CabellHuntington Hospital

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March 22, 2006

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U.S. Nuclear Regulatory Commission
Radioisotopes Licensing Division
Region I
475 Allendale Road
King Prussia, Pennsylvania 19406-1415

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REGION 1
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SUBJECT: Amendment to NRC license 47-00404-02
Cabell Huntington Hospital, Inc.
Huntington, West Virginia

Dear Reviewer:

We request the amendment of license 47-00404-02 with the following change:

In the 2005 4th Quarter Radiation Safety Committee meeting Richard McWhorter, M.D. requested he be replaced as the Radiation Safety Officer (RSO) with the understanding that he would continue as RSO until the NRC has amended this license.

In the 2006 1st Quarter meeting the Radiation Safety Committee proposed and voted 11-0 that Michael Biddy, M.S. replace Richard McWhorter, M.D. as the RSO.

Michael Biddy, M.S. has been the Radiation Safety Officer for three different licenses (agreement licenses # 011-00091-4; 0011-00091-5; 011-00091-6). A copy of the most recent agreement state license where Michael Biddy served as RSO has been included.

Regards,

Richard McWhorter, M.D.
Radiation Safety Officer

C. Keith Biddle
Vice President-Administration

138363

NMSS/RGN1 MATERIALS-002

RADIOACTIVE MATERIALS BRANCH
RADIATION PROTECTION SECTION
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES

RADIOACTIVE MATERIALS LICENSE

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer, and import radioactive materials listed below; and use such radioactive material for the purpose(s) and at the place(s) designated below. This License is subject to all applicable rules and regulations of the North Carolina Department of Environment and Natural Resources now and hereafter in effect and to any conditions specified below.

1.	Licensee Name:	Mission-St. Joseph's Health System d/b/a Memorial Mission Hospital	3. License No:	011-0091-4	License Type 0140
2a.	Mailing Address:	509 Biltmore Avenue Asheville, NC 28801	4. Expiration Date:	July 31, 2005	
b.	Physical Address:	509 Biltmore Avenue Asheville, NC 28801	[ ] New License [ ] Renewal	[X] Routine [ ] Administrative	[ ] Corrected Copy [ ] Termination
c.	Radiation Safety Officer:	Michael Biddy, MS	5.a. Amendment No.:	39	
			b. Issuance Date:	March 1, 2005	

6.	Radioactive Material (element and mass no.)	7.	Chemical and/or Physical Form	8.	Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee May Possess at Any One Time.
A.	Iridium 192 ✓	A.	Sealed Sources	A.	No single source to exceed 12 curies
B.	Iodine 125	B.	Seeds	B.	500 millicuries
C.	Palladium 103	C.	Seeds	C.	500 millicuries
D.	Iridium 192	D.	Seeds	D.	500 millicuries
E.	Cesium 137	E.	Sealed Sources	E.	900 millicuries
F.	Strontium 90	F.	Sealed Sources	F.	11 millicuries
G.	~~Phosphorus-32~~	G.	~~Sealed Sources~~	G.	~~No single source to exceed 600 millicuries~~
H.	Iodine 125	H.	Iotrex solution	H.	5000 millicuries
I.	Strontium 90	I.	Sealed Sources ✓	I.	750 millicuries

9. Authorized Use:

A. To be used for bronchial, intraluminal, intercavitary, and interstitial treatment of cancer in humans. The source will be used in a Nucletron MicroSelectron-HDR classic Remote Afterloading Brachytherapy Unit. Treatments shall be in accordance with a written directive signed by an authorized user.

B. - D. To be used in interstitial implantation for treatment of cancer in humans. Treatments shall be in accordance with a written directive signed by an authorized user.

E. To be used for intercavitary treatment of cancer in humans. Treatments shall be in accordance with a written directive signed by an authorized user.

F. To be used for instrument calibration and testing.

G. To be used in a Guidant Galileo Radiotherapy System to reduce the incidence of restenosis.

H. To be used in GliaSite Radiation Treatment System in accordance with a written directive signed by an authorized user.

I. To be used in a Novoste Beta-Cath 3.5F, Model 1767A Radiotherapy System in accordance with FDA approved uses.

added added added

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CONDITIONS (continued):

15. B. Notwithstanding the periodic leak test required by the preceding paragraph, any licensed sealed source containing radioactive material is exempted from periodic leak tests, provided the quantity of radioactive material contained in the source does not exceed the quantity specified for the radioactive material in 15A NCAC 11 .0304.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample, or in the case of radium, the escape of radon at a rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency.

D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with agency regulations. A report shall be filed within five (5) days of the test with the Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, NC 27699-1645, describing the equipment involved, the test results, and the corrective action taken.

E. Tests for leakage and/or contamination shall be performed by the licensee or by persons specifically authorized by the agency to perform such services.

16. Notwithstanding Condition No. 15. above, brachytherapy implant seeds that are being held in storage before being returned to the distributor are required to be tested for leakage and/or contamination at intervals not to exceed three (3) years. If the interval since the last leak test and the date the seeds are to be returned to the distributor exceeds six (6) months, the seeds must be tested for leakage and/or contamination prior to shipment back to the distributor and the leak test certificate must accompany the shipment.

17. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.

18. The licensee shall maintain accountability for all brachytherapy sources in storage or in use. Records of source accountability shall be maintained in accordance with the applicable provisions of 15A NCAC 11 .0702(e) & (f).

19. A. Patients administered either diagnostic or therapeutic quantities of unsealed radioactive material, or therapeutic quantities of permanently implanted sealed radioactive materials may be released in accordance with the provisions of 15A NCAC 11 .0358.

B. The licensee shall retain all records associated with the release of patients containing radioactive materials, when applicable, for a minimum of three (3) years following the administration.

20. The licensee shall perform and document radiation surveys of patients receiving implants in accordance with the applicable provisions of 15A NCAC 11 .0702(c).

21. Patients containing implants shall remain hospitalized until the implants are removed, except that patients containing Iridium 192, Palladium 103, or Iodine 125 seeds may be released from the hospital provided:

A. the attending physician has determined the seeds are secured and are not likely to be lost by the patient; and

B. The patient has been released in accordance with 15A NCAC 11 .0358.

C. The licensee shall retain all records associated with the release of patients containing radioactive materials, when applicable, for a minimum of three (3) years following the administration.

22. Sealed sources containing radioactive material shall not be opened.

23. The licensee shall not open needles or standard medical applicator cells containing Cobalt 60 as wire, unless specifically authorized by a condition in this license.

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RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

24. The licensee is hereby authorized to hold for decay-in-storage sealed sources with a physical half-life of 65 days or less if the licensee:

A. stores the sources in such a manner that radiation doses to individual members of the public do not exceed the limits specified in 15A NCAC 11 .1611(a);
B. will not use the sources for any other patient treatment;
C. conducts a physical inventory of the sources in accordance with Condition No. 16. above;
D. holds the radioactive material for decay for a minimum of 10 half-lives;
E. performs surveys with a survey instrument capable of detecting a dose rate of 0.1 millirem (1 microsievert) per hour and determines that the radioactive material is indistinguishable from background; and
F. removes or obliterates all radiation labels prior to disposal.

25. In lieu of 15A NCAC 11 .0702(c)(4), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a calibrated 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 15A NCAC 11 .0702(c)(4).

26. In lieu of the source inventory described in 15A NCAC 11 .0702(a)(1), the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote 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 survey instrument used, dose rate, time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 15A NCAC 11 .0702(a)(1).

27. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:

A. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:

1. That radiation doses to occupationally exposed individuals do not exceed the limits specified in 15A NCAC 11 .1604, .1609, and .1610.

2. That radiation doses to individual members of the public do not exceed the limits specified in 15A NCAC 11 .1611(a).

28. The following shall be performed only by persons specifically authorized by an Agreement State or the NRC to perform such service:

A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.

B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment 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.

29. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

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CONDITIONS (continued):

29. B. Each entrance to the treatment 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 each entrance door to the treatment 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 unit 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.

E. If the high dose rate remote afterloading brachytherapy unit is used in an accelerator treatment room, it shall not be possible to energize the accelerator and deliver beam into the treatment room while the remote afterloading device is in use.

30. 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 15A NCAC 11.0353 for establishing decommissioning financial assurance.

31. The licensee shall annually review its Radiation Protection Program for content and implementation [Ref. 15A NCAC 11 .1603(e)]. Documentation of the Radiation Protection program reviews shall be retained for inspection by the agency [Ref. 15A NCAC 11 .1636].

32. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of her pregnancy and the estimated date of conception.

33. The licensee shall ensure that no individual "member of the public" [Reference: 15A NCAC 11 .0104(64)] receives a radiation dose in excess of the limits specified in 15A NCAC 11 .1611(a) while conducting licensed operations.

34. Neither this license nor any subsequent amendments shall be deemed to constitute compliance with the requirements for health planning review contained in the Certificate of Need Statute, G.S. 131-175 *et seq.*, and regulations promulgated pursuant to that statute. Inquiries concerning the Certificate of Need Statute should be addressed to the Certificate of Need Section of the Division of Facility Services at (919) 733-6360.

35. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.

36. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6., 7., and 8. of this license in accordance with statements, representations and procedures and attachments listed below. The North Carolina Regulations for Protection Against Radiation shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application with attachments dated June 23, 2000, signed by Ramona C. Whichello, VP, Nurse Executive and letter with attachments dated August 15, 2000, signed by Melodee L. Wolfe, R.S.O.

B. Administrative review of license on October 20, 2000.

C. Facsimile dated October 23, 2000, signed by Eric F. Keuhn, MD

D. Amendment application with attachments dated August 28, 2001, signed by Ramona Craft Whichello, VP, Nurse Executive.

E. Amendment application with attachments dated January 21, 2002, signed by Ramona Craft Whichello, VP, Nurse Executive.

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CONDITIONS (continued):

36. F. Amendment application with attachments dated September 26, 2002, signed by Ramona Craft Whichello, VP, Nurse Executive.

G. Application for Amendment with attachments dated December 27, 2002, signed by Ramona C. Whichello, VP, Nurse Executive.

H. Application for Amendment with attachments dated October 21, 2003 signed by Ramona C. Whichello, VP, Nurse Executive.

I. Application for amendment with attachments dated October 23, 2003, signed by Ramona C. Whichello, VP Nurse Executive.

J. Application for amendment with attachments dated March 9, 2004, signed by Ramona Wichello, VP Nurse Executive.

K. Application for amendment with attachments dated August 19, 2004 signed by Rick Righi, Director Radiation Therapy and facsimile dated August 31, 2004 signed by Eric F. Kuehn, MD, RSO and Ramona Wichello, VP Nurse Executive.

L. **Application for Amendment dated February 1, 2005, signed by Richard Righi, Director Radiation Therapy, and facsimile with attachments dated February 28, 2005, signed by John G. Coletti, PhD.**

For: Beverly O. Hall
Chief, Radiation Protection Section