

Yun Wang, Ph.D., DABR  
Radiation Safety Officer  
Central Indiana Cancer Centers  
1346 East County Line Rd.  
Indianapolis, IN 46227

U.S. NRC Region III  
2443 Warrenville Road  
Suite 210  
Lisle, Illinois 60532-4352

Dear Colleen or some one in charge of this case:

I would like to add Bryce C. Lord, D.O. on our NRC license (our NRC license # is 13-32241-01, docket # 030-35383). He is hired as a radiation oncologist in our organization. He is currently on the radioactive material license in the State of Nevada. A copy of the license: Nevada Radioactive Material License No. 16-12-0244-02 is enclosed here.

If you have any question, Please call me at (317) 250-7435

Yours sincerely,

 1/2/08

Yun Wang, Ph.D., DABR  
Radiation Safety Office

RECEIVED JAN 07 2008

STATE OF NEVADA

JIM GIBBONS  
Governor

MICHAEL J. WILLDEN  
Director



ALEX HAARTZ, MPH  
Administrator

BRADFORD LEE, M.D.  
State Health Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
HEALTH DIVISION  
BUREAU OF HEALTH PROTECTION SERVICES

- Bureau Administration  
4150 Technology Way Ste. 300  
Carson City, NV 89706  
(775) 687-7550  
Fax (775) 687-7553
- Radiological Health  
4150 Technology Way Ste. 300  
Carson City, NV 89706  
(775) 687-7550  
Fax (775) 687-7552
- Environmental Health  
4150 Technology Way Ste. 300  
Carson City, NV 89706  
(775) 687-7550  
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- Health Protection Services  
620 Belrose Street, Ste 101  
Las Vegas, NV 89107  
Environmental Health  
(702) 486-5068  
Radiological Health  
(702) 486-5280  
Fax (702) 486-5024
- Health Protection Services  
850 Elm Street  
Elko, NV 89801-3349  
(775) 753-1138/1140
- Health Protection Services  
475 W. Haskell Street, Rm. 38  
Winnemucca, NV 89445  
(775) 623-6588
- Health Protection Services  
155 N. Taylor Street, Ste. 157  
Fallon, NV 89406-3324  
(775) 423-2281  
Fax (775) 423-0259
- Health Protection Services  
P.O. Box 151210  
Ely, NV 89315  
(775) 289-3325
- Health Protection Services  
P.O. Box 667  
Tonopah, NV 89409-0667  
(775) 482-3997

January 8, 2007

David Chamberlain, M.S.  
Radiation Safety Officer  
St. Mary's Regional Medical Center  
235 West Sixth Street  
Reno, NV 89520-0108

Re: Nevada Radioactive Material License No. 16-12-0244-02

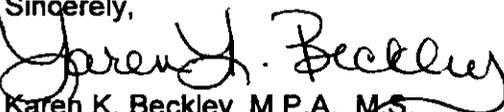
Dear Mr. Chamberlain:

Enclosed is Amendment No. 8 to Nevada Radioactive Material License No. 16-12-0244-02. This amendment names Dr. Bryce C. Lord as an authorized physician user. For ease of reference, the license is amended in its entirety. New and revised text is underlined and in bold font.

As an Assistant Radiation Safety Officer, Mr. Burris-Mog does not meet the requirement for personnel to be present during HDR treatments.

Since he has not been named as a Radiation Safety Officer or Authorized Medical Physicist on a radioactive material license, his training requirements for these positions are specified in 10 CFR 35.50 and 35.51.

Recently adopted 10 CFR Part 35 regulations may be viewed at the following web site:  
[http://health2k.state.nv.us/BHPS/nac\\_nrs/10CFR35.pdf](http://health2k.state.nv.us/BHPS/nac_nrs/10CFR35.pdf)

Sincerely,  
  
Karen K. Beckley, M.P.A., M.S.  
Supervisor, Radiological Health Section  
Bureau of Health Protection Services

David Chamberlain  
JAN 17 2007  
Reno, NV

KB\bvam\licensees\st marys hospital 02\st marys hospital 02 #8 amd



Amendment No. 8  
amends license No.  
16-14-0244-02 in its  
entirety

NEVADA STATE HEALTH DIVISION

**RADIOACTIVE MATERIAL LICENSE**

Pursuant to Nevada Revised Statute 459.030 and Nevada Administrative Code 459.196 and in reliance on statements and representations heretofore made by the licensee designated below a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material designated below and to use such radioactive material for the purpose(s) and at the location(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect and to any conditions specified below.

1. Name: St. Mary's Regional Medical Center	3. License Number: 16-12-0244-02
2. Address: 235 West Sixth Street Reno, Nevada 89520-0108	4. Expiration Date: March 31, 2010
	5.

6. Radioactive material:

7. Chemical and/or physical form:

8. Maximum quantity licensee may possess at any one time:

A. Iridium 192  
permitted by 10 CFR  
35.600

A. Sealed source (Varian  
Medical Systems Model  
VS 2000)

A. 21.9 curies  
(including the  
source in the  
remote afterloader  
and a replacement  
source in its  
shipping container).  
No single source to  
exceed 13 curies.

B. Any radioactive material  
identified in 10 CFR  
35.400

B. Any manual brachytherapy  
source permitted by 10 CFR  
35.400

B. 8 curies

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Continued . . .

- |  |   |   |
|--|---|---|
| 6.C. Strontium 90/<br>Yttrium 90 permitted<br>by 10 CFR 35.1000  | 7.C. Sealed Source (BEBIG<br>Model SrO.SO3)         | 8.C. Not to exceed 5<br>millicuries per<br>source; 120<br>millicuries per<br>device (for Model<br>A1730). Twelve<br>sources per train,<br>not to exceed 5<br>millicuries per<br>source, 60<br>millicuries per<br>device (for Model<br>A1732) and/or 16<br>sources per train,<br>not to exceed 5<br>millicuries per<br>source, 80<br>millicuries per<br>device (for Model<br>A1733). |
| D. Phosphorous 32<br>permitted by<br>10 CFR 35.1000              | D. Sealed source (Guidant<br>Model GDT P-32 Series) | D. 600 millicuries per<br>source assembly.<br>Two assemblies'<br>total  |
| E. Strontium 90/<br>Yttrium 90<br>permitted by<br>10 CFR 35.1000 | E. Sealed source (AEAT SICW.2)                      | E. 5 millicuries per<br>source and 80<br>millicuries per<br>device  |
-

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9. Authorized use:

- A. One source for medical use described in 10 CFR 35.600, in a Varian model VariSource HDR Remote Afterloader. One source for storage in a shipping container. No source shall be removed from its shipping container or installed into the afterloading device until the activity has decayed to 11 curies or less.
- B. Any manual brachytherapy use permitted by 10 CFR 35.400.
- C. For medical use in each Novoste (Best Vascular) A1000 series models for intravascular brachytherapy permitted by 10 CFR 35.1000.
- D. For use in Guidant Corporation VI Model GALILEO™ Intravascular Brachytherapy High Dose Rate Afterloader devices for intravascular brachytherapy permitted by 10 CFR 35.1000.
- E. For medical use in each Novoste (Best Vascular) A1000 series models for intravascular brachytherapy permitted by 10 CFR 35.1000.

**CONDITIONS**

- 10.A. Radioactive material described in Items 6, 7 and 8, Subitem A, shall be stored and used only at the licensee's facility located at 645 North Arlington Avenue, Suite 120, Reno, Nevada.
  - B. Radioactive material described in Items 6, 7 and 8, Subitem B, shall be received and stored at the licensee's facility located at 645 North Arlington Avenue, Suite 120, Reno, Nevada and may be use at the licensees facility located at 235 West Sixth Street, Reno, Nevada.
  - C. Radioactive material described in Items 6, 7 and 8, Subitems C through E, shall be stored and used only at the licensee's facility located at 235 West Sixth Street, Reno, Nevada.
- 11.A Radioactive material identified in Items 6, 7 and 8, Subitem A, shall be used only by, or under the supervision of:

Gary Campbell, M.D.  
Kathleen Legarza, M.D.  
 Jennifer Sutton, M.D.

Beth Hummer, M.D.  
Bryce C. Lord, D.O.  
 Jonathan Tay, M.D.

Roger D. Miercort, M.D.  
 Daphne Palmer, M.D.

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11.B. Radioactive material identified in 6, 7 and 8, Subitem B, shall be used by or under the supervision of the following individuals:

Gary Campbell, M.D.	Lawrence R. Dardick, M.D.	Beth Hummer, M.D.
Roger D. Miercort, M.D.	<b><u>Kathleen Legarza, M.D.</u></b>	<b><u>Bryce C. Lord, D.O.</u></b>
Daphne Palmer, M.D.	Jennifer Sutton, M.D.	Jonathan Tay, M.D.

C. Radioactive material identified in Items 6, 7 and 8, Subitems C through E, shall be used only by, or under the supervision of:

<b><u>Gary Campbell, M.D.</u></b>	<b><u>Beth Hummer, M.D.</u></b>	<b><u>Roger D. Miercort, M.D.</u></b>
<b><u>Daphne Palmer, M.D.</u></b>	<b><u>Jennifer Sutton, M.D.</u></b>	<b><u>Jonathan Tay, M.D.</u></b>

12. The Medical Physicist for activities authorized by this license shall be David K. Chamberlain, M.S. and Joe S. Herrick, M.S.

13.A. The Radiation Safety Officer for activities authorized by this license shall be David K. Chamberlain, M.S.

B. The Assistant Radiation Safety Officer for activities authorized by this license shall be **Trevor** Burris-Mog. Mr. Burris-Mog shall work under the direct supervision of David K. Chamberlain or Joe Herrick.

14. Radioactive material shall be disposed only by transfer to a person specifically licensed to possess the radioactive material.

15. Only persons specifically licensed by the Division, the Nuclear Regulatory Commission or an Agreement State to perform such services shall perform the following:

- A. installation, relocation, or removal of HDR units containing sources;
- B. source exchanges;

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- 15.C. any maintenance or repair operations on a Varisource HDR unit involving work on the source drawer, the shutter, 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.
- 16.A. Sealed sources shall be tested for leakage at intervals not to exceed 6 months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Division. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a source received from another person shall not be used until tested for leakage.
- B. The tests shall be sufficiently sensitive to detect 0.005 microcuries of contamination on the test sample.
- C. The test sample shall be taken from selected accessible surfaces of the HDR unit. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate. The test sample shall be taken with the source in the "safe" position.
- D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the source from use and take action to prevent spread of contamination. A report shall be filed within 5 days of the date the leak test result is known with the Radiological Health Section, Nevada State Health Division, 4150 Technology Way, Suite 300, Carson City, Nevada, 89706. The report shall specify the source involved, the test results and corrective action taken
- 17.A. Each entrance to the High Dose Rate Afterloader room shall be equipped with an electrical interlock system that will cause the source to be immediately withdrawn to the "safe" position upon opening of any entrance door. The interlock system shall be connected in such a manner that the high dose rate unit cannot be turned "on" until all treatment room entrance doors are closed and the high dose rate unit "on-off" control is reset at the control panel.

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## RADIOACTIVE MATERIAL LICENSE

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- 17.B. Electrical interlocks on entrance doors to the high dose rate remote afterloader unit room shall be tested for proper operation at least once every 6 months. Records of test results shall be maintained for inspection by the Division Records may be disposed of following Division inspection
- C. In the event of malfunction of any door interlock, the high dose rate unit control shall be locked in the "off" condition 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.
18. Before initiation of a high dose rate remote afterloader treatment program, and subsequent to each installation of a sealed source, radiation surveys and tests shall be performed in accordance with the following:
- A. A radiation survey shall be made of:
- (i) The high dose rate afterloader source housing, with the source in the "off" or "safe" position. The maximum dose rate at 20 centimeters from the surface of the source head shall not exceed 3-milliroentgens per hour.
  - (ii) All areas adjacent to the treatment room with the high dose rate remote afterloader in the "on" or "exposed" position. The survey shall be performed with a phantom in the primary beam of radiation and shall clearly establish:
    - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 459.322 of the Nevada Administrative Code (NAC).
    - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in NAC 459.326(2).

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- 19.A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the high dose rate remote afterloader unit that could result in increased radiation levels in areas outside the HDR treatment room shall be evaluated by a radiation survey made in accordance with Condition 18, and reported to the Division within 30 days following the completion of the change(s).
- B. Relocation of the high dose rate remote afterloader unit to a new facility is not permitted without prior approval of the plans and details by the Division. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 18, and reported to the Division within 30 days after completion of the move.
- 20.A. The licensee shall follow the manufacturer's recommendations for routine and extended maintenance on the high dose rate remote after-loader unit.
- B. The procedures contained in the manufacturer's instruction manual for the high dose rate remote afterloader device shall be followed and a copy of this manual shall be, available to each person using, or having responsibility for the use of, the device.
21. The following conditions and limitations apply to use of all makes of Intravascular Brachytherapy systems authorized by this license:
- A. The authorized user, interventional cardiologist/physician, and medical physicist will receive the vendor training for use of the device.
- B. Procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and medical physicist prior to initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the medical physicist.
- C. Prior to treatment, the written directive must specify treatment site, the radionuclide, and dose.

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- 21.D. Prior to the first patient treatment, independent measurement of source output must be performed by the Medical Physicist. Instrumentation used to perform these calibrations must have been appropriately calibrated by a laboratory accredited by NIST or AAPM with the previous two years and after any servicing that may have affected system calibration. (See 10 CFR 35.630).
- E. Written emergency procedures must be developed, implemented, and maintained for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.
- F. The licensee shall ensure that a survey of patient and IVB treatment catheter is performed immediately following source retraction or removal to confirm complete retraction of the source(s).
- G. The licensee's Quality Management Program should be revised as appropriate.
- H. The delivery device and source assembly must be kept in locked storage when not being used. The licensee must maintain key control for the console key to allow access only by authorized personnel.
- I. Shielding calculations are not necessary for areas outside the treatment room and device storage areas for sources which are beta emitters.
- J. The 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 services.
- K. Daily checks must be performed (prior to patient treatment) in accordance with the manufacturer's instructions to include: console operational checks, indicator lamps, source status indicators; visual inspection of the integrity of the source centering catheter and connectors; and source positioning accuracy.

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22. The following conditions and limitations apply to use of the Guidant GALILEO™ Intravascular Brachytherapy systems:
- A. The working life of a cartridge/source assembly shall be limited to sixty (60) days or 650 cycles, whichever comes first. The cartridge or GDT P-32 Series source may only be used in GALILEO™ or another IVP device for which an evaluation has been performed by the U.S. Nuclear Regulatory Commission (NRC), or an Agreement State, or broad licensee with proper authority and in accordance with NRC Information Notice 99-24 or equivalent guidance from Agreement State authorities.
  - B. The following tests must be performed at each source exchange (prior to patient treatment): contact radiographs to check integrity of welds; source uniformity via autoradiograph; source positioning accuracy within +/- 1 mm; battery backup for emergency source retraction upon power failure; source transit time to meet manufacturer's specifications; and timer accuracy and linearity to meet manufacturer's specifications.
  - C. The FDA approval includes a single step or pullback procedure, where the proximal position of the first treatment site is coincident with the distal position of the second treatment site in the center of the stent, is authorized. Alternative stepping or pullback procedures are subject to applicable FDA regulations and conditions of the device FDA approval.
  - D. Training in the proper use of GALILEO™ shall be provided by the manufacturer and include review of the Operator's Manual, the safe use of the device for routine and emergency conditions as well as cartridge exchange by the Licensed Medical Physicist.
  - E. The sources will be leak tested prior to shipment to document that they are not leaking. Because of the short half life of the radionuclide and limited useful life of its dedicated cartridge, no further leak tests will be made prior to the user transferring the sealed source to the manufacturer.

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- 22.F. The licensee shall not cut, splice or alter the source wire in any manner except in emergency situations as stipulated in the Operator's Manual. Emergency procedures shall be prominently posted and/or immediately available to personnel whenever GALILEO™ is used either for patient treatment or during QA procedures performed by Licensed Medical Physicists.
- G. The GALILEO™ shall not be used for treatment until QA tests are performed in accordance with the manufacturer's instructions. Records must be maintained licensee to document each test and procedure performed.
- H. Only manufacturer provided, single use, sterile catheters may be used with GALILEO™ for patient treatments. Quality assurance tests and measurements shall only be performed with the accessories provided or recommended by the manufacturer and in strict accordance with the procedures specified in the Operator's Manual.
23. The following conditions and limitations apply to use of the Novoste Intracoronary Radiation System or Beta-Cath System™ Intravascular Brachytherapy systems:
- A. An introducer sheath must be used, unless such use is contraindicated for an individual patient.
- B. A dual syringe system must be used, unless such use is contraindicated for an individual patient or unless contrary to the manufacturer's instructions.
- C. Source separations during treatment should be evaluated as possible misadministrations.

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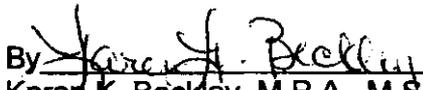
License Number 16-12-0244-02

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24. 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. NAC 459 shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated November 30, 2000.
  - B. Letter dated May 11, 1998, signed by E. Carl Chamberlain.
  - C. Letter dated August 15, 2000, signed by E. Carl Chamberlain.
  - D. Letter dated March 13, 2002, signed by E. Carl Chamberlain.
  - E. Telefaxed letter received April 23, 2002, signed by E. Carl Chamberlain.
  - F. Letter dated February 19, 2003, signed by E. Carl Chamberlain.
  - G. Letter dated February 18, 2003, signed by E. Carl Chamberlain.
  - H. Letter dated December 16, 2004, signed by David K. Chamberlain.
  - I. Letter dated January 28, 2005, signed by David K. Chamberlain.
  - J. Letter dated April 27, 2006, digitally signed by David K. Chamberlain.
  - K. Letter dated September 28, 2006, signed by David K. Chamberlain.
  - L. Letter dated September 13, 2006, signed by David K. Chamberlain.
  - M. Letter dated December 22, 2006, signed by Lucas J. Tucker, Esq.
  - N. Letter dated November 20, 2006, signed by David K. Chamberlain.

January 8, 2007

By   
Karen K. Beckley, M.P.A., M.S.  
Supervisor, Radiological Health Section  
Bureau of Health Protection Services

Yun Wang, Ph.D. DABR  
6845 Rama Drive  
Indianapolis, IN 46219



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