UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352

MAY 1 8 2005

Mark A. Keller
Radiation Safety Officer
CardioDiagnostics, Inc.
255 North Smith Avenue, Suite 100
St. Paul, MN 55102

Dear Mr. Keller:

This refers to your application dated April 1, 2005, signed by David D. Rothschiller, requesting an amendment to your license number 22-32018-01.

The information provided by your letter was insufficient to complete my review. I unsuccessfully attempted to contact your consultant, Sue Weiss, by telephone on May 18, 2005. The telephone number provided, (651) 351-0282, resulted in a recorded error message. I unsuccessfully tried to reach you by telephone also on May 18, 2005, but a recorded error message was received. Apparently the telephone numbers provided on your application dated April 1, 2005 are incorrect. Please advise us of the correct telephone and facsimile numbers for your licensed program and for your consultant.

As we cannot continue to process your request and cannot reach you by telephone, we have voided your request at this time. This action is without prejudice to resubmission. If you resubmit your request please state that the resubmission is additional information to Control Number 314391 and reference it to my attention at the above address.

1. Priscilla A. Hedburg, M.D. was not approved as an authorized user for the use of materials in 10 CFR 35.100 and 35.200 (excluding xenon-133 and aerosols, limited to clinical cardiovascular studies, because her preceptor statement did not adequately support her application for this type of use and her training and experience did not appear to completely meet the requirements in 10 CFR 35.290.

   Specifically, the preceptor statement for Dr. Hedburg did not include sections 5a (correlates with 10 CFR 35.390(c)(1)(ii)) and 9 completed (both were left blank). Also, section 5b did not include the dates when Dr. Hedburg's training was conducted so we can verify recentness of training, pursuant to 10 CFR 35.59.

   Please submit a revised, completed preceptor statement, currently signed and dated by an appropriate preceptor, documenting Dr. Hedburg's training and experience to clearly demonstrate compliance with 10 CFR 35.290.

   In addition, we could not verify the credentials of her preceptor, Dr. Frans Wacker, based upon the information given on the preceptor form. The referenced license for Dr. Wacker, Yale New Haven Hospital, is a broad scope license that does not include the names of specific authorized users. The Radiation Safety Committee for that license evaluates and approves/disapproves of authorized users internally.

   Please submit a letter currently signed and dated by either the RSO or the RSC Chairperson for Yale New Haven Hospital attesting that Dr. Wacker was an authorized user for materials in 10 CFR 35.100 and 35.200 under license no. 06-00183-03, including the date(s) of authorization.

   Please refer to the above regulatory requirements as well as section 8.11, item 7 and

Appendices B, D and E in NUREG 1556, Vol. 9, Final, for assistance in preparing your response.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc. Please do not submit copies of specialty board certifications that we do not recognize, such as the American Board of Internal Medicine.

2. Richard J. Brody, M.D. was not approved as an authorized user for the use of materials in 10 CFR 35.100 and 35.200 (excluding xenon-133 and aerosols, limited to clinical cardiovascular studies, because his preceptor statement did not adequately support his application for this type of use and his training and experience did not appear to completely meet the requirements in 10 CFR 35.290.

   Specifically, the preceptor statement for Dr. Brody did not include sections 5a (correlates with 10 CFR 35.390(c)(1)(ii)) and 9 completed (both were left blank).

   Please submit a revised, completed preceptor statement, currently signed and dated by an appropriate preceptor, documenting Dr. Brody's training and experience to clearly demonstrate compliance with 10 CFR 35.290.

   Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Final, for assistance in preparing your response.

   Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc. Please do not submit copies of specialty board certifications that we do not recognize, such as the American Board of Internal Medicine.

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.

If you have any questions or require clarification on any of the information stated above, you may contact me at (630) 829-9841.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 22-32018-01
Docket No. 030-34519