



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

JUN 20 2005

Larry Handlin, D.O.
Radiation Safety Officer
Mexico Cardiovascular Associates, LLC
201 E. Monroe Street
Mexico, MO 65265

Dear Dr. Handlin:

Enclosed is your NRC Material License No. 24-32578-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This also refers to the telephone conversation between your consultant, Marcia West and me on June 20, 2005. Ms. West confirmed my understanding that this license should be limited to authorization for cardiovascular clinical studies only. I also advised Ms. West that I will not authorize the request for unsealed technetium-99m as a line item for calibration purposes because 10 CFR 35.65(e) already grants you this authorization.

Your license has been prepared in accordance with newly revised 10 CFR Part 35. Since revised 10 CFR Part 35 has become effective and NUREG 1556, Vol. 9, Rev.1, has been issued please use these documents to prepare future licensing correspondence. Copies of 10 CFR Part 35 and NUREG 1556, Vol. 9, Rev.1, are available, respectively, on our website at:

"<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/> " and

"<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/nureg-1556-9.pdf> "

Using the above regulation and guidance, especially the NUREG 1556 series documents, will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner. You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

If you have further questions concerning your new license please contact me at (630) 829-9841 or (800) 522-3025.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations.

In particular, note that you must:

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1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days, pursuant to 10 CFR 35.14:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers, except as provided in 10 CFR 35.24(c);
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or the address or addresses of use identified in the license application or on the license, pursuant to 10 CFR 35.13(e), 10 CFR 35.13(f) and 10 CFR 35.14(b)(4); or
 - d. Change ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>

The enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-32578-01
Docket No. 030-36939

Enclosures:

1. License No. 24-32578-01
2. 10 CFR 35
3. New license packet