

## MATERIALS LICENSE

Amendment No. 47

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.

302011

Licensee		In accordance with letters dated October 30, 1996, and November 1, 1996 3. License Number 48-02417-01 is amended in its entirety to read as follows:	
1. Columbia Hospital Dept. of Nuclear Medicine			
2. 2025 E. Newport Avenue Milwaukee, WI 53211		4. Expiration Date September 30, 2000	
		5. Docket or Reference No. 030-03429	
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 (excluding generators)	B. As needed	
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed	
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed	
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed	
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. As needed	
G. Uranium depleted in Uranium-235	G. Cadmium plated metal	G. As needed	

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

48-02417-01

Docket or Reference Number

030-03429

Amendment No. 47

## 9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200 (excluding generator).
- C. Medical use described in 10 CFR 35.300.
- D. Medical use described in 10 CFR 35.400.
- E. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.
- F. In vitro studies.
- G. Shielding in a linear accelerator.

CONDITIONS

- 10. Location of Use: 2025 E. Newport Avenue, Milwaukee, Wisconsin
- 11. Radiation Safety Officer: Yu Kong Chan, Ph.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. En-lin Yeh, M.D.           | 10 CFR 35.100, 35.200 (excluding generators), 35.300, 35.500 and 31.11.           |
| B. Guenther P. Pohlmann, M.D. | 10 CFR 35.100, 35.200 (excluding generators), 35.300 and 35.500.                  |
| C. Stanton A. Marks, M.D.     | 10 CFR 35.400.  |
| D. David A. Slosky, M.D.      | 10 CFR 35.200 (excluding generators), limited to clinical cardiovascular studies. |
| E. David W. Grambow, M.D.     | 10 CFR 35.200 (excluding generators), limited to clinical cardiovascular studies. |

COPY

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

48-02417-01

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Authorized UsersMaterial and Use

- F. Carl E. Olson, M.D. 10 CFR 35.300 and 35.400.
- G. Ranjini Gandhavadi, M.D. 10 CFR 35.300 and 35.400.
- H. Ashima Saini, M.D. 10 CFR 35.300 and 35.400.
- I. John P. Whalen, M.D. 10 CFR 35.100, 35.200 (excluding generators) and 35.300.
13. Notwithstanding the provisions of 10 CFR 35.400(d), the license may use iridium-192 seeds encased in nylon ribbon as described in letter dated August 14, 1991, for intracavitary treatment of cancer.
14. 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.
15. Notwithstanding the provisions of Section 35.49(a) of Title 10, Code of Federal Regulations, the licensee is authorized to receive sealed brachytherapy sources listed in Section 35.400 from St. Mary's Hospital (NRC License No. 48-01828-01), as described in letters dated October 30, 1996, and November 1, 1996.
16. 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. Application dated May 22, 1990; and
- B. Letters dated July 10, 1990 (with attachment); April 9, 1991; May 28, 1991; August 14, 1991; August 2, 1995, October 5, 1995, February 8, 1996, February 26, 1996, October 30, 1996, and November 1, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 5 November 1996By William P. Reinhold  
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 2B  
Exp. Date: 20000930  
Fee Comments: CODE 23  
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: COLUMBIA HOSPITAL  
Received Date: 961101  
Docket No: 3003429  
Control No.: 302011  
License No.: 48-02417-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: \$440  
Check No.: 101374

3. COMMENTS

Signed  
Date

*Mary Pearson*  
11/1/96

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

1. Fee Category and Amount:

7C 2B \$440

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

Amendment ☒  
Renewal ☐  
License ☐

3. OTHER

Signed  
Date

SC  
11/8/96

*EXPEDITE*

NOV 22 1996

Log	<u>NOV 5 III</u>
Remitter	
Check No.	<u>101374</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>AMD</u>
Date Check Rec'd	<u>11/8/96</u>
Date Completed	<u>11/8/96</u>
By:	<u>SC</u>

1996 NOV -8 AM 9:07

## The United States Nuclear

03003429

## Regulatory Commission

Region III

801 Warrenville Road

Lisle, Illinois 60532-4351

Attention: Mr. John Madera

Dear Mr. Madera:

As per your advice, we applied for an amendment to our Material License #48-02417-01 for exemption to 10 CFR 35.49(a).

We have scheduled patients for brachytherapy in early November. We would like to ask for temporary approval to use these cesium sources transferred from St. Mary's Hospital in these upcoming cases. These sources are listed on the appendix A on the next page.

Thanks.

Sincerely,

Yu Kong Chan

Yu Kong Chan  
Radiation Safety Officer  
Columbia Hospital  
2025 E. Newport Avenue  
Milwaukee, Wisconsin 53211  
961-3850  
Fax No. 961-4035

YKC/bp  
dd:10/31/96  
dt:10/31/96

Columbia • St. Mary's, Inc.  
2025 East Newport Avenue, Milwaukee, WI 53211

Columbia Hospital, Milwaukee • Sacred Heart Rehabilitation Institute, Milwaukee • St. Mary's Hospital of Milwaukee • St. Mary's Hospital Organics, Mequon

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NOV 01 1996

REGION III

Pm 11/1/96

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302011





## Appendix A

Cesium-137 Sources List  
Columbia <> St. Mary's Hospital, Mil., Wis.YU KONG CHAN,  
25-Sep-96

#	Physical form	Model (tubes)	Serial No.	Nominal strength (mg. Ra. eq.)	3M assay (mg. Ra. eq.)	Date purchased
1	cesium tube	6D6C-CA	3M-15-3429	15	15.6	22, Mar. 85
1	cesium tube	6D6C-CA	3M-15-3436	15	15.6	22, Mar. 85
1	cesium tube	6D6C-CA	3M-10-5256	10	10.4	22, Mar. 85
1	cesium tube	6D6C-CA	3M-10-5263	10	10.5	22, Mar. 85
1	cesium tube	6D6C-CA	3M-10-2755	10	11.1	18, Jul. 77
1	cesium tube	6D6C-CA	3M-10-2756	10	11.3	18, Jul. 77
1	cesium tube	6500	3M-5-1977	5	5.52	10, Jan. 92
1	cesium tube	6D6C-CA	3M-20-1798	20	20.9	18, Aug. 81
1	cesium tube	6D6C-CA	3M-20-1835	20	20.9	18, Aug. 81
1	cesium tube	6D6C-CA	3M-20-1886	20	20.9	18, Aug. 81
1	cesium tube	6D6C-CA	3M-20-1860	20	20.9	18, Aug. 81
1	cesium tube	6500	3M-5-2012	5	5.41	10, Jan. 92
1	cesium tube	6501	3M-10-8028	10	11.06	10, Jan. 92
1	cesium tube	6501	3M-10-8042	10	11.14	10, Jan. 92
1	cesium tube	6504	3M-25-1549	25	26.54	10, Jan. 92
1	cesium tube	6D6C-CA	3M-25-1049	25	25.3	22, Mar. 85
1	cesium tube	6D6C-CA	3M-25-1054	25	25.4	22, Mar. 85

H O R I Z O N  
COLUMBIA • ST MARY'S  
SHARING OUR TRADITIONS FOR THE FUTURE

Constance Walker  
Radiation  
Oncology  
Center

Carl E. Olson, M.D.  
Stanton A. Marks, M.D., F.A.C.R.  
Ranjini B. Gandharadi, M.D.  
Ashima Sani, M.D.

(414) 961-3850  
FAX (414) 961-4035

FACSIMILE TRANSMISSION COVER SHEET



DATE: Nov. 1, 1996

TO: Mr. John Madera  
Material Licensing Branch  
U. S. NRC , Region III

FROM: Yu Kong Chan 414 961 5492

Columbia/St. Mary's Hospital  
Radiation Oncology Department  
2025 East Newport Avenue  
Milwaukee, Wisconsin 53211

NUMBER OF PAGES, INCLUDING COVER PAGE: 3

OUR FAX MACHINE CALL NUMBER IS: (414) 961-4035

IF YOU HAVE ANY PROBLEMS RECEIVING A TRANSMISSION, PLEASE  
CALL (414) 961-3850.

MESSAGE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Columbia • St. Mary's, Inc.  
2025 East Newport Avenue, Milwaukee, WI 53211

Columbia Hospital, Milwaukee • Sacred Heart Rehabilitation Institute, Milwaukee • St. Mary's Hospital of Milwaukee • St. Mary's Hospital's Cancer Center

H O R I Z O N  
**COLUMBIA • ST MARY'S**  
SHARING OUR TRADITIONS FOR THE FUTURE

Constance Walker  
Radiation  
Oncology  
Center

Carl E. Olson, M.D.  
Stanton A. Marks, M.D., F.A.C.R.  
Ranjini B. Gandhavadi, M.D.  
Ashima Saini, M.D.

(414) 961-3850  
FAX (414) 961-4035

October 31, 1996

Material Licensing Branch

Additional Information to be attached to the application  
of amendment dated October 30, 1996

From : Yu Kong Chan, Radiation Safety Officer  
Columbia Hospital, Milwaukee, Wisconsin

Date : November 1, 1996

*Yu Kong Chan*  
NOV. 1, 1996

RE: Material License No. 48-02417-01

We are applying an one time exemption from the requirements of  
10 CFR 35.49(a).

We transferred 17 sealed Cesium-137 sources from St. Mary's Hospital  
of Milwaukee to Columbia Hospital.

These sealed sources were purchased by St. Mary's Hospital from the  
3M Company of Minnesota some years ago for medical use.

These sources were manufactured, labeled, packaged and distributed by  
the 3M Company. We have the calibration certificates.

About two years ago, St. Mary's Hospital and Columbia Hospital had a  
joint operation agreement under the same administration.

The brachytherapy program at Columbia Hospital needed more sealed  
Cesium-137 sources. Rather than purchase more cesium sources, we  
would like to transferred some Cesium-137 sources from St. Mary's  
Hospital for medical use.

These Cesium-137 sources will stay at Columbia Hospital and are  
for medical use, Brachtherapy.

We are apply for an one time exemption to 10 CFR 35.49(a).

We do not plan any more transfer of Cesium-137 sources.

Before this application is to be sent out, we have two patients  
scheduled for Brachtherapy on early November, 96. I faxed a request  
for temporary approval to use these sources this morning (11/1/96).

We will greatly appreciate it if you would approve our application.

NOV 04 1996

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REGION III

302011

Columbia Health System, Inc.



Columbia Hospital, Inc.  
2025 East Newport Avenue  
Milwaukee, Wisconsin 53211  
Phone (414) 961-3300  
Fax (414) 961-8712

October 30, 1996

Columbia  
Hospital, Inc.

Columbia Service  
Corporation  
of Wisconsin

Newport Ventures, Inc.

Columbia Gift Shop

Mequon Park Pharmacy

Jewport Pharmacy

North Shore  
Surgical Center  
(Joint Venture)

Columbia College  
of Nursing, Inc.

Columbia  
Foundation, Inc.

Horizon Home Care  
& Hospice, Inc.

Mequon Care  
Center, Inc.

Wisconsin  
Psychoanalytic  
Foundation, Inc.

Member of  
Horizon Healthcare, Inc.

VHA Midwest

U.S. Nuclear Regulatory Commission  
Region III  
Nuclear Material Licensing Branch  
801 Warrenville Road  
Lisle, IL 60532-4351

Dear Sir/Madame:

RE: License No. 48-02417-01

Columbia Hospital would like to have the above license amended to exempt us from the requirements of 10 CFR, Section 35.49 (a). We are requesting this exemption in order to allow us to use Cesium-137 sources for medical use. These sources were transferred from St. Mary's Hospital of Milwaukee, Wisconsin (License No. 48-1828-01) to Columbia Hospital in December, 1995 and again in August, 1996.

There were a total of seventeen (17) sources, which are listed on the attached Appendix A. These sources were manufactured, labeled, packaged and distributed by The 3M Company with calibration certificates.

Before these sources were transferred, several phone calls were placed to the NRC Region III office requesting advice for the question, "Do we need to do anything with our license in order to transfer the Cesium sources from St. Mary's Hospital to Columbia Hospital for medical use?" The answer for each of these phone calls was NO.

On December 1, 1996 seven (7) Cesium-137 sources were transferred, and on August 27, 1996 ten (10) Cesium-137 sources were transferred. Each transfer followed NRC and DOT regulations which were forwarded to us by NRC Region III in response to our phone calls. At the time, they did not interpret these transfers as distribution, nor did Columbia Hospital interpret the transfers as distribution.

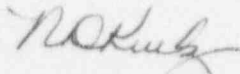
U.S. Nuclear Regulatory Commission  
October 30, 1996  
Page 2

We would also like to request that the spelling of the name of one of the authorized users in the above license be corrected. The correct spelling is **Ashima Saini, M.D.**

Please note that our Radiation Safety Officer, Yu Kong Chan, Ph.D. is authorized to sign correspondence with the NRC.

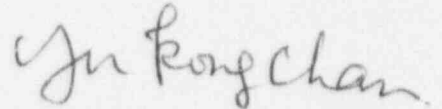
If you have any questions, please contact our Radiation Safety Officer, Yu Kong Chan, Ph.D. at 414-961-5492.

Sincerely,



Nancy D. Kuelz  
Vice President, Patient Services

NDK/ja



Yu Kong Chan  
RSO, Physicist

# Appendix A

Cesium-137 Sources List  
Columbia <> St. Mary's Hospital, Mil., Wis.

YU KONG CHAN, Ph.D.  
25-Sep-96

#	Physics form	Model (tubes)	Serial No.	Nominal strength (mg. Ra. eq.)	3M assay (mg. Ra. eq.)	Date purchased	phys. length (cm)	Active length (cm)	Current Strength (mg. Ra. eq.)
1	cesium tube	6D6C-CA	3M-15-3429	15	15.6	22, Mar. 85	2	1.4	12.11
1	cesium tube	6D6C-CA	3M-15-3436	15	15.6	22, Mar. 85	2	1.4	12.11
1	cesium tube	6D6C-CA	3M-10-5256	10	10.4	22, Mar. 85	2	1.4	8.08
1	cesium tube	6D6C-CA	3M-10-5263	10	10.5	22, Mar. 85	2	1.4	8.08
1	cesium tube	6D6C-CA	3M-10-2755	10	11.1	18, Jul. 77	2	1.4	6.99
1	cesium tube	6D6C-CA	3M-10-2756	10	11.3	18, Jul. 77	2	1.4	6.99
1	cesium tube	6D6C-CA	3M-10-2756	10	11.3	18, Jul. 77	2	1.4	6.99
1	cesium tube	6500	3M-5-1977	5	5.52	10, Jan. 92	2	1.4	4.96
1	cesium tube	6D6C-CA	3M-20-1798	20	20.9	18, Aug. 81	2	1.4	14.79
1	cesium tube	6D6C-CA	3M-20-1835	20	20.9	18, Aug. 81	2	1.4	14.79
1	cesium tube	6D6C-CA	3M-20-1886	20	20.9	18, Aug. 81	2	1.4	14.79
1	cesium tube	6D6C-CA	3M-20-1860	20	20.9	18, Aug. 81	2	1.4	14.79
1	cesium tube	6500	3M-5-2012	5	5.41	10, Jan. 92	2	1.4	4.90
1	cesium tube	6501	3M-10-8028	10	11.06	10, Jan. 92	2	1.4	9.0
1	cesium tube	6501	3M-10-8042	10	11.14	10, Jan. 92	2	1.4	9.0
1	cesium tube	6504	3M-25-1549	25	26.54	10, Jan. 92	2	1.4	23.89
1	cesium tube	6D6C-CA	3M-25-1049	25	25.3	22, Mar. 85	2	1.4	19.42
1	cesium tube	6D6C-CA	3M-25-1054	25	25.4	22, Mar. 85	2	1.4	19.42



NOV 12 1996

Nancy D. Kuetz  
Vice President, Patient Services  
Columbia Hospital  
Department of Nuclear Medicine  
2025 E. Newport Avenue  
Milwaukee, WI 53211

Dear Ms. Kuetz:

Enclosed is Amendment No. 47 to your NRC Material License No. 48-02417-01 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 note we have extended the expiration date of the license for five years in accordance with the regulations (10 CFR 30.36).

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.
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,

N. Kuetz

-3-

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  
W. P. Reichhold  
Nuclear Materials Licensing Branch

License No.: 48-02417-01  
Docket No.: 030-03429

Enclosure: Amendment No. 47

DOCUMENT NAME: M:\03003429.CL6

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 <i>MR</i>	C							
NAME	WREICHOLD:jaw								
DATE	11/5/96								

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