

MATERIALS LICENSE

Amendment No. 51
CORRECTED COPY

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 1, 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 June 6, 1996
1. Kettering Adventist Health Care		3. License Number 34-13857-01 is amended in its entirety to read as follows:
2. 3535 Southern Boulevard Kettering, OH 45429		4. Expiration Date January 31, 2001
		5. Docket or Reference No. 030-02864
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
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. Strontium-90	F. (Nuclear Enterprises Model 2403/3)	F. One source not to exceed 10 millicuries
G. Cesium-137	G. (J.L. Sheperd Model 28-6)	G. One source not to exceed 1 curie
H. Iridium-192	H. Sealed Sources (Byk Mallinckrodt Model CI LBV)	H. Two Sources not to exceed 12 curies each

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|---|-----------------------------------|--|
| 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 |
| I. Strontium-89 | I. As identified in 10 CFR 35.300 | I. 12 millicuries |
| J. Phosphorus-32 | J. As identified in 10 CFR 35.300 | J. 45 millicuries |

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. To be used for calibration of instruments.
- G. To be used for instrument calibration in a Model 28-6 J.L. Sheperd calibrator.
- H. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- I. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.
- J. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

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CONDITIONS

10. Location of Use:

- A. Kettering Medical Center
3535 Southern Boulevard, Kettering, Ohio
- B. Licensed material listed in Subitems A., B., E., I., and J. may be used and stored at Sycamore Hospital, 2150 Leiter Road, Miamisburg, Ohio.
- C. Licensed material listed in Subitems A., and B. (except xenon-133 as defined in 10 CFR 35.200) may be used and stored at Oakwood Kettering Nuclear Medicine, 2600 Far Hills Avenue, Suite 19, Oakwood, Ohio.
- D. Licensed material listed in Subitem A., and B. (except xenon-133 as defined in 10 CFR 35.200) may be used and stored at Springboro Nuclear Medicine Imaging Area, 536 W. Central Avenue, Springboro, Ohio.

- 11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Kettering Medical Center Radioisotope Committee, Robert Henderschedt, Chairman.
- B. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2(3) who meets the training and experience requirements as set forth in Subpart J of Code of The Federal Regulations 10 CFR Part 35.

12. The Radiation Safety Officer for this license is Steven Cartwright, Ph.D.

13. 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.

14. The licensee shall maintain records of information important to safe and effective decommissioning at 3535 Southern Boulevard, Kettering, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

15. A. Access to the rooms housing the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit 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.

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- 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" position 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.
16. Prior to initiation of a treatment program, and subsequent to each source exchange for the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit, 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 main source safe shall not exceed 1 milliroentgen 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 10 CFR 20.101.
 - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b).
 - B. Records of the survey results shall be maintained for inspection by the Commission for the duration of the license.
17. 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 the sealed sources contained in the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit.
 - B. Any maintenance or repair operations on the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit listed in Item 9., Subitem 9.L. involving work on the source safe, 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.
18. Notwithstanding the requirements of Section 35.415(a)(4) of 10 CFR Part 35, the licensee is authorized to perform radiation surveys in accordance with procedures outlined in letters dated August 20, 1992 and December 29, 1992.

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19. The licensee may possess 24 Curies of Iridium-192 (not to exceed 12 Curies per source) for use in the Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by an authorized individual.
20. 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 August 8, 1990; and
- B. Letters (with attachments) dated November 29, 1990, August 20, 1992, December 29, 1992, October 15, 1993, September 19, 1994 (excluding Item 4.), April 21, 1995, July 25, 1995, and November 16, 1995 (with attachments), December 18, 1995 (excluding items 2, 6, 10, 13, and 14), March 21, 1996 (except items 6, 12, and 13), and May 31, 1996, June 14, 1996, August 2, 1996, June 6, 1996 and August 28, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

February 20, 1997

By

Richard Watson

Nuclear Materials Licensing Branch, Region III

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FEB 20 1997

Steven Cartwright, Ph.D.
Radiation Safety Officer
Kettering Adventist Health Care
3535 Southern Boulevard
Kettering, OH 45429

Dear Dr. Cartwright:

It has come to our attention that Amendment Number 51 to License
Number 34-13857-01 issued on September 11, 1996 contained an error.

Enclosed is a corrected copy reflecting Condition 10. noted to be in error. We apologize
for any inconvenience this may have caused you.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 34-13857-01
Docket No.: 030-02864

Enclosure: Corrected Copy of
Amendment No. 51

DOCUMENT NAME: M:\03002864.CC7

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OFFICE	DNMS/RIII									
NAME	GWATSON:jaw									
DATE	02/19/97									

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Writer's Direct Dial Number

February 12, 1997

Gidget Watson
Materials Licensing Section
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

License Number 34-13857-01

Control No. 301601

Dear Ms. Watson:

In a recent review of our license we discovered an incorrect address for one of our locations of use. The area, listed as Condition 10.D. of our license, is located at 536 W. Central Avenue, Springboro, OH. The license incorrectly gives the address as 540. I apologize for any confusion this might cause. Please call me at 937-296-7818 if you have any questions.

Sincerely,

Steven Cartwright, Ph.D.
Radiation Safety Officer

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REGION III