



STATE OF IOWA

THOMAS J. VILSACK
GOVERNOR

DEPARTMENT OF PUBLIC HEALTH
STEPHEN C. GLEASON, D.O., DIRECTOR

SALLY J. PEDERSON
LT. GOVERNOR

September 18, 2001

Paul H. Lohaus, Director
One White Flint North
11555 Rockville Pike, 3rd Floor
Rockville, MD 20852

Dear Mr. Lohaus:

During the Nevada's IMPEP, George F. Johns, Jr. of my staff was informed by the Region III representative that the Novoste™ intravascular brachytherapy (IVB) is considered to be a Priority I inspection frequency. Has this information been transmitted to the Agreement States? The NRC Inspection Manual Chapter 2800 has not been revised to include this protocol. Therefore, it is unclear whether this policy is unique to Region III or if it has been adopted by all NRC Regions.

The Iowa Department of Public Health does not consider the Novoste™ or the Cordis(R) protocols to be the same as high dose rate afterloader (HDR) because both devices are manually controlled. In contrast, the Guidant(R) protocol is specifically identified as an HDR in the Sealed Source and Device Registry (SSDR) and the source is controlled by a computer software system. The rationale for Region III decision regarding the Novoste™ or the Cordis(R) appears to be that they deliver a high dose. IDPH does not consider that reason sufficient justification for increased inspection oversight and cost.

As with a number of other Agreement States, the IDPH has licensed the Novoste™ and Cordis(R) devices as Priority III by including them in medical institution licenses without a change in the inspection frequency. If this practice is inconsistent with NRC guidelines and is an issue of adequacy, IDPH needs to consider changing its licensing practices. Therefore, I am requesting a formal review of the issue and a written response. In addition, the NRC should notify all Agreement States to ensure that appropriate corrective actions are implemented nationwide.

If you have any questions concerning this issue, please contact George F. Johns, Jr. at (515) 725-0307, or me.

Sincerely,

Donald A. Flater, Chief
Bureau of Radiological Health
(515) 281-3478

cc: James L. Lynch

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Table with 4 columns: Director's Office, Executive Staff, Div. of Administration & Regulatory Affairs, Div. of Environmental Health, Div. of Family & Community Health, Div. of Health Promotion, Prevention & Addictive Behaviors, Div. of Tobacco Use Prevention & Control.