NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 44

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.

302410

Licensee	
1. Columbia St. Vincent Charity Hospital	In accordance with letters dated August 19, 1996 and February 20, 1997
2. 2351 East 22nd Street Cleveland, Ohio 44115	3. License Number 34-01856-01 is amended in its entirety to read as follows:
	4. Expiration Date October 31, 2000
	5. Docket or Reference No. 030-02689

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 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (Not to exceed 2 curies of iodine-131)
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 31.11	E. Prepackaged Kits	E. As needed
F. Uranium depleted in Uranium-235	F. Cadmium plated metal	F. As needed
G. Iridium-192	G. Sealed sources (ByK Mallinckrodt Model CI L BV)	G. 2 sources, 1 source not to exceed 444 gigabecquerels (Gbq) (12 curies (Ci)), and 1 source not to exceed 370 Gbq (10 Ci).

030072

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-01856-01

Docket or Reference Number
030-02689

Amendment No. 44

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. In vitro studies.

F. Shielding in a linear accelerator.

G. One source to be used in a Nucletron-Oldelft Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 370 Gbq (10 Ci) at the time of installation. One source in its shipping container for source replacement.

CONDITIONS

10. Location of Use: St. Vincent Charity Hospital, 2351 East 22nd Street, Cleveland, Ohio.

11. A. Radiation Safety Officer: Robert J. Porter, M.D.

B. Assistant Radiation Safety Officer, limited to HDR brachytherapy: Robert Carlson, B.A., R.T.(T).

C. Brachytherapy Physicists: Ronald Scala, M.S., Raymond Kaczur, M.S., and Neal Smarra, M.S.

D. The licensee's Radiation Safety Committee may approve medical physicists for their HDR brachytherapy program. Authorizations are limited to naming those physicists who meet the requirements of 10 CFR 35.961 (substituting similar experience in HDR brachytherapy specific tasks for those listed in 10 CFR 35.961(c)), or who are named on a current NRC or Agreement State license, or a permit issued by a licensee of broad scope as an HDR medical physicist. In addition, the physicist must meet the recentness of training requirement in 10 CFR 35.972; and, the physicist must possess recent, device specific training and experience for each make and model of HDR device used by the licensee as specified in Policy and Guidance Directive FC 86-4, Rev. 1. A record of such authorization must be maintained for subsequent inspection.

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SUPPLEMENTARY SHEET

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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 Users	Material and Use
A. Robert J. Porter, M.D.	10 CFR 35.100, 35.200, 35.300, 34.400, 31.11 and iridium-192 in remote afterloading brachytherapy unit.
B. John L. Porter, M.D.	10 CFR 35.100, 35.200, 35.300 (except iodine-131 for treatment of thyroid carcinoma), 35.400 and iridium-192 in remote afterloading brachytherapy unit and 31.11.
C. Dong Kim, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.
D. Christine M. Zirafi, M.D.	10 CFR 35.100 and 35.200, limited to clinical cardiovascular studies.
E. Robert M. Konstan, M.D.	10 CFR 35.100, 35.200 and 35.300.
F. Dawn Donich, M.D.	10 CFR 35.100, 35.200 and 35.300.
G. Christina M. Wirtz, M.D.	10 CFR 35.100, 35.200 and I-131 for treatment of hyperthyroidism and cardiac dysfunction.

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.

14. The licensee shall establish and implement Items 6.g through 6.k of Appendix C to Regulatory Guide 10.8 for measuring geometry independence of their dose calibrator(s).

15. The licensee's survey instruments shall be calibrated by a commercial service licensed by the NRC or an Agreement State to perform such services.

16. 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.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 2351 East 22nd Street, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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18. A. The source(s) specified in Item(s) 7.G. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date of the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

19. A. Access to the room housing the MicroSelectron-HDR irradiation device shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

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20. Prior to the initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron-HDR, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 Centimeters from the surface of the source head shall not exceed 3 milliroentgens per hour.

(2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.1201, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation."

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301.

B. Records of the survey results shall be maintained for inspection by the Commission.

21. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of sources contained in the MicroSelectron-HDR irradiation device.

B. Any maintenance or repair operations on the irradiator involving work on the source head, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

22. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

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23. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

24. 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. Applications dated April 10, 1990, November 26, 1991 and April 25, 1995;

B. Application dated March 27, 1985 (limited to Item 20, Form A on Page 3 of 11 of "Therapeutic Use of Sealed Sources");

C. Letter received July 10, 1995; and

D. Letters dated June 13, 1995, November 10, 1995 and December 2, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 25 1997

By Colleen C. Casey
Nuclear Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02230
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20001031
Fee Comments: CODE 21
Decom Fin Assur Reqd: N

S6

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: COLUMBIA ST. VINCENT CHARITY HOSP.
   Received Date: 970311
   Docket No: 3002689
   Control No.: 302410
   License No.: 34-01856-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: *
   Check No.: *

* ADDL INFO
301439 - S6

3. COMMENTS

Signed D. Hen
Date 3-14-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered [✓])

1. Fee Category and Amount: 7C 2B NOT REQUIRED

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 3/17/97

MAR 19 1997

RECEIVED BY LFDCB
Date Mar. 17, 1997
Log Mar 6 III
By SC
Date Completed 3/17/97

COLUMBIA℠
St. Vincent Charity Hospital
A Ministry of the Sisters of Charity of St. Augustine
2351 East 22nd Street
Cleveland, Ohio 44115
FAX (216) 363-3333/Phone (216) 861-6200
COLUMBIA's home page is http://www.columbia.net

Date: 2/20/97

Colleen Casey
U.S. Nuclear Regulatory Commission
Region III
301 Warrenville Road
Lisle, Illinois 60532-4351

RE: Amendment #43
License #34-01856-01
Additional supporting information per your request.

Dear Ms. Casey:

A request was contained in your cover letter issued with Amendment #43 asking us to commit to a specific possession limit of I-131. Our total possession limit for I-131 will not exceed 2 Ci including radioactive waste, which is well under the 10 Ci limit discussed in your correspondence.

All of the documents referenced in Amendment #43 are now available in our files. Thank you for taking the time to have these sent to us per our previous request.

If you need any further information on the above matter, please feel free to call.

Sincerely,

Samuel H. Turner, President and CEO
Administrator

MAR 25 1997

Samuel H. Turner
President and CEO
Columbia St. Vincent
Charity Hospital
2351 East 22nd Street
Cleveland, OH 44115

Dear Mr. Turner:

Enclosed is Amendment No. 44 to your NRC Material License No. 34-01856-01 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 that we deleted Shereif Khalil, M.D. from Condition No. 12 of your license, in accordance with your letter dated August 19, 1996.

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).

302410

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,

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
Colleen C. Casey
Nuclear Materials Licensing Branch

License No.: 34-01856-01
Docket No.: 030-02689

Enclosure: Amendment No. 44

DOCUMENT NAME: M:\03002689.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 CCkc	C							
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DATE	03/24/97								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 14, 1997

Robert J. Porter, M.D.
Radiation Safety Officer
Columbia St. Vincent Charity Hospital
Radiology and Department of Nuclear Medicine
2351 East 22nd Street
Cleveland, OH 44115

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 02/20/97)

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 _X_ 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. 302410
License No. 34-01856-01