UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

October 1, 2004

E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
Little Rock, AR 72114

SUBJECT: DEPARTMENT OF VETERANS AFFAIRS (DVA) LETTER DATED JANUARY 8, 2004, REQUESTING ALTERNATIVE CRITERIA FOR APPROVING AUTHORIZED USER PHYSICIANS TO PERFORM INTRAVASCUALR BRACHYTHERAPY (IVB)

Dear Mr. McGuire:

This is in response to your January 8, 2004, letter in which you requested that we review proposed alternate criteria for approving authorized users to perform IVB procedures. The procedures were submitted to you by the VA Eastern Colorado Health Care System, a permittee under the DVA's Master Materials License (MML).

The proposed training and experience described in your letter is not adequate for intravascular brachytherapy use under 10 CFR 35, Section 35.1000. While the cardiologist may be the individual that positions the catheter, and determines the size of the vessel, the radiation dosimetry and radiation treatment knowledge needed to safely use a high-dose-rate afterloader and to recognize and evaluate the consequences of unexpected treatment events significantly exceeds what can be learned in the proposed 24-hour training period, including five clinical studies.

In your letter you also stated that if your proposal to deviate from current NRC licensing guidance is not approved, then it will be treated as a petition to modify NRC's licensing guidance and/or 10 CFR 35. In order to request a change to 10 CFR 35, you will need to submit a petition for rulemaking meeting the criteria of 10 CFR 2.802.

If, however, you wish to propose another alternative training criterion, the new criterion will be reviewed on a case-by-case basis. If an alternative criterion is acceptable and has broad applicability to other medical use licensees, it could provide a basis for revision of the NRC's web site guidance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection 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 Public Electronic Reading Room).

Please feel free to contact me at 630-829-9854 if you have any questions.

Sincerely,

Kevin G. Null
Materials Licensing Branch

Docket No.: 030-34325
License No.: 03-23853-01VA