



Mr. Paul Lohaus
Director of Office of State and
Tribal Affairs
United States Nuclear Regulatory Commission
Washington, D.C. 20555

May 16, 2001

Dear Mr. Lohaus;

At this institution we are now treating in-stent restenosis in coronary arteries with brachytherapy using the Cordis Checkmate system. This system has received pre-market approval (PMA) by the U.S.F.D.A.. The PMA specified for use in treating in-stent restenosis in native vessels and therefore any other use would be "off label". There is considerable discussion about off-label use of this therapy and the regulatory position of the N.R.C.; specifically that the N.R.C. considers any off label use in this instance a misadministration or misuse. My question is therefore would the N.R.C. choose to regulate this directly even though Florida is an agreement state? I look forward to your answer and thank you in advance for your attention to this.

Sincerely;

A handwritten signature in black ink, appearing to read "T. F. McLeod".

Thomas F. McLeod, Ph.D.
Radiation Safety Officer

cc: Martha Smith
Vice President
Chairman, Radiation Safety Committee

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