



**Allegiance**  
HEALTH

**RSO / EXECUTIVE MANAGEMENT  
LETTER OF UNDERSTANDING**

June 7, 2010

Samir Parikh, M.D.  
Allegiance Health  
205 North East Avenue  
Jackson, MI 49201

Re: Radiation Safety Officer / Executive Management  
Letter of Understanding

Dear Dr. Parikh:

You have been appointed Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.

Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:

- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
  1. Identify radiation safety problems;
  2. Initiate, recommend, or provide corrective actions;
  3. Stop unsafe operations; and,
  4. Verify implementation of corrective actions.

Our signatures noted below will attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

Samir Parikh, M.D.  
Radiation Safety Officer

Executive Management  
Robyn Pulliam  
Director Imaging Services  
(517) 788-1498



**Allegiance**  
HEALTH

June 7, 2010

UNITED STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Re: Additional information to Control Number 318980  
License No. 21-00258-06, Allegiance Health**

Please disregard our request to make Dr. Asad our permanent Radiation Safety Officer. We have appointed Samir Parikh, M.D. as Radiation Safety Officer for this facility. Dr. Parikh was previously the Radiation Safety Officer at Ingham Regional Medical Center, NRC license number 21-04073-01. A copy of that license with his name listed as Radiation Safety Officer is enclosed.

A copy of the RSO / management letter of understanding is also enclosed.

Thank you for your cooperation in this matter. If you have any questions, please contact our consulting physicist, Dawn Edwards, at 734-662-3197 or [dedwards@mpcphysics.com](mailto:dedwards@mpcphysics.com).

Sincerely,

Administrator

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Amendment No. 61

**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 90, 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.

PC 02 230

311944

Licensee

1. Ingham Regional Medical Center

2. 401 Greenlawn Avenue  
Lansing, MI 48910-2819

In accordance with letters dated  
December 18, 2002, January 29, 2003,  
April 30, 2003, and June 2, 2003,

3. License number 21-04073-01 is amended  
in its entirety as follows:

4. Expiration date March 31, 2004

5. Booklet No. 030-02037  
Reference only.

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
- B. Any byproduct material permitted by 10 CFR 35.200
- C. Any byproduct material permitted by 10 CFR 35.300
- D. Any byproduct material permitted by 10 CFR 35.400
- E. Iridium-192
- F. Uranium, depleted in uranium-235
- G. Iridium-192

- A. As needed
- B. As needed
- C. As needed (not to exceed 1 curie of iodine-131)
- D. 1 curie
- E. 12 curies per source; 24 curies total.
- F. Not to exceed 12 kilograms total possession limit.
- G. No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10, or 14 seeds per ribbon. 1.1 curies per set, 3 sets total



UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
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Docket or Reference Number  
030-02037

Amendment No. 61

6. Byproduct, source, and/or special nuclear material

H. Phosphorus-32

7. Chemical and/or physical form

H. Sealed source wires  
(Guidant Corporation Model  
GDT P-32 Series)

8. Maximum amount that licensee may possess at any one time under this license

H. Three source assemblies not to exceed 600 millicuries each

9. Authorized Use:

A. Medical use permitted by 10 CFR 35.100.

B. Medical use permitted by 10 CFR 35.200 (excluding xenon-133).

C. Medical use permitted by 10 CFR 35.300.

D. Medical use permitted by 10 CFR 35.400.

E. One source to be used in a Guidant Model GDT Remote Afterloading Brachytherapy Device for Interstitial, intracavitary and intraluminal therapy treatment in humans. One source in a shipping container for source replacement.

F. Shielding material for Guidant Model GDT Remote Afterloading Brachytherapy Device.

G. Notwithstanding the requirements of 10 CFR 35.400, two ribbon sets to be used in the Cordis Checkmate Catheter System for intravascular brachytherapy, physics calibrations and quality assurance testing; and one ribbon set in its shipping container for ribbon set replacement.

H. Notwithstanding the requirements of 10 CFR 35.400, two source assemblies to be used in Guidant Corporation VI Model GAL LEO Intravascular brachytherapy HDR devices for intravascular brachytherapy, physics calibrations and quality assurance testing; one source assembly in its shipping container for replacement and disposal.

CONDITIONS

10. Licensed materials listed in Items 9.A through 9.H. may be used at the Greenlawn Campus, 401 W. Greenlawn Avenue, Lansing Michigan, 48910.

11. A. Radiation Safety Officer: Samir Parikh, M.D.

B. Intravascular Brachytherapy (IVBT) and HDR Brachytherapy Physicists: Maria Graves Diltman, M.S., Randall TenHaken, Ph.D., James Balter, Ph.D., Peter L. Roberson, Ph.D. and Bryan Tollenaar, M.S.



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MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 21-04073-01

Docket or Reference Number 030-02037

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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, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. 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  |
|---------------------------------|---|
| (1) Jerrold M. Weiss, M.D.      | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (2) Bing Tai, M.D.              | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (3) Hasrnukh I. Patel, M.D.     | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (4) Thomas J. Archambault, M.D. | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (5) Gary Leago, M.D.            | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (6) George E. Kleiber, D.O.     | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (7) Donald C. Simion, M.D.      | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (8) Mark W. Cimminer, M.D.      | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (9) Samir Parikh, M.D.          | 35.100 and 35.200 (excluding xenon-133).  |
| (10) Gregory Mitchinson, M.D.   | 10 CFR 35.100 and 35.200 (excluding xenon-133).   |
| (11) Robert E. Dorfman, M.D.    | 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.   |
| (12) David A. DeBiose, D.C.     | 10 CFR 35.300, 35.400, Iridium-192 in remote afterloading brachytherapy device, Iridium-192 in the Cordis Checkmate system and phosphorus-32 in the Guidant Galileo intravascular brachytherapy device. |
| (13) Janaki Moni, M.D.          | 10 CFR 35.300, 35.400, Iridium-192 in remote afterloading brachytherapy device, Iridium-192 in the Cordis Checkmate system and phosphorus-32 in the Guidant Galileo intravascular brachytherapy device. |



13. Licensed material listed in Subitem Nos. G. and H. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No. 12., and in the physical presence of an authorized user named in Condition No. 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition No. 12. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.

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14. 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).
15. 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 ( $\mu$ Sieverts/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).
16. Prior to initiation of a treatment program and subsequent to each source exchange using the remote afterloading brachytherapy device, a 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 20.1201.
    2. That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.
17. 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.
  - B. Any maintenance or repair operations on the remote afterloading brachytherapy unit listed in Item 9., Subitem E. 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.
18. A. Access to the rooms housing the GammaMed 12i HDR remote afterloading brachytherapy device shall be controlled by a door at each entrance.



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- 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 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.
19. 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 of registration 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 of a sealed source or irradiator 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.
  - 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.

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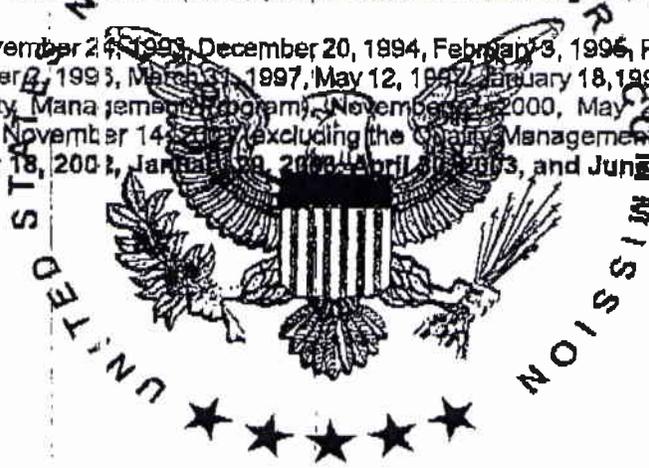
**MATERIALS LICENSE  
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- 20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 21. Except as specifically provided otherwise 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 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 May 21, 1993 (with attachments, excluding item 10.14), September 20, 1994, May 24, 2001 and November 14, 2001 (with attachments excluding QMP); and
  - B. Letters dated November 24, 1993, December 20, 1994, February 9, 1996, February 29, 1996, November 4, 1996, December 2, 1996, March 31, 1997, May 12, 1997, January 18, 1999, memo dated May 18, 1999 (excluding Quality Management Program), November 2, 2000, May 24, 2001 (with attachments, excluding QMP), November 14, 2001 (excluding the Quality Management Program) and February 21, 2002, December 18, 2002, January 29, 2003, April 3, 2003, and June 2, 2003.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 02 2003

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

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Amendment No. 62

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.

<p>Licensee</p> <p>1. Ingham Regional Medical Center</p> <p>2. 401 Greenlawn Avenue Lansing, MI 48910-2819</p>	<p>In accordance with application dated February 23, 2004,</p> <p>3. License number 21-04073-01 is renewed in its entirety as follows:</p> <p>4. Expiration date <b>May 31, 2014</b></p> <p>Docket No. 030-02037 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 26.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200 (excluding xenon-133)</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Iodine-125 as permitted by 10 CFR 35.400</p> <p>E. Iridium-192</p> <p>F. Depleted uranium</p> <p>G. Iridium-192 permitted by 10 CFR 35.1000</p> <p>H. Phosphorus-32 permitted by 10 CFR 35.1000</p>	<p>1. Chemical and/or physical form</p> <p>Any</p> <p>Sealed Sources (MDS Nordlon, Inc. Model 711 (OncoSeed™))</p> <p>Sealed Sources (Models 721 or 724 or MDS Nordlon, Inc. Model GammaMed 212 source assembly)</p> <p>Solid Metal</p> <p>Sealed source seeds encased in nylon ribbon (Best Industries Model No. 81-01)</p> <p>Sealed source wires (Guldant Corporation Model GDT P-32 Series)</p>	<p>Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed (not to exceed 1 curie of iodine-131)</p> <p>D. 1 curie</p> <p>E. 12 curies per source; 24 curies total</p> <p>F. Not to exceed 12 kilograms total possession limit</p> <p>G. No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10, or 14 seeds per ribbon, 1.1 curies per set, 3 sets total</p> <p>H. Three source assemblies not to exceed 600 millicuries each</p>
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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

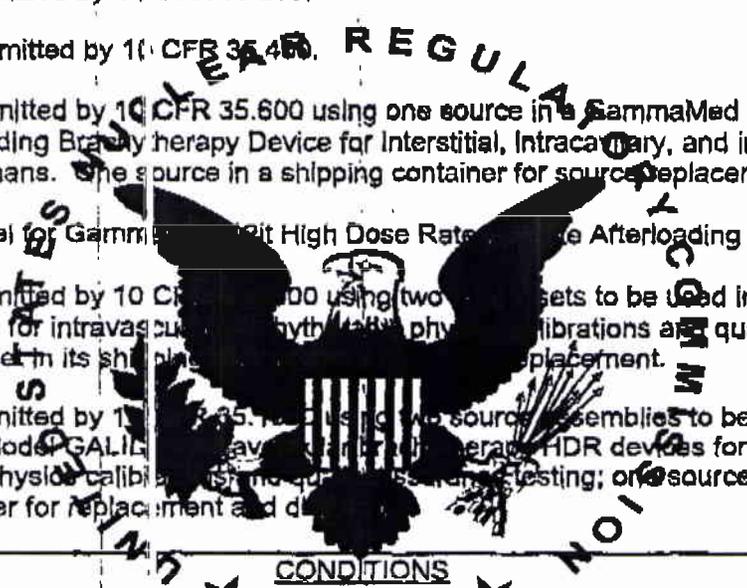
License Number  
21-04073-01

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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 35.600 using one source in a GammaMed 12it High Dose Rate Remote Afterloading Brachytherapy Device for Interstitial, Intracavitary, and intraluminal therapy treatment in humans. One source in a shipping container for source replacement.
- F. Shielding material for GammaMed 12it High Dose Rate Remote Afterloading Brachytherapy Device.
- G. Medical use permitted by 10 CFR 35.700 using two source assemblies to be used in the Cordis Checkmate Catheter System for intravascular brachytherapy, physical calibrations and quality assurance testing; and one ribbon set in its shipping container for replacement.
- H. Medical use permitted by 10 CFR 35.700 using two source assemblies to be used in Guidant Corporation VI Model GALILEO Intravascular Brachytherapy HDR devices for intravascular brachytherapy, physical calibrations and quality assurance testing; one source assembly in its shipping container for replacement and delivery.



10. Licensed material may be used at 401 W. Greenbush Avenue, Lansing Michigan.

11. A. Radiation Safety Officer: **Jaraki Moni, M.D.**

B. Intravascular Brachytherapy (IVBT) and HDR Brachytherapy Physicists: **Maria Graves Ditman, M.S., Randall TenHaken, Ph.D., James Balter, Ph.D., Peter L. Roberson, Ph.D. and Bryan Tollenaar, M.S.**

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. 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:

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Authorized Users

Material and Use

Jerrold M. Weiss, M.D.	10 CFR 35.100 and 35.200
Bing Tai, M.D.	10 CFR 35.100 and 35.200
Hasmukh I. Patel, M.D.	10 CFR 35.100 and 35.200
Thomas J. Archambeau, M.D.	10 CFR 35.100 and 35.200
Gary Leago, M.D.	10 CFR 35.100 and 35.200
George E. Kleiber, D.O.	10 CFR 35.100 and 35.200
Donald C. Simon, M.D.	10 CFR 35.100 and 35.200
Mark W. Cimmerer, M.D.	10 CFR 35.100 and 35.200
Samir Parikh, M.D.	10 CFR 35.100 and 35.200
Gregory Mitchinson, M.D.	10 CFR 35.100 and 35.200
Robert E. Dorfman, M.D.	10 CFR 35.100, 35.200 and 35.300.
David A. DeBiose, D.O.	10 CFR 35.300, 35.400, iridium-192 in remote afterloading brachytherapy device, iridium-192 in the Curie Checkmate system and phosphorus-32 in the Galileo intravascular brachytherapy device.
Janaki Mont, M.D.	10 CFR 35.300, 35.400, iridium-192 in remote afterloading brachytherapy device, iridium-192 in the Curie Checkmate system and phosphorus-32 in the Galileo intravascular brachytherapy device.
Paullne Woon-Lin Chee, M.D.	10 CFR 35.100 and 35.200
Rajesh Dilip Dhamecha, M.D.	10 CFR 35.100 and 35.200

13. Licensed material listed in Subitem Nos. G. and H. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No. 12., and in the physical presence of an authorized user named in Condition No. 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition No. 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. 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.

JUN 7 2010

9:56AM

IRMC RADIOLOGY

NO. 904

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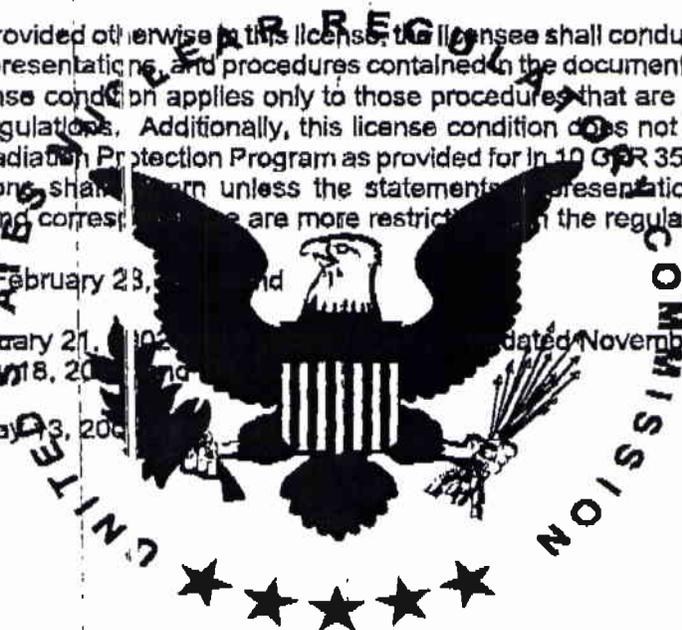
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15. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such service.

16. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. 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 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 February 23, 2004 and
- B. Letters dated February 21, 2004 (dated November 14, 2001), April 30, 2004, May 18, 2004 and
- C. Facsimile dated May 13, 2004



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 18 2004

By James R. Mullauer  
James R. Mullauer, M.H.S.  
Materials Licensing Branch  
Region III

2010-06-07

17:12

(517) 841-7845

Allegiance Health

P 1

FAX # 630-515-1078

Attn: Jose Macatagar

From: Kevin Kensch

Allegiance Health  
517-788-4792

Subject: RSO