

MATERIALS LICENSE

Amendment No. 17

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, 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 application dated June 19, 1984	
1. Lutheran Medical Center Department of Radiology		3. License number 34-01869-02 is amended in its entirety to read as follows:	
2. 2609 Franklin Blvd. Cleveland, OH 44113		4. Expiration date June 30, 1990	
		5. Docket or Reference No. 030-00404	
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. Teletherapy sealed sources (AECL Model C-146 or C-151)	A. 12,000 curies (2 sources of not more than 6000 curies each)	
9. Authorized Use			
A. One source to be used in an AECL Theratron 780 teletherapy unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary to the replacement of the source in the teletherapy unit only.			

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2609 Franklin Blvd., Cleveland, Ohio.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. Licensed material shall be used by, or under the supervision of, Theodore J. Castele, M.D., Celia Yap, M.D. or Reynaldo F. Guillermo, M.D.
13. The teletherapy facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.

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14. A. Teletherapy sources shall be tested for leakage at intervals not to exceed six months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Commission. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a source received from another person shall not be used until tested for leakage.
- B. The tests shall be sufficiently sensitive to detect 0.05 microcurie of contamination on the test sample.
- C. The test sample shall be taken from selected accessible surfaces of the teletherapy head. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cones or beam collimating device. The test sample shall be taken with the source in the "off" position.
- D. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall promptly take action to prevent spread of contamination and shall file a report within five (5) days of the test with the Nuclear Materials Safety Section, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the test results and the corrective action taken.
15. Prior to initiation of a treatment program, each teletherapy unit shall be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to ensure compliance with Section 20.105(b), Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation," as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with Condition No. 18.
16. A set of written emergency instructions shall be posted at the teletherapy machine control. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room.
17. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.
- B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation "off" immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned "on" until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.
- C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained for inspection by the Commission.

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D. In the event of malfunction of any door interlock, the teletherapy machine control 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.

18. Prior to initiation of a treatment program, and subsequent to each installation of a teletherapy source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

- (i) The teletherapy source housing, with the teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.
- (ii) All areas adjacent to the treatment room with the teletherapy source in the "on" position. The survey, except Item (c), shall be performed with a phantom in the primary beam of radiation and 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 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation" (10 CFR 20).
 - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.103(b), 10 CFR 20.
 - (c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of:

- (i) Electrical interlocks on entrance doors to the teletherapy treatment room.
- (ii) The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.
- (iii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism).
- (iv) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Material Licensing Section, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, not later than thirty (30) days following each installation of a teletherapy source. A copy of such report shall be sent to the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

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19. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the teletherapy unit that could result in increased radiation levels in areas outside the teletherapy treatment room shall be evaluated by a radiation survey made in accordance with Condition No. 18., and reported to the Commission within thirty (30) days following completion of the change(s).
- B. Relocation of the teletherapy unit to a new facility is not permitted without prior approval of the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition No. 18., and reported to the Commission within thirty (30) days after completion of the move.
20. The licensee shall comply with the requirements in Sections 35.21 through 35.27, inclusive, of Title 10, Chapter 1, Code of Federal Regulations, Part 35, "Human Use of Byproduct Material."
21. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.
- B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.
22. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:
- A. Installation, relocation, or removal of teletherapy units containing sources.
- B. Source exchange.
- C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, 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.
23. 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 the uranium contained as shielding material in the teletherapy units authorized by this license.

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24. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

- (a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and
- (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
- (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in Subitem (a) above and of the license(s) specified in Subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under Subitem (a) above.

25. Pursuant to Section 20.105(a) of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation," and in reliance of statement, procedures and representations made by the licensee in his letter dated September 26, 1980, the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level

8 milliroentgens per hour

Unrestricted Area

Outside the Northwest Wall of the Theratron 780 facility

26. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in applications dated January 22, 1979 and June 19, 1984; and letters dated May 23, 1979, September 26, 1980 and May 10, 1984 (with enclosed survey report). The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Original Signed

By Patricia J. Whiston

Materials Licensing Section, Region III

Date June 19, 1985

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