11 June 2007

MS16
J-1

Michelle Beardsley
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Blue Ridge Isotopes, LLC, Request for Additional Information Concerning Application for New License, Control No. 140462 (Docket 03037463 License 45-31244-01MD)

Dear Ms. Beardsley,

This letter will contain the responses to you Request for Additional Information dated May 31, 2007. The numbered paragraphs will follow your outline.

1. Dr. Mitchell is part of the management structure. Please see the response for bullet 11.
2. Please disregard the two brachytherapy sources in question. (Imagyn Medical Model IS-125 Series and Source Tech Model STM 1251) The names of these particular seeds may have been changed through company mergers or sales. We will request additional brachytherapy seeds, in writing, as needed.
3. With regard to Item 5.G.f., the Mills Biopharmaceuticals Model should be I-125SH. This was a typographical error on our part.
4. With respect to Item 5.G, the maximum amount requested should be 1 Curie total for all brachytherapy inventory.
5. The sealed sources we wish to distribute are manufactured by International Isotopes of Idaho, Inc. The SSDR numbers for the E-vials and Flood sources are NR-1235-S-102-S (amended 1/5/2007) and TX-1153-S-101-S (amended 3/29/2007) respectively. If you would like paper copies of these SSDR's please inform us and we will e-mail them to you.
6. Regarding Item 5 (Radioactive Material) the activity per source will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by and agreement state.
7. We will submit this information when it is received by the manufacturer of each Mo/Tc generator we wish to possess.

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8. As per Item 6.1.i: Sealed sources for brachytherapy and diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State Requirements.
9. Item 6.3.1 should reference Item 5.c row I, sources as described in 10 CFR 35.65(a)
10. We confirm that Blue Ridge Isotopes, LLC will not perform service activities unless the license is amended to include the same.
11. Please see the attached organizational chart for Blue Ridge Isotopes, LLC.
12. Please see the attached Cardinal Health USNRC master license 34-29200-01 Docket #030-36973 which lists Dr. Arnold as an Authorized Nuclear Pharmacist. Also, please see Dr. Arnold's Virginia State Board of Pharmacy License. The scanned copy is difficult to read and the certificate number is 0202206791 and the expiration date is 12/31/2007.
13. Please see the documentation for Dr. Arnold in bullet 12.
14. The Virginia State Board of Pharmacy has tentatively set up our inspection for the last week of June 2007. Assuming this inspection is favorable we will, immediately, fax the pharmacy license to your attention.
15. In order to speed the review process, we are submitting these responses without the updated floor plans. The construction is now underway on the pharmacy and the radiation protection equipment is being moved in. We will submit the response to questions 15 and 16 as the equipment is placed in the building.
16. See Question 15.
17. At this time we are not aware of commercially available Alpha emitting radioisotopes that are approved for human use. We agree that when/if these drugs become commercially available, we will amend our license before dispensing patient doses to our customers.

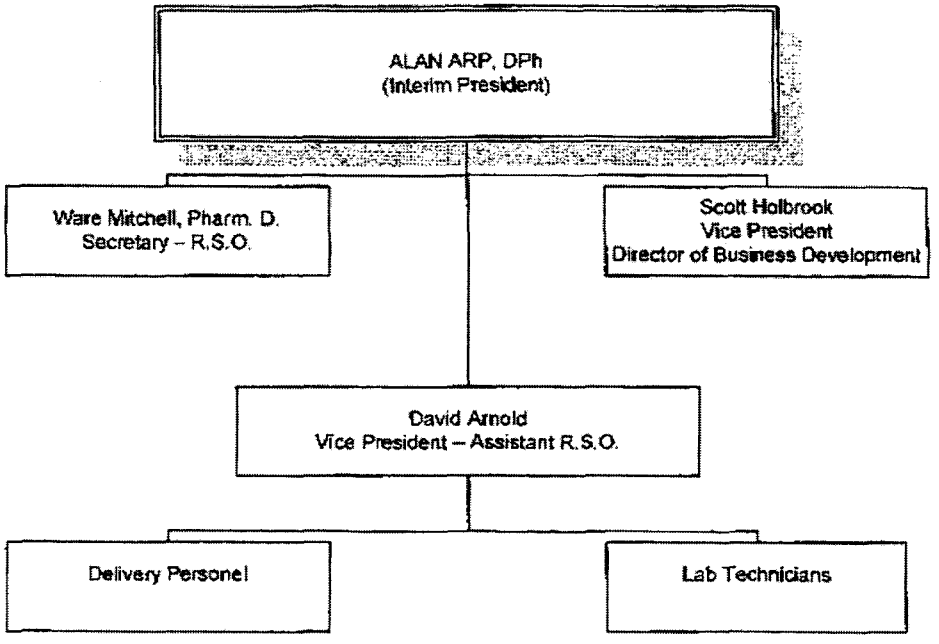
We hope that this information will help you with your review. If you should require any further information, please do not hesitate to contact us.

Respectfully Submitted,

Ware Mitchell, Pharm.D.
Radiation Safety Officer

BLUE RIDGE ISOTOPES, LLC

1630 MIDLAND ROAD
SALEM, VA 24153



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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 letter dated January 24, 2006,
1. Cardinal Health Nuclear Pharmacy Services 2. 7000 Cardinal Place Dublin, Ohio 43017	3. License number 34-29200-01MD is amended in its entirety to read as follows: 4. Expiration date August 31, 2011 5. Docket No. 030-36973 Reference No. Docket 030-33224 & License No. 04-26507-01MD

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
		Maximum amount per licensed facility identified in Condition 10
A. Any unsealed byproduct material, except iodine-131, technetium-99m and xenon-133	A. Any	A. 1 Curie
B. Molybdenum-99	B. Any	B. 200 curies
C. Technetium-99m	C. Any	C. 200 curies
D. Xenon-133	D. Any	D. 5 curies
E. Iodine-131	E. Any	E. 3 curies
F. Iodine-131	F. Any	F. 5 curies for Bristol, Pennsylvania facility only
G. Any byproduct material in a brachytherapy source listed in 10 CFR 35.400	G. Sealed sources	G. 500 millicuries
H. Any byproduct material in a sealed source for diagnosis listed in 10 CFR 35.500	H. Sealed sources	H. 4.5 curies total and no single source to exceed 1.5 curies

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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. Cesium-137	I. Sealed sources (3M 4P6E, 4F6H, 4D6L, or 4F6S; U.S. Nuclear 375; Isotope Products 193; Amersham X.9 and X.8; Industrial Research Labs 2.4 and 2.10; J.L. Shepherd Model 6810)	I. 1 curie for the Kansas City, Missouri facility only
J. Cesium-137	J. Sealed source (Amersham 72602)	J. 100 millicuries for the Kansas City, Missouri facility only
K. Cesium-137	K. Sealed source (T[illegible] Operations Model [illegible])	K. 165 millicuries for the 7920 Georgetown Road, Indianapolis, Indiana facility only
L. Any byproduct material authorized under 10 CFR 35.65(a)	L. Sealed sources	L. 50 millicuries
M. Depleted Uranium	M. Metal	M. 440 kilograms
N. Any byproduct material with atomic numbers 2-83, inclusive	N. Analytical samples	N. As needed (see Item 9.N)

9. Authorized use:

A. through F. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for non-medical use.

G. and H. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.

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I. To be used in a J.L. Shepherd and Associates Model 28-6A calibrator at the Kansas City, Missouri facility for instrument calibration including calibration of survey meters as a service for customers and other clients.

J. To be used in an Amersham (formerly Technical Operations) Model 726 calibrator at the Kansas City, Missouri facility for instrument calibration including calibration of survey meters as a service for customers and other clients.

K. To be used in a Victoreen Gamma Survey Instrument Calibrator at the licensee's 7920 Georgetown Road, Indianapolis, Indiana facility for instrument calibration including calibration of survey meters as a service for customers and other clients.

L. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for in vitro medical use.

M. Shielding for Mo99/Tc99m generators.

N. Possession incident to [illegible] customer sealed sources.

10. Except as specified otherwise [illegible] identified in Items 6.A through 6.M shall be used only at the licensee's facilities located at:

A. 2444 Brodhead Road, Suite F, Bethlehem, Pennsylvania 18020
B. 570 Chestnut Street Extension, Bradford, Pennsylvania 16701
C. 200 Rittenhouse Circle, Unit 9 East, Bristol, Pennsylvania 19057
D. 4618 Airpark Blvd., Duluth, Minnesota 55811
E. 3432 Route 764, Sugar Run Plaza, Building 1, Duncansville, Pennsylvania 16635
F. 30 Murray Hill Parkway, East Rutherford, New Jersey 07073
G. 1100 Airport North Office Park, Suite D, Fort Wayne, Indiana 46825
H. 628 Hebron Avenue, Building 4, Glastonbury, Connecticut 06033
I 212 South Ivanhoe Court, Griffith, Indiana 46319-3454
J. 8181 President's Drive, Hummelstown, Pennsylvania 17036
K. #1 Syncor Drive, University Heights, U.S. Route 60 East, Huntington, West Virginia 25705
L. 7920 Georgetown Road, Suite 100, Indianapolis, Indiana 46268
M. 1864 Pine Ridge Drive, #A, Jenison, Michigan 49428
N. 2131 E. 32nd Street, Suite 1, Joplin, Missouri 64804
O. Marion Ridge Business Park, 9668 Marion Ridge, Kansas City, Missouri 64137
P. 1610 30th Avenue South, Moorhead, Minnesota 56560
Q. 70 33rd Street, Suite A, Pittsburgh, Pennsylvania 15201
R. 1500 Tomlyn Street, Richmond, Virginia 23230
S. 6102 Stein HWY, Seaford, Delaware 19973
T. 650 Elmwood Avenue, Sharon Hill, Pennsylvania 19079

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U. 1603 "C" Avenue, Sioux Falls, South Dakota 57104
V. 3305 Lathrop Street, Suite 100, South Bend, Indiana 46628
W. 21681 Melrose Avenue, Southfield, Michigan 48075
X. 3040 East Elm Street, Springfield, Missouri 65802
Y. 1909 Beltway Drive, St. Louis, Missouri 63114
Z. 1045 Westgate Drive, Suite 100, St. Paul, Minnesota 55114
AA. 28 Omega Drive, Building #7, Stanford, Connecticut 06907
BB. 5370 Miller Road, Suite #25, Swartz Creek, Michigan 48473
CC. 527 Honey Creek Drive, Terre Haute, Indiana 47802
DD. 230 Clearfield Avenue, Suite 125, Virginia Beach, Virginia 23462
EE. 34 New Hope Road #4, Princeton, West Virginia 24740

11. Licensed material identified in Item 6.N may be used at the licensee's facilities listed in Condition 10 and at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

12. A. Licensed material shall be used by, or under the supervision of a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

B. Licensed material for other [illegible] shall be used by or under the supervision of:

Tony Adamo		Wes Rogers
T. John Alexander		Dan Schmitz
Kory Kodimer, Ph.D.		Mark Vorhees
Jack L. Coffey	Robert E. Lew[illegible]	David Wilson
Edward A. Corros	Brend[illegible]K. Norkosky	Michael Young
W. Robert Davis	Chris Walters	Adam J. Fleshner
Tara J. Simonian	David W. Pellicciarini	James T. Chimelewski, Jr.
Candice Goodyear	Robert Lapena	Carl Collier
Colleen M. Glynn	Corey W. Woods	Willie Regits, Ph.D.
Dean Polar	Burr Johnson	Lonze Townsend
David Breuning	Dennis Kephart	Edward E. Gann III
Jason Luper	Jason K. Steincamp	Richard B. Hasselkus
Paul Friedenberg	Elias Garcia	Brent Marlow
Jason Cash	John Haag	Andrew Fu
Thaibinh Dang	Alonzo Keys	Craig O'Dell
Barbara M. Atunrase	Cami O'Connor	Vai Paye
Lisa Frantz		

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C. The Radiation Safety Officer for this license is Paul R. Gotti, MS, BCNP, R.Ph.

13. Notwithstanding the requirements of 10 CFR 32.72(b)(2)(ii), the licensee may approve authorized nuclear pharmacists in accordance with application dated March 29, 2001.

14. 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 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 (185 becquerels) of radioactive material on the test sample and shall be sufficient to reveal the presence of 0.005 microcurie (185 becquerels) or more of removable contamination. A report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 31.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

E. Tests for leakage and/or contamination shall be performed by the licensee or by 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.

15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

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16. The licensee shall conduct a physical inventory every 6 months, or at other interval approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.

17. 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."

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed material for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. Except for maintaining labelling required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before [illegible] the sealed source, device, or source-device combination that would [illegible] as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.

20. The licensee is authorized to retrieve, receive and dispose of radioactive waste from it's customers limited to radiopharmacy supplied syringes and vials and their contents.

21. 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.

22. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may re-distribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.

23. This license does not authorize distribution to persons exempt from licensing.

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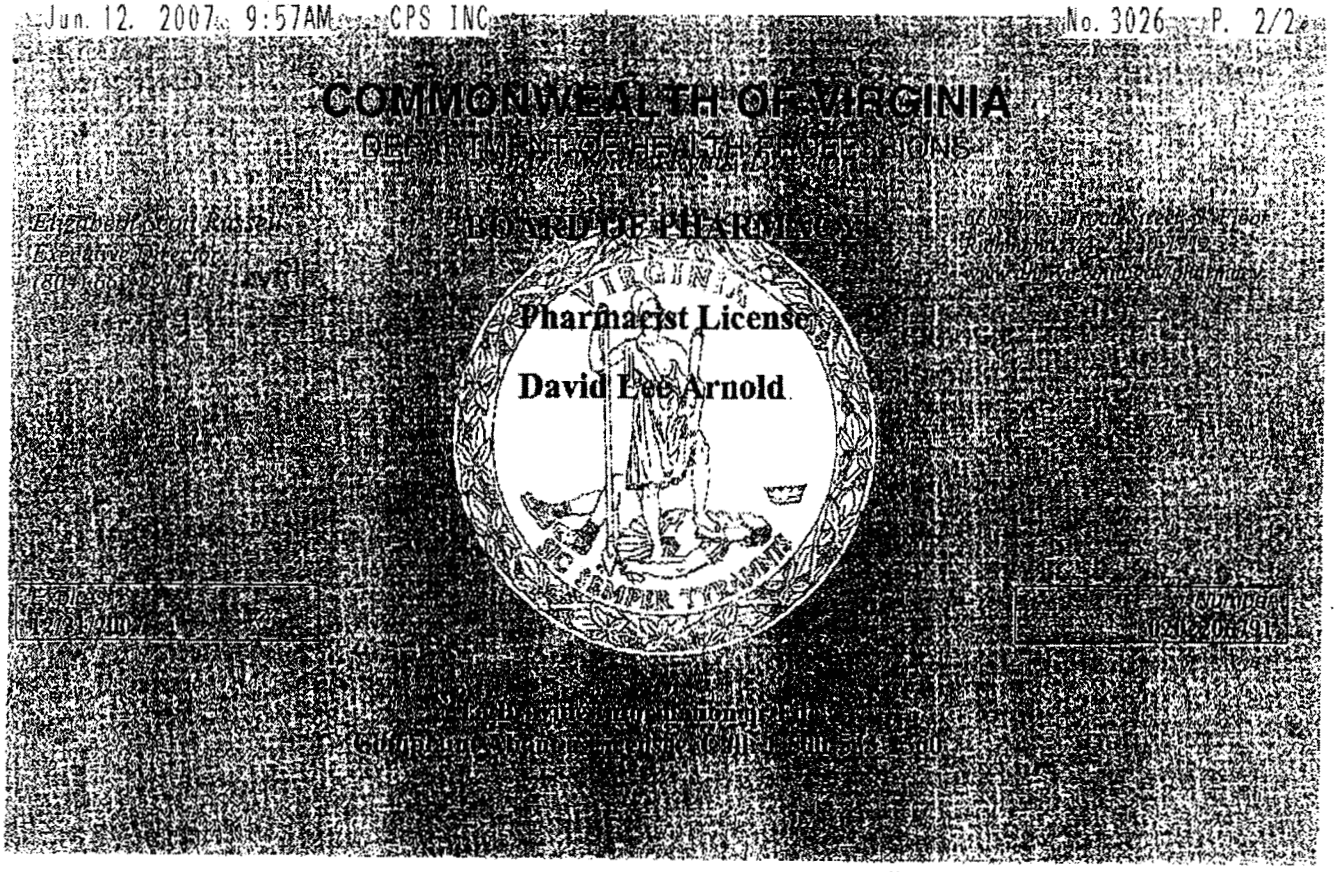
24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated March 29, 2001
B. Letter dated August 9, 2001
C. Letter dated August 24, 2001
D. Letter dated September 17, 2001
E. Letter dated November 30, 2001
F. Letter dated March 11, 2002
G. Letter dated August 16, 2002
H. Letter dated November 21, 2002
I. Letter dated December [illegible], 2002
J. Letter dated February 13, [illegible]
K. Letter dated May 20, 2003
L. Letter dated August 7, 2003
M. Letter dated August 22, 2003
N. Letter dated April 1, 2004
O. Letter dated August 30, [illegible]
P. Letter dated October 7, [illegible]
Q. Letter dated October 8, [illegible]
R. Letter dated January 14, [illegible]
S. Letter dated March 11, 2005
T. Letter dated June 29, 2005
U. Letter dated July 15, 2005
V. Letter dated November 8, 2005
W. Letter dated January 24, 2006

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 0 2 2006

By Toye L. Simmons
Toye L. Simmons
Materials Licensing Branch
Region III


COMMONWEALTH OF VIRGINIA
Pharmacist License
David Lee Arnold