



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 7, 2005

Docket No. 03032623
Control No. 136197

License No. 37-28723-01

James P. MacKrell, M.D.
Medical Director/Radiation Safety Officer
Consultants in Cardiovascular Diseases, Inc.
311 West 24th Street
Suite 401
Erie, PA 16502

SUBJECT: CONSULTANTS IN CARDIOVASCULAR DISEASES, INC., ISSUANCE OF
LICENSE AMENDMENT, CONTROL NO. 136197

Dear Dr. MacKrell:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosures:

J. MacKrell
Consultants in Cardiovascular Diseases, Inc.

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1. Amendment No. 16
2. 10 CFR Part 35

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| OFFICE | DNMS/RI | N | DNMS/RI | N | DNMS/RI | | | |
|--------|------------------|---|-----------------|---|---------|--|--|--|
| NAME | JNicholson /JJN/ | | TThompson /TKT/ | | | | | |
| DATE | 01/07/2005 | | 01/07/2005 | | | | | |

OFFICIAL RECORD COPY

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.

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|---|--|
| <p style="text-align: center;">Licensee</p> <p>1. Consultant's in Cardiovascular Diseases</p> <p>2. 311 West 24th Street Suite 401 Erie, Pennsylvania 16502</p> | <p>In accordance with the letter dated December 21, 2004,</p> <p>3. License number 37-28723-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date June 30, 2012</p> <hr/> <p>5. Docket No. 030-32623 Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.200</p> <p>B. Any byproduct material permitted by 10 CFR 35.500</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Sealed Sources (North American Scientific Model MED 3601, Isotope Products Laboratories Model A3410)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. 300 millicuries per source and 1 curie total</p> |
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9. Authorized use:

A. Any imaging and localization study permitted by 10 CFR 35.200.

B. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 311 West 24th Street, Suite 401, Erie, Pennsylvania.
- 11. The Radiation Safety Officer for this license is James P. MacKrell, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-28723-01

Docket or Reference Number
030-32623

Amendment No. 16

- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

| <u>Authorized Users</u> | <u>Material and Use</u> |
|------------------------------|-------------------------|
| James P. MacKrell, M.D. | 35.200; 35.500 |
| Tulio Estrada-Quintero, M.D. | 35.200; 35.500 |
| Manuel F. Forero, M.D. | 35.200; 35.500 |

- 13. 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.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 13, 2002
 - B. Letter dated March 26, 2003
 - C. Letter dated January 8, 2004

For the U.S. Nuclear Regulatory Commission

Original signed by Thomas K. Thompson

Date January 7, 2005
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By _____
Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406