Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
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CardinalHealth

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October 24, 2006

US Nuclear Regulatory Commission
Region I – Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415
Attention Bryan A. Parker

03036977

RE: Amendment Request for Radioactive Materials License 34-31064-01MD, Cardinal Health, Charlottesville, VA and Roanoke, VA.

Dear Mr. Parker:

Please amend the above referenced license to add David Arnold, R.PH as an Authorized Nuclear Pharmacist. Mr. Arnold was previously licensed in North Carolina on license number 092-0794-6 and has since received his Virginia Board of Pharmacy License (copies enclosed).

Please contact David Breuning at 614.757.3116 with any questions regarding this request.

Sincerely,

Dave Breuning
Health Physicist

cc: Rob Whitmore, R.Ph., Location 223
Kristell Wright-Jimenez, R.Ph., PRSO Location 222
License File Location 222 & 223 (3)

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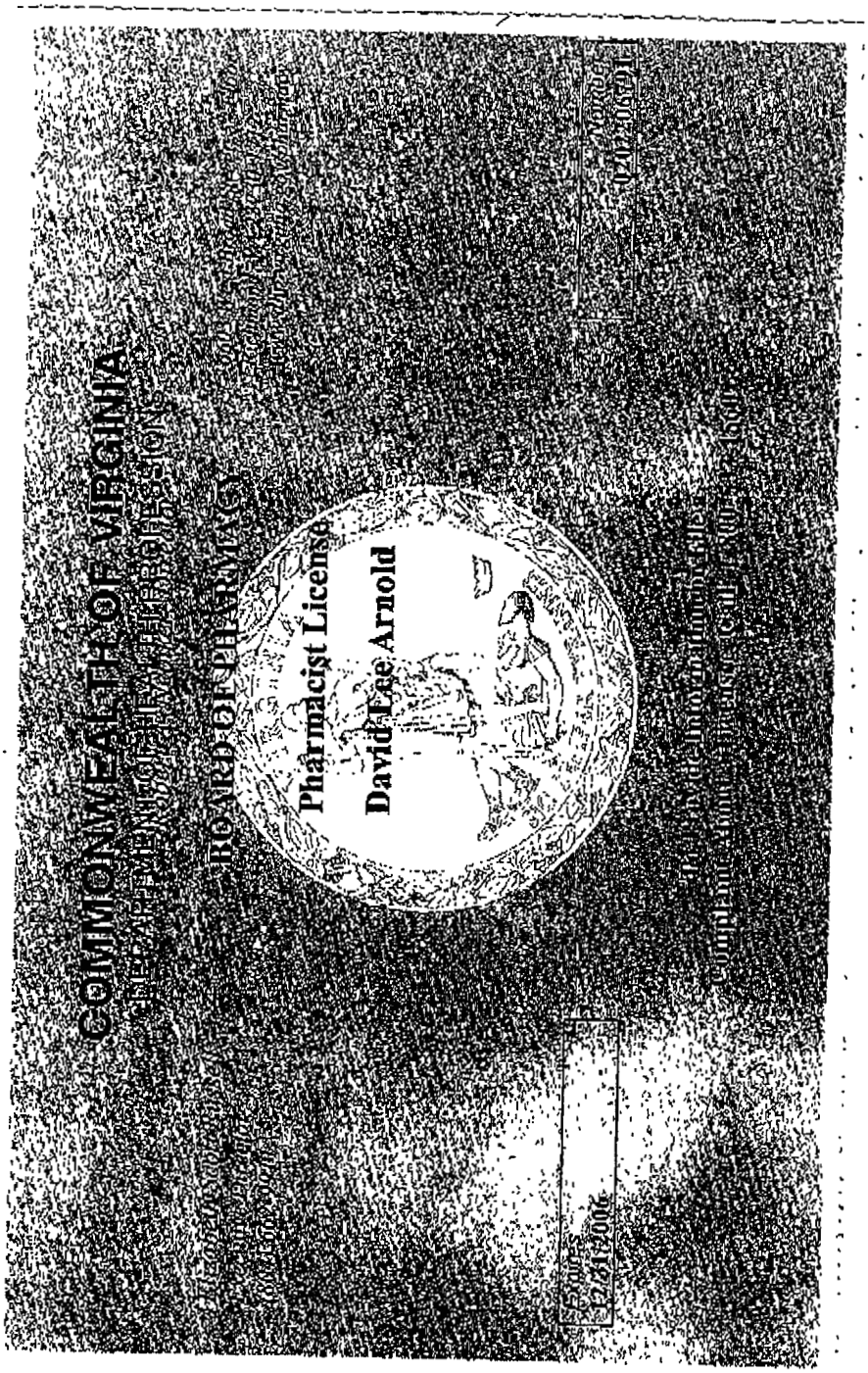
NMSS/RGN1 MATERIALS-002


COMMONWEALTH OF VIRGINIA
BOARD OF PHARMACY
Pharmacist License
David Lee Arnold

NCDENR
North Carolina Department of Environment and Natural Resources

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:** | Cardinal Health | 3. **License No:** 092-0794-6 | License Type 0550 |
| 2a. | **Mailing Address:** | 6464 Canoga Avenue<br>Woodland Hills, CA 91367 | 4. **Expiration Date:** August 31, 2009 | |
| b. | **Physical Address:** | 23 Sunnybrook Road, Suite 101<br>Raleigh, NC 27610 | New License / Renewal: [ ] / [X] — Routine / Administrative: [X] / [X] — Corrected Copy / Termination: [ ] / [ ] | |
| c. | **Radiation Safety Officer:** | Anthony J. Caristo, R.Ph. | 5.a. **Amendment No.:** 8<br>b. **Issuance Date:** August 25, 2006 | |

| 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. | Molybdenum 99 | A. | Any Molybdenum 99 / Technetium 99m generator authorized pursuant to 15A NCAC 11 .0321(c)(2)(B) | A. | 200 curies |
| B. | Technetium 99m | B. | Any form listed in Groups I – IV as listed in the latest revision of DRP Publication 97-01, or for other procedures listed in a valid license issued by the Agency, USNRC, or an Agreement State. | B. | 200 curies |
| C. | Any radioactive material except Iodine 131 and Technetium 99m, listed in Groups I – IV in the latest revision of DRP Publication 97 – 01 | C. | Any radiopharmaceutical except Iodine 131 and Technetium 99m as listed in Groups I – IV in the latest revision of DRP Publication 97-01 or for other procedures listed in a valid license issued by the Agency, USNRC, or an Agreement State. | C. | 4 curies total possession limit. |
| D. | Iodine 131 | D. | Any form listed in Groups I – IV in the latest revision of DRP Publication 97 – 01, or for other procedures listed in a valid license issued by the Agency, USNRC, or an Agreement State. | D. | 3 curies |
| E. | Xenon 133 | E. | Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by the FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA. | E. | 5 curies |

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

| 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. |
|---|---|---|---|---|---|
| F. | Any radioactive material authorized under 15A NCAC 11 .0321(c)(5) | F. | Any form specified in 15A NCAC 11 .0321(c)(5)(A) – (D) | F. | No single source to exceed the limits specified in 15A NCAC 11 .0321(c)(5)(A) – (D). |
| G. | Any radioactive material listed in 15A NCAC 11 .0314. | G. | Pre-packaged *in vitro* diagnostic kits | G. | No single kit activity to exceed the limits specified in 15A NCAC 11 .0314(a). |
| H. | Uranium (depleted in Uranium 235) | H. | Uranium metal encased in stainless steel | H. | 600 kilograms |
| I. | Yttrium-90 | I. | Ibritumomab Tiuxetan (Zevalin) | I. | 200 millicuries |
| J. | Indium 111 | J. | Ibritumomab Tiuxetan (Zevalin) | I. | 100 millicuries |
| K. | Yttrium-90 | K. | Glass or Plastic Microspheres | K. | 2000 millicuries |
| L. | Iodine 131 | L. | Bexxar | L. | 500 millicuries |
| M. | Sr-82/Rb-82 | M. | Generator | M. | 800 millicuries |
| N. | Sr-85 | N. | Solid | N. | 2 Curies |

**9. Authorized Use:**

A. To be used for the production of Technetium 99m Pertechnetate.

B – E. To be used for the preparation and/or distribution of radiopharmaceuticals to specifically authorized recipients.

F. To be used for the following:
1) Instrument quality assurance and quality control, and/or
2) Distribution or redistribution as calibration and reference standards to specifically authorized recipients.

G. To be used for redistribution to recipients licensed pursuant to 15A NCAC 11 .0314 or to specifically licensed individuals pursuant to 15A NCAC 11 .0321(c)(4), provided all packaging and labeling remains unchanged.

H. To be used as shielding for Molybdenum 99 / Technetium 99m generators.

I. – L. For preparation and distribution to authorized recipients in accordance with manufacturer's compounding procedures for a FDA approved drug.

M. To be used for distribution and redistribution to authorized licensees.

N. To be contained as byproduct in a Sr-82/Ru-82 Generator.

## CONDITIONS

10. Radioactive material may be used at the licensee's address stated in Item 2b above, and at 2300 Westinghouse Boulevard, Lincoln Park Central – Building 5, Suites 108 – 109, Raleigh, NC 27604.

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

**CONDITIONS (continued):**

11. The licensee shall comply with the provisions of 15A NCAC 11 .1600, "Standards for Protection Against Radiation," and 15A NCAC 11 .1000, "Notices, Instructions, Reports and Inspections." (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)

12. A. Radioactive material shall be used by, under the supervision of and in the physical presence of Bruce Lewandowski, David L. Gilliland, Ray Holland, Anthony J. Caristo, Craig Barlow, Shawn N. Hardesty, RPh, MS, Gregory Sosnowski, RPh, Daniel E. Ault, RPh, Grace McQuay, RPh, Clayton G. Hollingsworth III, Ray D. Courtney, R.Ph., David Arnold, RPh. and/or Casey Hydro, PharmD, or individuals who hold a current valid North Carolina Board of Pharmacy License and are listed on the current US NRC Master License No. 04-26507-01 MD.

B. At least one individual authorized by Condition A. above shall be physically present at the authorized place of use wherever licensed material is being used.

C. The Radiation Safety Officer for the activities authorized by this license shall be Anthony J. Caristo, R.Ph.

13. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

A. Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

B. Prepared from generators and reagent kits that are the subject of a FDA-approved NDA or for which FDA has accepted an IND.

C. Notwithstanding Conditions 13 A and B above, the licensee is authorized to dispense and/or distribute for human use radiopharmaceuticals which are listed in the latest revision of DRP Publication 97-01 "List of Radioactive Materials Approved for the Four 'Groups of Diagnostic Uses' as defined in 15A NCAC 11 .0321." DRP Publication 97-01 is available by request from the agency pursuant to 15A NCAC 11 .0321(d).

14. A. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

i. In accordance with the directions provided by the sponsor of the IND, and

ii. Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

B. The licensee shall inform, in writing, each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

15. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

16. A. Reagent kits may be distributed to persons licensed pursuant to 15A NCAC 11 .0321, or under equivalent licenses issued by the USNRC, or an Agreement State, for Group III.

B. Notwithstanding Condition A above, the licensee is also authorized to redistribute reagent kits to persons who are licensed pursuant to 15A NCAC 11 .0320.

17. The licensee shall keep on file a copy of the Sealed Source and Device Registration for each model of sealed source redistributed.

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

**CONDITIONS (continued):**

18. A. Each sealed source containing radioactive material, other than Hydrogen 3, with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested.

B. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma-emitting material or 10 microcuries or less of alpha-emitting material.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. 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, N.C. 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 persons specifically authorized by the Agency to perform such services.

19. 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.

20. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material For Transport."

21. Any proposed changes in packaging, shielding, or labeling shall be submitted for review to the North Carolina Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, N.C. 27699-1645.

22. In addition to the possession limits in Item 8 above, 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.

23. A. Radioactive waste may be removed from the customer's place of use by a licensee representative and disposed of in accordance with the procedures, statements, and representations outlined in the application dated March 29, 1996, signed by David L. Gilliland, Ph.D., R.Ph., President.

B. Notwithstanding Condition A above, the licensee may only remove spent syringes and/or other paraphernalia which was directly involved in the administration of the radiopharmaceutical to the patient.

C. Notwithstanding Conditions A & B above, the licensee is not authorized under this license to receive or accept sealed sources for disposal.

24. Radioactive gases as free gas or gas in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.

25. Unless otherwise specified in 15A NCAC 11 or by license condition, the licensee shall maintain all required records for a minimum of three (3) years.

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

**CONDITIONS (continued):**

26. A. The licensee shall establish written procedures for performing the following tests on dose calibrator(s) used to determine the quantity and quality of radiopharmaceuticals:

    1. Geometric variation to be performed upon installation and following repair.

    2. Accuracy to be performed upon installation and at intervals not to exceed one (1) year and following repair.

    3. Linearity to be performed upon installation and at intervals not to exceed three (3) months and following repair:

        a. The dose calibrator shall be tested for linearity from the highest dosage administered to a patient down to 30 microcurie,

        b. The licensee may use a commercially available attenuator set for performing linearity tests of his dose calibrator provided that the current manufacturer instructions are followed.

    4. Constancy to be performed daily and following repair.

    B. Records of the results of the tests outlined in Condition A above shall be maintained for a minimum of two (2) years following the completion of the test for inspection by the agency.

    C. The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (0.37 MBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

27. The licensee shall conduct a decay-in-storage program in accordance with 15A NCAC 11 .0362.

28. The licensee shall perform surveys of all areas where radioactive materials and/or radiopharmaceuticals are used, prepared, administered, and/or stored in accordance with 15A NCAC 11 .0360.

29. 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.

30. 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.

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

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

33. Neither this license nor any subsequent amendments shall be deemed to constitute compliance with the Pharmacy Laws of North Carolina and the regulations promulgated by the N.C. Board of Pharmacy contained in 21 NCAC 46 .2700 *et seq.* Inquiries into the N.C. Pharmacy regulations should be directed to the Board of Pharmacy at (919) 942-4454.

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

**CONDITIONS (continued):**

34. In addition to the possession limits referenced in Item 8. above, the licensee shall further restrict possession of radionuclides listed in the table below to the quantities noted within the table. Sum of fractions for the radionuclides listed below shall not exceed unity:

| Radionuclide | Quantity (curies) | Radionuclide | Quantity (curies) |
|---|---|---|---|
| Am-241 | 16 | Pm-147 | 11,000 |
| Am-241:Be | 16 | Pu-238 | 16 |
| Cf-252 | 5.4 | Pu-239:Be | 16 |
| Cm-244 | 14 | Se-75 | 54 |
| Co-60 | 8.1 | Sr-90 (Y-90) | 270 |
| Cs-137 | 27 | Tm-170 | 5,400 |
| Gd-153 | 270 | Yb-169 | 81 |
| Ir-192 | 22 | | |

35. 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. All information previously submitted in support of N.C. Radioactive Materials License No. 092-0780-2, which includes: Application with attachments dated March 23, 2000, signed by David L. Gilliland, President; Letter with attachments dated July 19, 2000, signed by Anthony J. Caristo, R.Ph., RSO; Licensee submitted request and procedures dated December 10, 2000, January 17, 2001, both signed by George F. Gilliland, and February 27, 2001, signed by Anthony Caristo, RSO; Application for license amendment with attachments dated April 4, 2001, and the facsimile with attachments dated May 3, 2001, both signed by Anthony J. Caristo; Corrected copy based on an administrative review of this license performed on May 30, 2001; Letters dated May 15 and July 20, 2001, both signed by Anthony J. Caristo, R.Ph., R.S.O. in response to field inspection conducted April 19, 2001; Amendment application dated November 29, 2001 signed by George F. Gilliland, COO; Application for Amendment dated March 5, 2002, signed by David L. Gilliland, President; Letter with attachments dated December 2, 2002, signed by Anthony Caristo, R.Ph.; Letter dated March 21, 2003, signed by David L. Gilliland, Ph.D., President; Application for amendment dated April 9, 2003 signed by Anthony J. Caristo, RPH, RSO; Application for amendment dated November 17, 2003 signed by Anthony J. Caristo, RPH, RSO; Application for Amendment with attachments dated May 04, 2004, signed by Anthony J. Caristo, R.Ph., R.S.O., and letter with attachments dated July 19, 2004, signed by Kory Kodimer, Ph.D., Manager, Health Physics, Cardinal Health.

B. Application for amendment with attachments dated October 22, 2004, signed by Kory Kodimer, PhD, Manager, Health Physics.

C. Application for Amendment dated November 12, 2004, signed by Kory Kodimer, Ph.D., Manager, Health Physics.

D. Application for Amendment dated November 17, 2004, signed by Kory Kodimer, Ph.D., Manager, Health Physics.

E. Application for Amendment with attachments dated August 20, 2004, signed by Kory Kodimer, PhD, Manager, Health Physics

F. Letter dated January 19, 2005, signed by Kory Kodimer, PhD, Manager, Health Physics.

G. Application for Amendment with attachments dated June 13, 2006, signed by Dave Breuning, Health Physicist.

H. Letters with attachments dated July 13, 2006 and July 19, 2006, both signed by Dave Breuning, Health Physicist, and an administrative amendment to restrict possession of certain radionuclides below the quantities of concern.

NCDENR
North Carolina Department of Environment and Natural Resources

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

RADIOACTIVE MATERIALS LICENSE

CONDITIONS (continued):

35. I. Letter with attachment dated July 31, 2006, signed by Dave Breuning, Health Physicist and administrative corrections to license.

For: Beverly O. Hall
Chief, Radiation Protection Section