

August 09, 2012

Mr. Gonzalo Perez
Chief, Radiological Health Branch
California Department of Public Health
Mail Station 7610
P.O. Box 997414
Sacramento, CA 95899-7414

Dear Mr. Perez:

This is a response to your letter, dated June 15, 2012, requesting the U.S. Nuclear Regulatory Commission (NRC) provide technical assistance for developing uniform guidance for licensing a MASEP Infini Radiosurgery and Radiotherapy Device. The State specifically requests that the NRC provide a staff person to participate on a State workgroup to develop 10 CFR 35.1000 licensing guidance for the device that can be used by California, the NRC and other Agreement States. You also request that the NRC provide a second level review of the final proposed licensing document.

Management Directive (MD) 5.3, "Agreement State Participation in Working Groups" explains the formation and participation of NRC and Agreement State working groups. At this time, NRC does not participate on working groups sponsored by a single State, especially when the subject involves a State specific licensing issue or developing State specific guidance documents. However, as stated in MD 5.3 Part I Section General (A), an NRC office (Headquarters or regional) or the Organization of Agreement States (OAS) Executive Board may recommend the establishment of an NRC/Agreement State working group to address a wide range of issues and to develop a variety of different products which would include guidance documents. We have contacted the OAS Board and they have agreed to form a MD 5.3 working group to develop licensing guidance for computerized teletherapy units, including the MASEP Infini Device. Both the OAS Board and NRC are in the process of indentifying members of this working group.

Your letter stated that a temporary constraint on human resources is the basis for your request for technical assistance. As we previously explained in the June 29, 2012 reply to your March 9, 2012 letter requesting technical assistance for conducting the sealed source and device (SSD) safety evaluation for the Model MASEP Infini Radiosurgery and Radiotherapy device, the provisions in MD 5.7 require the State to include additional information to support a request for technical assistance.

Specifically, the provisions of MD 5.7 require evidence that the State pursued alternative means of addressing the issue on its own, including attempting to obtain assistance from other agencies within the State, other Agreement States, or independent organizations, such as the OAS, CRCPD, or procuring contractors or consultants. Furthermore, this section of MD 5.7 also states that such technical assistance will be based on the availability of NRC staff resources and any assistance will be cost-reimbursable. (The current rate for NRC professional staff is \$273 per hour (see 10 CFR 170.20)).

Should the State of California decide to continue to seek NRC technical assistance, we will require additional information regarding your search for alternative methods of developing uniform guidance for licensing a MASEP Infini Radiosurgery and Radiotherapy Device, estimation of requested NRC resources for this effort, and California's acceptance of cost reimbursement to the NRC.

If you need further information regarding these issues, please contact please contact Duncan White, Chief, Agreement State Programs Branch, of my staff at duncan.white@nrc.gov or (301) 415-2598.

Sincerely,

/RA Pamela Henderson for/

Brian J. McDermott, Director

Division of Materials Safety and State Agreements

Office of Federal and State Materials and

Environmental Management Programs

G. Perez

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