RADIATION ONCOLOGY ASSOCIATES P.C.

J.N. Crawford, M.D. F.A.C.R.

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R. Mantravadi, M.D. F.A.C.R., F.A.C.R.O.

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Angola, IN 46703
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U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road – Suite 210
Lisle, IL 60532-4352

RE: License 13-32551-01

Please amend our license to change our Radiation Safety Officer to Gareth Williams, Ph.D. Dr. Williams has had previous experience as a Radiation Safety Officer at Elkhart General Hospital, Elkhart, Indiana, from July, 1996 through June, 2005. Also, Dr. Williams should be added to our license as an Authorized Medical Physicist. He was the Authorized Medical Physicist on the Elkhart General Hospital license from July, 1997 through June, 2005. The license number for Elkhart General Hospital is 13-18879-01. Please see the attached copy of the Elkhart General Hospital license page #2 and page #4.

Please delete Earl Dietrich M.S. from our license as he is no longer employed at Radiation oncology Associates.

Thank you for your attention to these matters.

Sincerely yours,

R. Prasad Mantravadi, M.D.
F.A.C.R., F.A.C.R.O.

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Amendment No. 31

MATERIALS LICENSE

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 letters dated July 9, 2003, August 25, 2003, and September 8, 2003,**
1. Elkhart General Hospital	3. License number 13-18879-01 is amended in its entirety as follows:
2. P.O. Box 1329 Elkhart, IN 46515-1111	4. Expiration date March 31, 2011
	5. Docket No. 030-17305 Reference No.

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 **permitted by** 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material **permitted by** 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material **permitted by** 10 CFR 35.300	C. Any	C. As needed (not to exceed 9 curies of iodine-131)
D. Any byproduct material **permitted by** 10 CFR 35.400	D. Any brachytherapy sources **permitted by** 10 CFR 35.400	D. As needed
E. Any byproduct material **permitted by** 10 CFR 35.500	E. Sealed sources **permitted by** 10 CFR 35.500	E. As needed
F. Uranium, depleted in uranium-235	F. Solid Metal	F. Not to exceed 12 kilograms total possession limit.
G. Iridium-192	G. Sealed Sources (Models RTS 721 or 724)	G. 12 curies per source; 24 curies total.
H. Iridium-192	H. Sealed Sources (**Varian**GammaMed Model 232)	H. 12 curies per source; 24 curies total.

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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-90 **permitted by 10 CFR 35.1000**	I. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)	I. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries.

9. Authorized Use:

A. Medical use **permitted by** 10 CFR 35.100.

B. Medical use **permitted by** 10 CFR 35.200.

C. Medical use **permitted by** 10 CFR 35.300.

D. Medical use **permitted by** 10 CFR 35.400.

E. Medical use **permitted by** 10 CFR 35.[illegible] which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

F. Shielding material for GammaMed 12i High Dose Rate Remote Afterloading brachytherapy device.

G. One source to be used in a GammaMed 12i High Dose Rate Remote Afterloading Brachytherapy device for bronchial, interstitial and intracavitary therapy treatment in humans. One source in a shipping container for source replacement.

H. One source to be used in a **Varian** GammaMed Plus High Dose Rate Remote Afterloading Brachytherapy device for bronchial, interstitial and intracavitary therapy treatment in humans. **The source activity may not exceed 10 curies at the time of installation.** One source in a shipping container for source replacement.

I. **As permitted by 10 CFR 35.1000,** the sources may be used in Novoste Model A1000 series devices for intravascular brachytherapy, physics calibrations and quality assurance testing.

CONDITIONS

10. Location of Use: 600 East Blvd., Elkhart, Indiana.

11. Radiation Safety Officer: Gareth Williams, Ph.D.

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12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for medical uses:

Authorized Users	Material and Use
(1) F. K. Dean, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(2) James C. Field, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(3) R. P. Tokars, M.D.	10 CFR 35.400.
(4) Tim H. Emory, M.D.	10 CFR 35.100, 35.200 and 35.500.
(5) Daniel A. Bolt, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(6) J. A. VanDyke, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 as sodium iodide for treatment of thyroid carcinoma) and 35.500.
(7) John C. Collingwood, M.D.	10 CFR 35.100, 35.200 and 35.500.
(8) J. L. Wind, M.D.	10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500.
(9) T. E. Seiffert, M.D.	10 CFR 35.100, 35.200 and 35.500.
(10) Mark J. Ormson, M.D.	10 CFR 35.100, 35.200 and 35.500.
(11) Francoise Marie Dion, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(12) Gerard Duprat, M.D.	10 CFR 35.100, 35.200, iodine-131 for hyperthyroid treatments and 35.500.
(13) Russell Johnson, M.D.	10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.
(14) Karl W. Schultz, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(15) David A. Hornback, M.D.	10 CFR 35.400, 35.500, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.

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(16) Nina F. Johnson, M.D.	10 CFR 35.300, 35.400, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.
(17) Michael R. Holt, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(18) Pedro A. Micro, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(19) Alphonse H. Harding, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(20) Thomas Fischbach, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(21) Ian Boiskin, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(22) Russell B. Midkiff, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
(23) Marc Thomas Fields, M.D.	10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.
(24) Allison Marie Lemont, M.D.	10 CFR 35.100 and 35.200.
(25) David Charles D'Andrea, M.D.	10 CFR 35.100, 35.200 and 35.300.
(26) Samir B. Patel, M.D.	10 CFR 35.100, 35.200, iodine-131 for hyperthyroid treatments and thyroid carcinoma therapy and 35.500.
(27) Ramesh Gopal, M.D., Ph.D.	10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.
(28) Thomas Louis Borek, M.D.	10 CFR 35.300, 35.400, 35.500, iridium-192 in remote afterloading brachytherapy device, and strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices.

C. Authorized Medical Physicists: Gareth Williams, Ph.D.
Jennifer Hann Fisher, M.S.
Liang Wang, M.S.

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13. Licensed material listed in Subitem I. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition 12. and in the physical presence of an authorized user named in Condition 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user (named in Condition 12.) shall consult with a medical physicist (who meets the requirements in 10 CFR 35.961) and an interventional cardiologist prior to each treatment.

14. The licensee shall have survey instruments calibrated by an individual or organization licensed by the NRC or an Agreement State to perform survey instrument calibrations as a service.

15. In additional to the possession limits in Item 9, 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.

16. In lieu of **10 CFR 35.404(b)**, 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(c).**

17. In lieu of the source inventory required in [redacted] 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(c).**

18. Prior to initiation of a treatment program, and subsequent to each source exchange using the remote afterloading brachytherapy devices, a radiation survey shall be made of:

A. 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.

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

1. That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.10 CFR 20.1201.

2. That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301

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19. The following shall be performed only by manufacturer's representatives or 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 afterloading brachytherapy device(s).

B. Any maintenance or repair operations on the remote afterloading brachytherapy unit(s) listed in Item 9., Subitem G. involving work on the source safe, the source drive 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.

20. A. Access to the rooms housing the afterloading brachytherapy 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 radiation room shall be tested for proper operation at least once each day of use.

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.

21. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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D. The leak 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, a report shall be filed with the U. S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

E. Tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples but not perform the analysis: analysis of leak samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

F. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.

22. The licensee shall perform it's daily quality control tests prior to initiation of patient treatment whenever an HDR device is transported between authorized locations of use.

23. In lieu of **10 CFR 35.404(b)** immediately after each use of the source from the patient into its shielded position in the Novoste A1000 series intravascular brachytherapy device, a radiation survey shall be made of the patient and the Novoste A1000 series intravascular brachytherapy device with a portable radiation detection survey instrument to confirm 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(c)**.

24. 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 Novoste A1000 series intravascular brachytherapy treatment.

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).

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25. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 September 25, 2000 (excluding EOMP); and

B. Letters dated March 15, 2001 and November 19, 2001.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 10 2003

By Colleen C. Casey

Colleen C. Casey
Materials Licensing Branch
Region III

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