



21st Century Oncology
RADIATION THERAPY SERVICES, INC.

Branch 1

January 5, 2012

Sandra Gabriel, Ph.D.
Senior Health Physicist
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED
REGION 1
2012 JAN 10 PM 3:06

03033538

RE: Amendment Request to Radioactive Materials License # 47-25296-01
210 New Hope Road, Princeton, West Virginia

Dear Dr. Gabriel:

We wish to request an amendment to the referenced license in order to include Joseph Baisden, M.D. as Authorized User. Dr. Baisden is currently listed as AU in State of Kentucky License 202-352-27 (copy enclosed).

We would like to notify the NRC that Dr. Baisden will cover a HDR cases in the referenced facility during January and February, 2012.

Please remove Becki Sue Hill, MD as Authorized User.

Should you have any questions or comments, feel free to contact me at 239-768-7377.

Sincerely,

Daniel H. Galmarini, DABR
Chief Technology Officer

576696

NMSS/RGN1 MATERIALS-002

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
RADIOACTIVE MATERIAL LICENSE

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1. LICENSEE AND 2. ADDRESS

21ST CENTURY/LOUISVILLE
RADIATION ONCOLOGY
4500 CHURCHMAN AVE., SUITE 100
LOUISVILLE, KY 40215-1199

ATTENTION: REBECCA RICHARDSON, PHYSICIST
TELEPHONE: 502-363-3100

PURSUANT TO KRS 211.842 ET SEQ., THE KENTUCKY CABINET FOR HUMAN
RESOURCES REGULATIONS, 902 KAR 100, AND IN RELIANCE ON STATEMENTS
AND REPRESENTATIONS HERETOFORE MADE BY THE LICENSEE, A LICENSE IS
HEREBY ISSUED TO RECEIVE, ACQUIRE, OWN, POSSESS AND TRANSFER
RADIOACTIVE MATERIAL LISTED BELOW; AND TO USE SUCH RADIOACTIVE
MATERIAL FOR THE PURPOSE(S) AND AT THE PLACE(S) DESIGNATED BELOW.
THIS LICENSE IS SUBJECT TO ALL APPLICABLE RULES, REGULATIONS, AND
ORDERS OF THE CABINET FOR HEALTH SERVICES, NOW OR HEREINAFTER IN
EFFECT AND TO ANY CONDITIONS SPECIFIED BELOW.

3. LICENSE NUMBER: 202-352-27
AMENDMENT NO. 12
4. EXPIRATION DATE: JANUARY 31, 2013
5. REVIEWER: 44

6. LICENSED MATERIAL	7. FORM	8. POSSESSION LIMIT
A. IRIIDIUM 192	A. SEALED SOURCE (NUCLETRON, MALLINCKRODT B.V. OR QSA GLOBAL MODEL 105.002)	A. NO SINGLE SOURCE TO EXCEED 12 CURIES INSTALLED OR 13 CURIES AWAITING DECAY, TOTAL POSSESSION NOT TO EXCEED 21 CURIES

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B. YTTRIUM 90 B. LIQUID B. 200 MILLICURIES

9. AUTHORIZED USE

- A. TO BE USED IN NUCLETRON ENGINEERING B.V. MICROSELECTRON-HDR MODEL 106.999 REMOTE AFTERLOADING BRACHYTHERAPY UNIT FOR TREATMENT OF CANCER. TWO (2) SOURCES MAY BE IN POSSESSION, ONE (1) IN THE DEVICE AND ONE (1) STORED IN ITS SHIPPING CONTAINER.
- B. RADIOIMMUNOTHERAPY OF NON-HODGKIN'S LYMPHOMA WITH IBRITUMOMAB TIUXETAN.

CONDITIONS:

10. THE LICENSEE SHALL COMPLY WITH THE PROVISIONS OF THE KENTUCKY CABINET FOR HEALTH SERVICES ADMINISTRATIVE RADIATION REGULATIONS, 902 KAR 100.
11. THIS LICENSE AND THE RIGHT TO POSSESS OR UTILIZE RADIOACTIVE MATERIAL GRANTED BY THIS LICENSE ISSUED UNDER 902 KAR CHAPTER 100 CHAPTER 100 SHALL NOT BE TRANSFERRED, ASSIGNED, OR OTHERWISE DISPOSED OF, THROUGH TRANSFER OF CONTROL OF A LICENSE TO A PERSON UNLESS THE CABINET, AFTER SECURING FULL INFORMATION, FINDS THAT THE TRANSFER IS IN ACCORDANCE WITH THE REQUIREMENTS OF 902 KAR CHAPTER 100 AND GIVES ITS CONSENT IN WRITING IN ACCORDANCE WITH 902 KAR 100:040, SECTION 11.
12. RADIOACTIVE MATERIAL SHALL BE USED ONLY AT THE LICENSEE'S ADDRESS STATED IN ITEM 2.
13. COPIES OF RECORDS REQUIRED PURSUANT TO 902 KAR 100 OR CONDITIONS OF THE LICENSE SHALL BE MAINTAINED FOR INSPECTION BY THE CABINET AT THE LICENSEE'S ADDRESS LISTED IN ITEM 2.
14. RADIOACTIVE MATERIAL SHALL BE USED BY, OR UNDER THE SUPERVISION OF:

JOSEPH BAISDEN, M.D.
BETH CRAYCRAFT, M.S.
BILLY CRAYCRAFT, M.S.
DANIEL GALMARINI, M.S.

MARK JONES, M.D.
ERIC LEE, M.S.
WOMAH NEERANJUN, M.S.
REBECCA RICHARDSON, M.S.

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15. RADIOACTIVE MATERIAL LISTED IN ITEM 6 ABOVE IS AUTHORIZED FOR USE BY, OR UNDER THE SUPERVISION OF, THE FOLLOWING INDIVIDUAL(S) FOR THE MATERIALS AND USES INDICATED:

A. MARK JONES, M.D.	A. IR-192, Y-90
B. JOSEPH BAISDEN, M.D.	B. IR-192
BETH CRAYCRAFT, M.S.	
BILLY CRAYCRAFT, M.S.	
DANIEL GALMARINI, M.S.	
ERIC LEE, M.S.	
WOMAH NEERANJUN, M.S.	
REBECCA RICHARDSON, M.S.	

16. THE RADIATION SAFETY OFFICER FOR THE ACTIVITIES AUTHORIZED BY THIS LICENSE IS MARK JONES, M.D. .

17. TESTS FOR LEAKAGE AND/OR CONTAMINATION SHALL BE PERFORMED BY PERSONS SPECIFICALLY AUTHORIZED BY THE CABINET, U.S. NUCLEAR REGULATORY COMMISSION, OR AN AGREEMENT STATE.

18. SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL SHALL NOT BE OPENED.

19. FOR RADIOPHARMACEUTICALS WHERE THE BETA EMISSION IS OF PRIMARY INTEREST, LOCALLY PREPARED OR SUBDIVISION DOSES SHALL BE ASSAYED IN A PROPERLY CALIBRATED DOSE CALIBRATION AFTER PREPARATION AND BEFORE DISPENSING FOR USE. PROPER CALIBRATION OF AN IONIZATION-TYPE DOSE CALIBRATOR SHALL INCLUDE PARTICIPATION IN A STANDARDIZATION PROTOCOL WITH THE NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST), OR THE PHARMACEUTICAL MANUFACTURER, THAT INCLUDES USE OF NIST STANDARD SOLUTIONS AND CONTAINERS FOR THE RADIOPHARMACEUTICAL OF INTEREST. THE LICENSEE SHALL RETAIN DOCUMENTATION OF PARTICIPATION, INCLUDING THE NIST CALIBRATION CERTIFICATE OR MATERIAL DATA SHEET FOR THE CALIBRATION SOURCE, FOR THE DURATION OF THE LICENSE.

THE DOSE CALIBRATOR SHALL BE RE-CALIBRATED ANNUALLY USING Y-90 NIST STANDARD SOLUTIONS AND CONTAINERS FOR THE RADIOPHARMACEUTICAL OF INTEREST.

20. ACCESS TO THE ROOMS HOUSING EACH HIGH DOSE RATE AFTERLOADING BRACHYTHERAPY UNIT SHALL BE CONTROLLED BY A DOOR AT EACH ENTRANCE.

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25. IN LIEU OF THE SOURCE INVENTORY REQUIRED IN 902 KAR 100:072, SECTION 38, 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 MILLIREM/HOUR, TIME, DATE, AND NAME OF INDIVIDUAL MAKING THE SURVEY.
- D. RETAIN THE RECORD OF THE SURVEY IN LIEU OF THE RECORD REQUIRED IN 902 KAR 100:072, SECTION 38.

26. 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. THE CABINET FOR HEALTH SERVICES REGULATIONS, 902 KAR 100, SHALL GOVERN UNLESS STATEMENTS, REPRESENTATIONS, AND PROCEDURES IN THE LICENSEE'S APPLICATION AND CORRESPONDENCE ARE MORE RESTRICTIVE THAN THE REGULATION.

A. APPLICATION DATED NOVEMBER 22, 2005, SIGNED BY PAT JARNAGIN, REGIONAL ADMINISTRATOR.

B. LETTERS DATED:

- 1. AUGUST 25, 2006, SIGNED BY DANIEL GALMARINI, DIRECTOR OF PHYSICS.
- 2. FEBRUARY 7, 2007, SIGNED BY MARK JONES, M.D., RSO.
- 3. JUNE 7, 2007, SIGNED BY MARK JONES, M.D., RSO.
- 4. MARCH 7, 2008, SIGNED BY MARK JONES, M.D., RSO.
- 5. AUGUST 1, 2008, SIGNED BY MARK JONES, M.D., RSO.
- 6. DECEMBER 10, 2009, SIGNED BY MARK JONES, M.D., RSO.
- 7. MARCH 21, 2011, SIGNED BY DANIEL E. DOSORETZ, M.D., CHIEF EXECUTIVE OFFICER.
- 8. APRIL 11, 2011, SIGNED BY LEANDRO BARRECA, PHYSICS AND ENGINEERING.

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9. SEPTEMBER 9, 2001 (EMAIL), SIGNED BY LEANDRO BARRECA,
PHYSICS AND ENGINEERING.



MANAGER
RADIATION HEALTH BRANCH

JANIE MILLER

SECRETARY
CABINET FOR HEALTH AND FAMILY
SERVICES

DATE ISSUED DECEMBER 21, 2011

THIS IS TO acknowledge the receipt of your letter application dated

01/05/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576696.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.