512	
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. Cobalt-60	A. Sealed source model designation Theratronics International Ltd (AECL) C-146 or C-151)	A. 10,000 curies per source	
B. Cobalt-60	B. Sealed source model designation Theratronics International Ltd (AECL) C-146 or C-151)	B. 7000 curies per source	
C. Uranium depleted in uranium-235	C. Solid metal	C. 275 kilograms total possession limit	

9. Authorized Use:

- A. and B. Medical use described in 10 CFR 35.600 in two (2) Theratronics International Ltd. (AECL) 780 teletherapy units.
- C. Shielding in teletherapy units.

CONDITIONS

10. Licensed material in Subitem 6.A. shall be used only in St. Luke's Hospital, Cobalt/1516, First Floor 11311 Shaker Blvd., Cleveland, Ohio. Licensed material listed in Subitem 6.B. shall be used only in St. Luke's Medical Center of Solon, First Floor, Room 108, 33001 Solon Road, Solon, Ohio.

110085



9704140085 970403
PDR ADOCK 03017512
C PDR

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

34-00398-10

Docket or Reference Number

030-17512

Amendment No. 11

11. Radiation Safety Officer: Thomas K. Stefanakos, M.S.N.E.
12. Authorized Users: Phillip Catanzaro, M.D., Kenneth C. Lane, M.D.,
Hae-Kyung Hong, M.D. and Dong Youn Kim, M.D.

Teletherapy Physicists: Thomas K. Stefanakos, M.S.N.E.
13. Notwithstanding the requirements of 10 CFR 35.632, the licensee is authorized to extend until June 30, 1997, the time interval for full calibration measurements of its teletherapy unit located at St. Luke's Hospital, Cobalt/1516, First Floor, 11311 Shaker Blvd., Cleveland, Ohio.
14. Notwithstanding the requirements of 10 CFR 35.647, the licensee is authorized to extend until June 30, 1997, the time interval for inspection and servicing of its teletherapy unit located at St. Luke's Hospital cobalt/1516, First Floor, 11311 Shaker Blvd., Cleveland, Ohio.
15. 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. 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. Letters dated July 26, 1985; January 3, 1986, July 7, 1987, July 17, 1987, October 6, 1987, October 5, 1992, November 21, 1996 (excluding consultants report dated June 7, 1996, excluding Escrow Agreement and Amendment No. 1 to the Escrow Agreement and excluding Section V, Radioactive Waste Management Plan), February 26, 1997, February 27, 1997, and March 21, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

APR 03 1997

By

Loren J. Hunter
Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02300
Status Code: 0
Fee Category: 7A 2B
Exp. Date: 20040430
Fee Comments: CODE 23
Decom Fin Assur Req'd: Y
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: COLUMBIA ST. LUKE'S MEDICAL CNTR
Received Date: 970324
Docket No: 3017512
Control No.: 302448
License No.: 34-00398-10
Action Type: Amendment

2. FEE ATTACHED

Amount: 470
Check No.: 791

3. COMMENTS

Signed D. Hershey
Date 3-25-97

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

1. Fee Category and Amount: 7A 2B 470

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

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed SC
Date 3/26/97

MAR 31 1997

Log	<u>Mar 11 70</u>
Remitter	
Check No.	<u>191</u>
Amount	<u>470</u>
Fee Category	<u>7A 2B</u>
Type of Fee	<u>Amnd</u>
Date Check Rec'd	<u>3/26/97</u>
Date Completed	<u>3/26/97</u>
By	<u>SC</u>

1997 MAR 26 AM 11:28

 **COLUMBIA**
Saint Luke's Medical Center

† *A Ministry of the Sisters of Charity of St. Augustine*

11311 Shaker Boulevard

Cleveland, Ohio 44104

216-368-7000

COLUMBIA's home page is <http://www.columbia.net>

SAINT LUKE's home page is <http://www.en.com/stluke's>

March 21, 1997

B.J. Holt
U.S. Nuclear Regulatory Commission
Nuclear Material Licensing, Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

RE: License #34-00398-10

Dear Ms. Holt:

For the past six months, this institution was in negotiations for its purchase. During this time, it was uncertain as to whether the therapy department would be closed or continue to operate. The finalization of the sale was February 28, 1997. The new owners have since decided to maintain a teletherapy department. The sources that are in need of replacement are at the Solon campus and the main campus. However, only the source at the main campus is scheduled to be replaced. Theratronics can not deliver the desired source by the 5 year/annual anniversary date of the present source.

It is requested that reference license be permitted to delay the 5 year inspection required by 10CFR, Part 35.645 and the annual full calibration required by 10 CFR, 35.632 to on or before June 30, 1997. This would be most cost effective and preclude duplication of efforts. It is felt that this would pose no health or safety concern since the unit in question is under a service contract and has had routine P.M. through the life of the source.

It is further requested that the authorized source limit for the main campus unit be increased to 10,000 Ci which is equivalent to a 165 rmm output. It is felt that the shielding of the vault is adequate to accommodate the increased source. Documentation to this effect is attached.

The anniversary date for the present source is April 18, 1997. Consequently, it is respectfully requested that this license request/amendment be expedited so as to allow us the time to purchase and install the new source and not be in violation of the aforementioned sections of Part 35.

RECEIVED

MAR 24 1997

REGION III

302448

MAR 24 1997

Pm: 3-21-97

A Joint Venture of the CSA Health System and a Columbia Affiliate

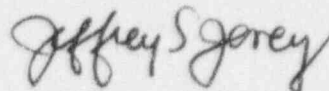
Page 2-

To: B.J. Holt

From: J. Jeney

Any questions regarding this request should be addressed to Mr. Thomas K. Stefanakos, MSNE either in writing or by telephone (216)447-1045. A check in the amount of \$470.00 to cover the cost of this amendment is enclosed. again, your expeditious response to this request would be most appreciated.

Sincerely,

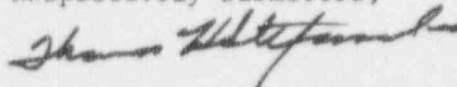
A handwritten signature in cursive script, reading "Jeffrey S. Jeney".

Jeffrey S. Jeney, Sr. VP
Ancillary Services

VERIFICATION OF SHIELDING FOR UP-GRADED SOURCE

1. The vault has not been altered since the original license and the unit is still equipped with a beam stopper which has a transmission factor of 0.3%.
2. With the present shielding, the maximum exposure rate was 7.6 mR/hr on the roof. Next highest rate was 5.2 mR/hr, also on the roof (see enclose 1). Both areas are inside a fenced area whose only access is a locked gate (see enclosure 2). The key for this lock is controlled by the Engineering Department and it is tagged not to be issued without clearance by the therapy personnel (physicist, physician or therapist). Furthermore, there are no ventilation ducts, AC unit, etc. in the fenced area negating the need for service personnel to enter it.
3. The requested source 10,000 Ci would have maximum output of 165 Rmm (per Theratronics). The ratio of this output and that of the source for which the survey was conducted, (102.9 Rmm) is 1.60. By multiplying the exposure of all areas by this factor, except the roof, you obtain a dose rate of 0.16 mR/hr, which is well below the allowable limits. The limits for the roof would be 12.2 and 8.3 mR/hr respectively. Since the areas are right over the isocenter and well inside the fence, they pose no health hazard to the staff or general public. All drawings are presently on file with the Region III office at the NRC.
4. A full survey will be conducted of all adjoining spaces prior to the full operational use of the new source. Also, a full calibration of the unit as prescribed by 10 CFR 35.632 will be done before its use.

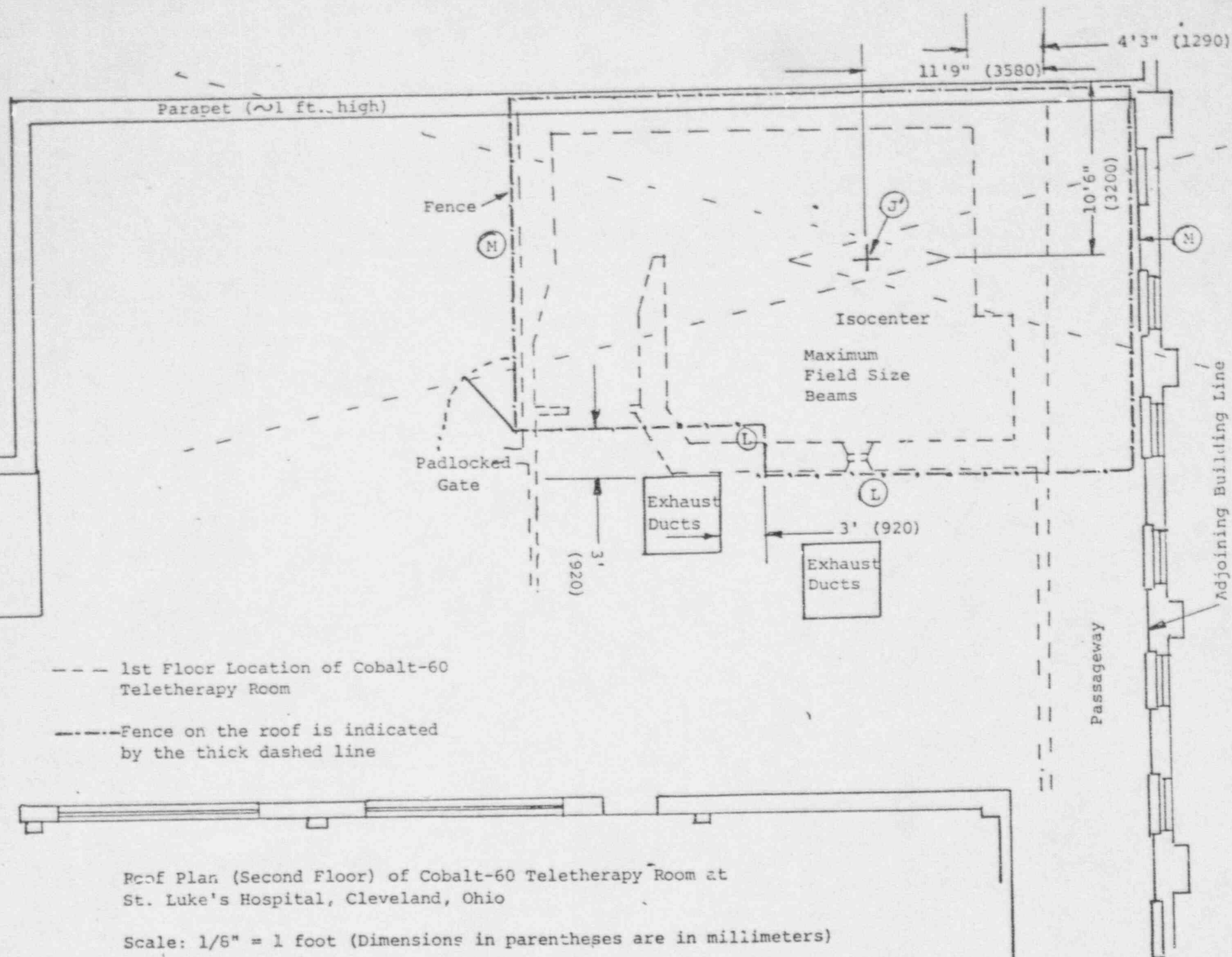
Respectively submitted,



Thomas K. Stefanakos MSNE
Physicist

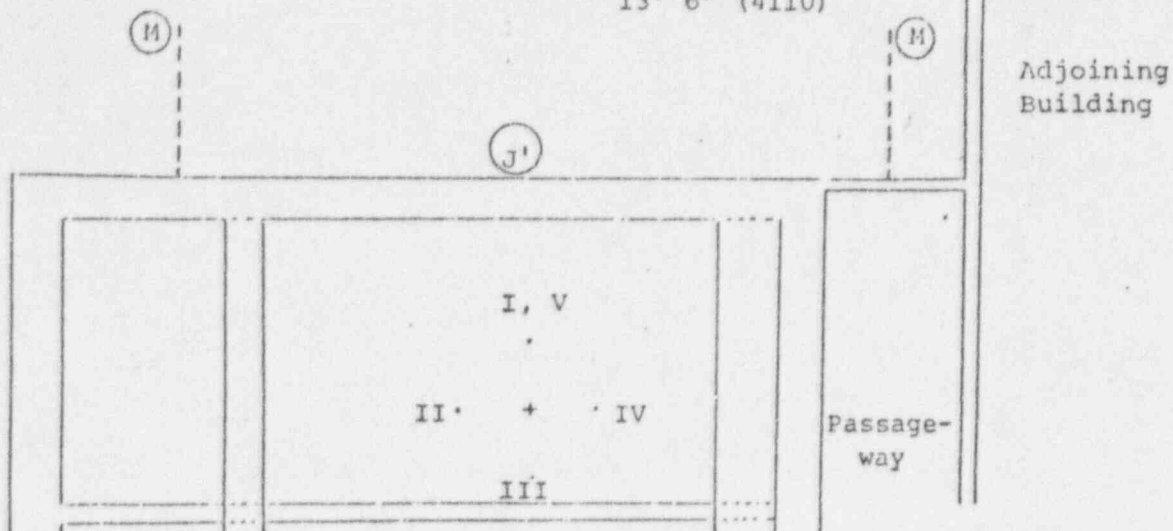
ST. LUKE'S HOSPITAL
Theratron-780 Area Survey.

	Barrier	Location	Beam Absorber	Prim. Scat.	Scat. Angle deg.	Gantry Angle deg.	Swivel Angle deg.	mR/h
1.	South Wall	D	No	S	90	0	270	< 0.1
2.	"	D	Yes	S	45	270	0	< 0.1
3.	"	E	No	S	120	0	270	< 0.1
4.	"	E	Yes	S	90	0	0	< 0.1
5.	"	G	Yes	S	30	90	0	< 0.1
6.	Door	-	Yes	S	-	90	0	< 0.1
7.	"	-	Yes	S	-	45	0	< 0.1
8.	West Wall	H	Yes	S	90	90	0	< 0.1
9.	"	H	Yes	S	45	135	0	< 0.1
10.	"	H	Yes	S	30	120	0	< 0.1
11.	East Wall	B	No	P	-	0	270	< 0.1
12.	"	C	No	P	-	0	270	< 0.1
13.	"	C	Yes	S	30	270	0	< 0.1
14.	North Wall	A	No	P	-	0	270	< 0.1
15.	"	A	Yes	S	90	0	0	< 0.1
16.	"	A	Yes	S	60	90	0	< 0.1
17.	Roof	J'	Yes	S	30	150	0	7.6
18.	"	J'	Yes	S	45	135	0	5.2
19.	"	L	Yes	S	45	180	0	< 0.1
20.	"	M	Yes	S	30	120	0	< 0.1
21.	Adj. Bldg.	Window	No	S	45	0	90	< 0.1
22.	" "	"	Yes	S	45	180	0	< 0.1

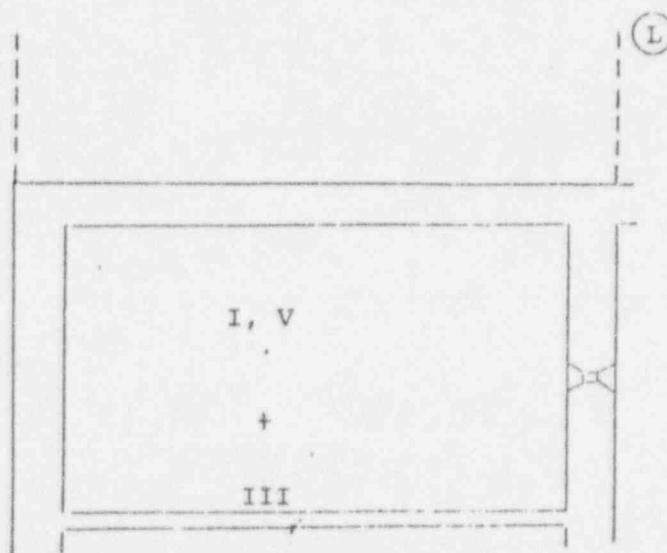


17' 10 3/4" (5460)

13' 6" (4110)



View Looking Toward North

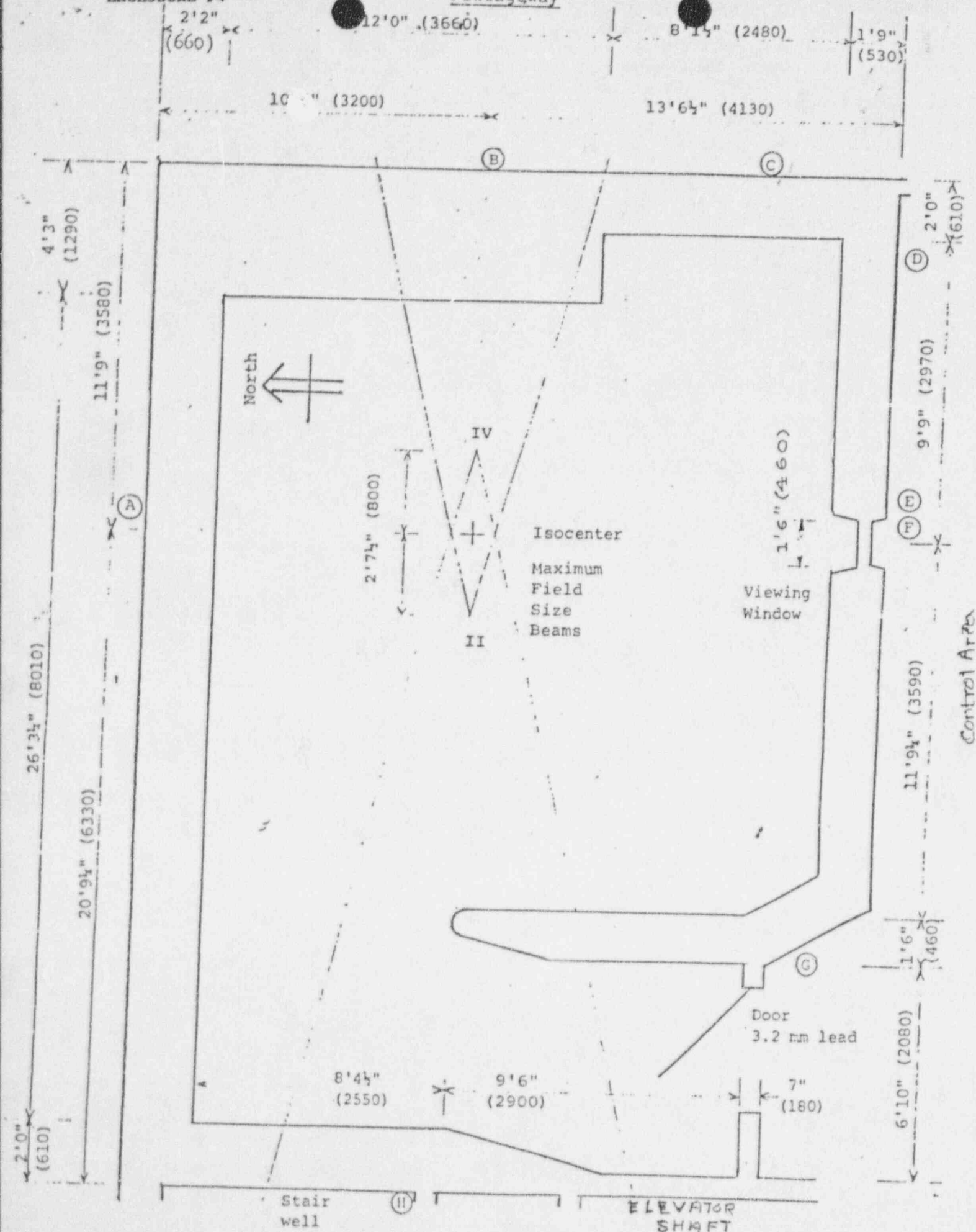


View Looking Toward East

Elevations of Cobalt-60 Teletherapy Room at St. Luke's Hospital, Cleveland, Ohio

Scale: 1/8" = 1'

Fence on the roof is indicated by the thick dashed line.



Plan of Cobalt-60 Teletherapy Room at St. Luke's Hospital, Cleveland, Ohio.
 Scale: $\frac{1}{4}" = 1'$ (Dimensions in parentheses are in millimeters.)

APR 03 1997

Jeffrey S. Jeney, Sr. VP
Ancillary Services
Columbia-CSA/HS Greater Cleveland Area
Healthcare System, L.P. d/b/a
Columbia St. Luke's Medical Center
a Ministry of the Sisters of Charity
of St. Augustine
11311 Shaker Boulevard
Cleveland, OH 44104

Dear Mr. Jeney:

Enclosed is Amendment No. 11 to your NRC Material License No. 34-00398-01 in accordance with your request.

Please note the revisions made in License Items No. 6., 7., 8. and 9. and in License Condition No. 10 to accommodate your amendment request.

Also, note the addition of License Conditions No. 13 and 14 which authorize the short term extension of the time interval for both the full calibration measurements and the inspection and servicing of the teletherapy unit located at St. Luke's Hospital, on a one time basis.

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, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license 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.
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 or Teletherapy Physicists;
 - 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.

J. Jeney

-3-

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 Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, 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
Loren J. Hueter
Nuclear Materials Licensing Branch

License No. 34-00398-01
Docket No. 030-17512

Enclosures:

1. Amendment No. 11
2. NRC Form 313

DOCUMENT NAME: M:\03017512.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/> N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	LJHueter:brt	<i>LJH</i>						
DATE	04/03/97							

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME

DATE

3-31-97

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Thomas Stefanakos, MSNE Columbia - CSA/HS District Cleveland area

4150

216-447-1045

or 9947

SUBJECT

CN 302448

SUMMARY

I discussed the proposed changes used in the license to grant their request. He had no problem with these changes.

We also discussed the maximum anticipated ^{annual} dose rate, in ^{to a member of the public} an unrestricted area. Even with anticipated dose rate of 0.16 mR/hr during one hour of visit, the dose to a member of the public should be well below 100 mrem/yr (10 CFR 20.101(a)(1)) due to the limited on time and limited number of patients treated.

Discussed with ^{acting branch chief} Andy Frazier, whether these short term exemptions should be listed on LTS sheet. We concluded not to based on the short term nature of the exemptions and no mechanism for their removal.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Loren Hunter

3-31-97

ACTION TAKEN

SIGNATURE

TITLE

DATE



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 27, 1997

Thomas K. Stefanakos, MSNE
Radiation Safety Officer
Columbia St. Luke's Medical Center
11311 Shaker Boulevard
Cleveland, OH 44104

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 03/21/97)

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
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

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.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. 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. 302446
License No. 34-00398-10